

SEALED

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

v.

(1) MICHAEL L. BABICH

(2) ALEC BURLAKOFF

(3) MICHAEL J. GURRY

(4) RICHARD M. SIMON

(5) SUNRISE LEE

(6) JOSEPH A. ROWAN

Defendants.

CRIMINAL NO.
VIOLATIONS:

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

18 U.S.C. § 1349
(Mail Fraud Conspiracy)

18 U.S.C. § 1349
(Wire Fraud Conspiracy)

18 U.S.C. § 371 (Conspiracy)

18 U.S.C. §§ 1963, 982(a)(7) and
981(a)(1)(C); 28 U.S.C. §
2461(c) (Forfeiture)

16cr10343

Table of Contents

INTRODUCTION TO ALL COUNTS

I.	Overview	3
A.	The Defendants	3
B.	Co-Conspirator Practitioners	4
C.	Summary of the Allegations	5
II.	The Fentanyl Spray	6
III.	The Market for the Fentanyl Spray.....	9
IV.	Bribing Practitioners and Defrauding Insurers	10
A.	Bribery of Practitioners.....	11
B.	Defrauding Insurers and Pharmacy Benefit Managers	17
V.	Examples	20
A.	Examples of Bribing Medical Practitioners	21
<i>Practitioner #1</i>		21
<i>Practitioner #2</i>		22
<i>Practitioner #3</i>		24
<i>Practitioner #4</i>		26
<i>Practitioner #5</i>		28
<i>Practitioner #6</i>		30
<i>Practitioner #7</i>		33
<i>Practitioner #8</i>		35
<i>Practitioner #9</i>		37
<i>Practitioner #10</i>		39
B.	Examples of Defrauding Insurers and Pharmacy Benefit Managers	42
	Criminal Counts.....	49

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 **MICHAEL L. BABICH** (“**BABICH**”) resided in Scottsdale, Arizona. At various times relevant to the indictment **BABICH** was President and Chief Executive Officer (“CEO”) of a publicly traded entity located in Arizona (“the Company”). At various times between in or about March 2012 and December 2016, the Company manufactured, marketed, and sold a fentanyl spray (“Fentanyl Spray”) in interstate commerce, including in the District of Massachusetts. As President and CEO of the Company, **BABICH** was responsible for managing the development, promotion, distribution, and sale in interstate commerce of the Fentanyl Spray.

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

3. The defendant **MICHAEL J. GURRY** (“**GURRY**”) resided in Scottsdale, Arizona. At various times relevant to the indictment **GURRY** held executive management positions at the Company, including Vice President of Managed Markets.

4. The defendant **RICHARD M. SIMON** (“**SIMON**”) resided in Seal Beach, California. At various times relevant to the indictment **SIMON** held executive management

positions at the Company, including Regional Sales Manager for the Central Region and National Director of Sales.

5. The defendant **SUNRISE LEE** (“**LEE**”) resided in Byron Center, Michigan. At various times relevant to the 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.

6. The defendant **JOSEPH A. ROWAN** (“**ROWAN**”) resided in Panama City, Florida. At various times relevant to the 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

7. 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 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 the following 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 Florida.
- 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 Arkansas.

C. Summary of the Allegations

8. In or about late March of 2012, the Company launched the Fentanyl Spray, a powerful, and potentially dangerous, rapid onset opioid approved to treat breakthrough cancer pain, into a small, crowded, and tightly controlled market.

9. From in or about June 2012 and continuing until in or about December 2015, **BABICH, BURLAKOFF, SIMON, LEE, and ROWAN**, the co-conspirator practitioners, and other co-conspirators known and unknown to the Grand Jury, sought to profit by devising and fostering a scheme to bribe practitioners who were licensed to practice in various states, many of whom ran pain clinics. In exchange for those bribes and kickbacks, the practitioners wrote large numbers of Fentanyl Spray prescriptions, most often for patients who did not have cancer. The bribes and kickbacks took different forms, but were most frequently disguised as fees the Company paid the practitioners for marketing events.

10. While the bribery scheme succeeded at generating new Fentanyl Spray prescriptions, insurers, private sector employer-sponsored employee benefit plans (referred to herein as “insurers”), and their agents, were reluctant to approve payment for the Fentanyl Spray

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, **BABICH** and **GURRY**, together with co-conspirators known and unknown to the Grand Jury, created and fostered a scheme to mislead insurers, and the agents of insurers, into authorizing payment for the Fentanyl Spray.

11. Each of the Defendants directed Company employees, including sales force employees, to obtain information necessary to defraud insurers. From a call center at corporate headquarters, Company employees, acting at the direction of **BABICH** and **GURRY**, and co-conspirators known and unknown to the Grand Jury, defrauded insurers by disguising the identity and location of their employer, and by lying about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication.

12. By bribing practitioners to write prescriptions for the Fentanyl Spray, and then defrauding, insurers, the Defendants and co-conspirators known and unknown to the Grand Jury, dramatically increased the volume of prescriptions written for the Fentanyl Spray, and thereafter, the rate at which insurers approved payment for the drug, generating substantial profits for the Company, the Defendants, and co-conspirators known and unknown to the Grand Jury, including the co-conspirator practitioners.

II. The Fentanyl Spray

13. 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 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.

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

The Fentanyl Spray Label

15. 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 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.

16. On or about March 4, 2011, the Company submitted an NDA to the FDA seeking approval of its 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.

The TIRF REMS Access Program

17. 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 opioid therapy for their underlying persistent cancer pain.

18. Each of the TIRF drugs was approved subject to a risk evaluation and mitigation strategy (“REMS”) in order to ensure that the benefits of the drug outweighed the risks associated with the drug, including the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors. Consequently, the FDA required the Company to submit, and ultimately to implement, a REMS strategy for the Fentanyl Spray called the TIRF REMS Access Program.

19. The TIRF REMS Access Program included several elements designed to protect patients from the risks associated with TIRF drugs. 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.

Schedule II

20. 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.

21. Fentanyl, including the Fentanyl Spray, was a Schedule II controlled substance.

III. The Market for the Fentanyl Spray

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

Crowded TIRF Market

23. In or about 2012, there were an estimated one to two million patients in the United States suffering from breakthrough cancer pain.

24. At the time of its launch, the Fentanyl Spray was the fourth new branded drug in the TIRF market in four years. 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.

25. In the first year after the Fentanyl Spray was launched, fewer than 1,900 practitioners wrote approximately 90 percent of all TIRF product prescriptions in the United States. Approximately 30 percent of all TIRF prescriptions were written by fewer than 200 practitioners nationwide.

Insurance

26. 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.

27. 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”).

Managed Care

28. 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. Insurers and pharmacy benefit managers controlled the costs of prescription drugs by using, among other restrictions, prior authorizations.

29. In the six years before the launch of the Fentanyl Spray, managed care restrictions dramatically reduced the market for branded TIRF medications in favor of generics, the most affordable of the TIRF drugs. When the Fentanyl Spray was launched in 2012, the generic forms of TIRF medicines retained nearly two-thirds of the market for TIRF drugs.

Prior Authorizations

30. While their specific requirements varied, almost all insurers required patients to obtain prior authorization 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.

31. 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. Bribing Practitioners and Defrauding Insurers

32. Beginning in or about June 2012 and continuing until in or about December 2015, **BABICH, BURLAKOFF, GURRY, SIMON, LEE, and ROWAN**, the co-conspirator

practitioners including those described in paragraph 7, and other persons and entities known and unknown to the Grand Jury, conspired with one another to use bribes and kickbacks, as well as materially false and fraudulent pretenses, representations, and promises, to gain influence over and control of market demand, and ultimately payment, for the Fentanyl Spray.

A. Bribery of Practitioners

The Speaker Program

33. 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 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.

34. 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.

Using The Speaker Program to Pay Bribes

35. 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, the Company’s leadership had

grown dissatisfied with sales of the Fentanyl Spray. **BABICH**, the President and CEO, began making personnel changes within the Company.

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

37. On or about June 27, 2012, approximately one week after **BURLAKOFF** joined the Company, **BABICH** sent an email to his sales managers, including **BURLAKOFF**. The email, entitled "Live Speaker Targets," compelled **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."

38. 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 [Fentanyl Spray prescriptions]."

39. 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.

40. **BABICH** and **BURLAKOFF** hired new sales employees throughout the summer and autumn of 2012, including **SIMON**, **ROWAN**, and **LEE**.

41. **SIMON** was promoted to Director of Sales for the Company in or about July of 2013. As Director of Sales, **SIMON** directly reported 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**.

Quid Pro Quo

42. Using pharmacy data acquired from third parties, **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.

43. On his first day as Vice President of Sales for the Company, in September 2012, **BURLAKOFF** emailed a newly hired sales representative, with copies to 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).

44. **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 Fentanyl Spray prescriptions written by the speaker, the percentage of Fentanyl Spray prescriptions versus its competitor drugs written by the speaker, the net revenue of profit 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 for each speaker.

45. In return for bribes and kickbacks paid to co-conspirator practitioners, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, expected the co-conspirator practitioners to prescribe the Fentanyl Spray to their patients. If a co-conspirator practitioner did not write an appropriate number of prescriptions, the Defendants and their co-conspirators 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.

46. 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.

47. 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."

Targeting Pain Clinics

48. **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and other 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.

49. 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].

50. 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.

51. 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."

52. **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.

Other Bribes and Kickbacks

53. Fees paid to speakers were the most common form of bribes and kickbacks paid to co-conspirator practitioners. **BABICH, BURLAKOFF, SIMON, LEE, and ROWAN** sought to and did use other forms of bribes and kickbacks to reward co-conspirator practitioners. In exchange for Fentanyl Spray prescriptions:

a. **BABICH, BURLAKOFF, SIMON, LEE, and ROWAN** sought to employ friends and family members of co-conspirator practitioners.

b. **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.

c. **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 support staff employed by the speaker. Many speaker events had no attendees at all. When this occurred, sales representatives were told 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 a bribe in the form of a free dinner with friends.

Administrative Support as Kickbacks

54. 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.

55. Co-conspirator practitioners who wrote large numbers of Fentanyl Spray prescriptions 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. Several of the ABLs and BRMs employed by the Company were family or friends of co-conspirator practitioners.

56. **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.

B. Defrauding Insurers and Pharmacy Benefit Managers

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

58. 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, **BABICH**, **GURRY**, **BURLAKOFF**, and other co-conspirators known and unknown to the Grand Jury sought to create a comprehensive plan to increase profits generated by prior authorizations.

The Reimbursement Unit

59. In or about October 2012, **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury launched the Prior Authorization Tracking Program (“PA Tracking program”). The 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”).

60. In or about November 2012, the PA Tracking program demonstrated that insurers and pharmacy benefit managers only approved payment for approximately 30 to 33 percent of all prescriptions for the Fentanyl Spray. **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury began planning a pilot program to increase the percentage of successful prior authorizations.

61. 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.

62. Using information learned from the pilot program, in or about January 2013 through in or about December 2015, **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 as the “Reimbursement Unit”) changed a number of times, but its purpose and functions remained roughly the same.

63. Practitioners using the Reimbursement Unit 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 medical records of patients.

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

The Gate

65. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury created a pay structure for Reimbursement Unit 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 whole Reimbursement Unit. A Reimbursement Unit employee, no matter how productive, could not qualify for a bi-weekly bonus until the entire Reimbursement Unit reached each week’s threshold number of

approvals. Once the Reimbursement Unit met its threshold, an employee could earn a bonus based upon the number of prior authorizations obtained.

Defrauding Insurers and Pharmacy Benefit Managers

66. **GURRY**, and other co-conspirators known and unknown to the Grand Jury, held team meetings with Reimbursement Unit 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. Reimbursement Unit 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.

67. In or about December 2013, approximately one year after it was created, the Reimbursement Unit handled prior authorization requests for practitioners nationwide. At or about the same time, the Reimbursement Unit reported that insurers and pharmacy benefit managers granted prior approval for more than 85 percent of all prescriptions handled by Reimbursement Unit employees.

V. Examples

68. The schemes to profit from 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.

A. Examples of Bribing Medical Practitioners

Practitioner #1

69. Practitioner #1 and Practitioner #2 owned and co-directed a pain management clinic in two locations in or around Mobile, Alabama. Practitioner #1 and Practitioner #2 also owned a pharmacy, which was next to one of their clinic locations.

70. In or about March of 2012, a Company sales representative approached both Practitioner #1 and Practitioner #2 because both had been identified as pain specialists who wrote a substantial number of prescriptions for TIRF drugs. Practitioner #1 and Practitioner #2 began writing Fentanyl Spray prescriptions soon after it 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 Fentanyl Spray prescriptions per week. Practitioner #2 averaged roughly one Fentanyl Spray prescription every other week.

71. 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.

72. 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 ...[Fentanyl Spray prescriptions] a day for one straight quarter, you would make at least 40 grand for the quarter!"

73. 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 Fentanyl Spray prescriptions. By on or about September 28, 2012, the end of the third quarter of 2013, Practitioner #1 averaged approximately 11 Fentanyl Spray prescriptions per week.

74. 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.

75. Between in or about August 2012 and in or about May 2015, many of the Speaker Program events attended by Practitioner #1 were sham events that were mere social gatherings also attended by friends and office staff of Practitioner #1.

76. Between in or about August 2012 and in or about May 2015, payment was authorized for approximately 2,148 Fentanyl Spray prescriptions written by Practitioner #1.

77. Between in or about August 2012 and 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, sent and caused to be sent to Practitioner #1 checks totaling approximately \$229,640.00 for Speaker Program bribes and kickbacks.

Practitioner #2

78. At or around the end of the first quarter of 2013, Practitioner #2 wrote approximately two to three prescriptions for the Fentanyl Spray each week.

79. 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 Fentanyl Spray prescriptions as Practitioner #1 did.

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

81. 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].”

82. Between in or about February 2013 and May 2015, many of the Speaker Program events attended by Practitioner #2 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioner #2.

83. Between in or about February 2013 and May 2015 insurers and pharmacy benefit managers authorized payment for approximately 984 Fentanyl Spray prescriptions written by Practitioner #2.

84. Between in or about February 2013 and 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, sent and caused to be sent to Practitioner #2 checks totaling approximately \$103,350.00 for Speaker Program bribes and kickbacks.

Practitioner #3

85. 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.

86. 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.

87. **BURLAKOFF** was not satisfied with the number of Practitioner #3's Fentanyl Spray prescriptions. 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...."

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

89. 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 Fentanyl Spray prescriptions. 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 Fentanyl Spray prescriptions.

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

91. Many of the Speaker Program events 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 attended by Practitioner #3 included no attendees at all.

92. Between in or about November 2012 through in or about June 2014, insurers and pharmacy benefit managers authorized payment for approximately 2,847 Fentanyl Spray prescriptions written by Practitioner #3.

93. Between in or about November 2012 through in or about June 2014, 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, sent and caused to be sent to Practitioner #3 checks totaling approximately \$138,435.07 for Speaker Program bribes and kickbacks.

94. 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, a Reimbursement Unit employee sent an email to **BURLAKOFF** and **GURRY** stating that the Reimbursement Unit had 153 charts of Practitioner #3's, "in progress, ... and ... 88 charts that we have not worked on yet."

95. **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 Reimbursement Unit with all of the patient information needed to navigate the prior authorization process.

96. 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's Human Resource Generalist ("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 [sic] 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.

97. 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.'"

Practitioner #4

98. Practitioner #4 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 #4 was first and foremost a business

man, **BURLAKOFF** directed the sales representative to use the Speaker Program as a way to pay Practitioner #4 for writing Fentanyl Spray prescriptions.

99. At or about the beginning of August 2012, when the Speaker Program was set to begin, Practitioner #4 averaged 0.8 Fentanyl Spray prescriptions each week. A month earlier, **BURLAKOFF** had acknowledged to the South Florida sales representative that Practitioner #4 was a good speaker, but that “even the docs he spoke to won’t write.”

100. 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 #4 \$36,000 for 15 Speaker Program events.

101. By in or about early January 2013, Practitioner #4 averaged approximately 3.3 Fentanyl Spray prescriptions per week. This was an improvement, but **BABICH**, **BURLAKOFF**, and **ROWAN** believed Practitioner #4 had potential to write many more Fentanyl Spray prescriptions.

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

103. One week later, the sales representative assigned to Practitioner #4 informed **BURLAKOFF** and **ROWAN** that Practitioner #4 had written 17 Fentanyl Spray prescriptions in less than a week. The same day, **ROWAN** texted Practitioner #4, “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.”

104. Practitioner #4 continued to receive Speaker Program bribes and kickbacks, and by July of 2013 averaged approximately five prescriptions per week. By January 2014, Practitioner #4 averaged approximately seven Fentanyl Spray prescriptions per week.

105. Between in or about August 2012 and November 2015, insurers and pharmacy benefit managers authorized payment for approximately 2,030 Fentanyl Spray prescriptions written by Practitioner #4.

106. Between in or about August 2012 and November 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, the Defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #4 checks totaling approximately \$260,050.00 for Speaker Program bribes and kickbacks.

Practitioner #5

107. 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 Fentanyl Spray prescriptions and was paid for only one Speaker Program event.

108. 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 Fentanyl Spray prescriptions each week.

109. **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.”

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

111. Most of the Speaker Program events 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.”

112. By the end of the third quarter of 2013, Practitioner #5 averaged more than 12 Fentanyl Spray prescriptions each week. Between in or about January 2013 and January 2014, insurers and pharmacy benefit managers authorized payment for approximately 527 Fentanyl Spray prescriptions written by Practitioner #5.

113. Between in or about January 2013 and January 2014, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, 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.

114. **BABICH, BURLAKOFF, and SIMON** expected more than just a large volume of prescriptions from co-conspirator practitioners in exchange for their bribes and kickbacks. The bonus structure for sales representatives rewarded not just the number of prescriptions written, but also the dosage and the number of sprays, or “units,” prescribed.

115. 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

116. 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.

117. 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] 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.

118. 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."

119. 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 Fentanyl Spray prescriptions.

120. 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...."

121. 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 Fentanyl Spray prescriptions per week. By in or about the second week of January 2013, Practitioner #6 averaged 3.6 Fentanyl Spray prescriptions each week.

122. 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 Fentanyl Spray prescriptions each week.

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

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

125. Between in or about February 2013 and July 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, 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

126. 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.”

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

[d]amn 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.

128. By in or about March of 2013, Practitioner #7 averaged approximately 0.9 Fentanyl Spray prescriptions 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.

129. 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.

130. 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.

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

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

133. Between in or about December 2012 and April 2015, insurers and pharmacy benefit managers authorized payment for approximately 556 Fentanyl Spray prescriptions written by Practitioner #7.

134. Between in or about December 2012 and April 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, 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

135. 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.

136. 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.

137. 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.

138. 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.

139. 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.

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

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

142. Between in or about August 2013 and November 2014, insurers and pharmacy benefit managers authorized payment for approximately 672 Fentanyl Spray prescriptions written by Practitioner #8.

143. Between in or about August 2013 and November 2014, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, 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.

144. The number of Fentanyl Spray prescriptions 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 a 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 Reimbursement Unit in Arizona.

Practitioner #9

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

146. 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.

147. 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.

148. 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 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.

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

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

151. 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.

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

153. 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]).

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

155. 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 Fentanyl Spray prescriptions each week.

156. **BURLAKOFF** was not satisfied with the increase in the number of Fentanyl Spray prescriptions 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?

157. Between in or about August 2012 and in or about August 2015, insurers and pharmacy benefit managers authorized payment for approximately 1,178 Fentanyl Spray prescriptions written by Practitioner #9.

158. Between in or about August 2012 and in or about August 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, 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

159. Practitioner #10 owned and managed a pain management clinic in Sherwood, Arkansas, where he saw as many as 75 to 100 patients a day. As early as 2012, **BABICH**, **BURLAKOFF**, and **SIMON**, and co-conspirators known and unknown to the Grand Jury, identified Practitioner #10 as an important priority. **BABICH**, **BURLAKOFF**, and **SIMON** knew that Practitioner #10 wrote TIRF prescriptions and believed he had potential to write even more.

160. As they had with other co-conspirator practitioners, **BABICH, BURLAKOFF,** and **SIMON**, and co-conspirators known and unknown to the Grand Jury, sought to use Speaker Program bribes and kickbacks to compel Practitioner #10 to write Fentanyl Spray prescriptions.

161. 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 #10:

9/7 – Spoke to staff and they informed me ... [Practitioner #10] would like to be taken off my call list. They would not give reason and I have been unable to reach ... [Practitioner #10] 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.

162. On a different date the same sales representative told **BABICH** and **SIMON** that Practitioner #10 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.

163. **BABICH, BURLAKOFF, and SIMON** continued to pursue Practitioner #10. On or about October 8, 2012, the sales representative assigned to Practitioner #10 sent **BABICH** and **SIMON** another update:

10/5-RSM Rich Simon and I took ... [Practitioner #10] and his office manager to dinner and turned things around 180 degrees. We set out a plan to conduct dinner programs for ... [Practitioner #10] to speak at his request. ... [Practitioner #10] 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 Director of Trade and Distribution for the Company] & ... [Practitioner #10] to resolve the issue but have a guarantee from ... [Practitioner #10] to have "more scripts than we can handle" once the pharmacy issue is resolved and begins to speak."

164. Beginning in or about November 2012, despite concerns about a potential investigation, the Company began paying Practitioner #10 for Speaker Program events.

165. While Practitioner #10 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 #10. In an email to the assigned sales representative, copied to **BURLAKOFF**, the manager explained that she had canceled scheduled Speaker Programs for Practitioner #10 because the doctor was not giving the Company enough business.

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

“[Practitioner #10] 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.”

167. By the end of 2013, Practitioner #10 was writing approximately one Fentanyl Spray prescription each week. **BURLAKOFF**, **SIMON**, and **ROWAN** hired a new sales representative who had a pre-existing relationship with Practitioner #10, and assigned him to the Company’s Arkansas territory.

168. In or about December 2013, **BURLAKOFF** transferred responsibility for Practitioner #10 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.

169. Working with his new sales representative and a new manager, Practitioner #10 wrote large numbers of Fentanyl Spray prescriptions in exchange for Speaker Program bribes

and kickbacks. Practitioner #10 was paid for eight Speaker Program events during the first quarter of 2014. By in or about the end of March 2014, Practitioner #10 was writing as many as 30 Fentanyl Spray prescriptions in one week.

170. By in or about March of 2014, Practitioner #10 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.

171. Many of the Speaker Program events attended by Practitioner #10 were mere social gatherings also attended by friends and office staff of Practitioner #10 and involved no presentation regarding the Fentanyl Spray.

172. Between in or about November 2012 and in or about June 2015 insurers and pharmacy benefit managers authorized payment for approximately 1,454 Fentanyl Spray prescriptions written by Practitioner #10.

173. Between in or about November 2012 and in or about June 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, the Defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #10 checks totaling approximately \$143,253.89 for Speaker Program bribes and kickbacks.

B. Examples of Defrauding Insurers and Pharmacy Benefit Managers

Disguising the Reimbursement Unit

174. After the Reimbursement Unit launched, in or about January of 2013, **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 a third party such as the Reimbursement Unit in the prior authorization process.

175. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury responded to this problem by seeking to conceal the identity of Reimbursement Unit employees communicating directly with insurers and pharmacy benefit managers. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury promoted the Reimbursement Unit 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.

176. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury instructed Reimbursement Unit 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 Reimbursement Unit 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 Reimbursement Unit employees to hang up when agents of insurers and pharmacy benefit managers pursued the identity of their employer. **GURRY** and another co-conspirator told Reimbursement Unit staff to call back later, in hopes of connecting with a new, less persistent agent. **BABICH** was also aware of, and approved of, the practice.

177. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury also sought to mask the geographical location from which Reimbursement Unit employees were calling. **BABICH, GURRY**, and other co-conspirators set up the Reimbursement Unit phone system to block access to the unit’s number, so that agents of insurers and pharmacy benefit managers would not notice that the Reimbursement Unit employees were calling from an

area code different than the area code of the prescribing practitioner. Employees at the Reimbursement Unit did not identify the Company when answering the phone.

Breakthrough Pain

178. While practitioners acting in the usual course of professional practice possessed the authority to write a prescription for any legitimate medical purpose, **BABICH, GURRY**, and a co-conspirator known 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.

179. 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. **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.

180. **GURRY**, and co-conspirators known to the Grand Jury directed Reimbursement Unit 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).’

181. **GURRY** and co-conspirators known to the Grand Jury approved different versions of “the spiel.”

Fake diagnoses

182. Even with the identity of the Reimbursement Unit disguised, insurers and pharmacy benefit managers reacted differently to prior authorization requests. For some insurers and pharmacy benefit managers, the Reimbursement Unit’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, Reimbursement Unit 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.

183. 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.

184. 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.

185. **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 Reimbursement Unit employees regarding when and how to deceive insurers and pharmacy benefit managers.

i. Dysphagia

186. As a sublingual spray, the Fentanyl Spray was not swallowed, but absorbed into the blood stream after being applied beneath the tongue. **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 Reimbursement Unit 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.

187. 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.

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

ii. A Diagnosis of Cancer

189. **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 Reimbursement Unit 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 Reimbursement Unit 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 Reimbursement Unit 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

190. **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. **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 Reimbursement Unit employees regarding when and how to deceive insurers and pharmacy benefit managers. Reimbursement Unit 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**.

The Calls

191. After the Reimbursement Unit received the Opt-In forms and accompanying medical records, Reimbursement Unit 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, Reimbursement Unit employees misled and deceived insurers regarding their employment, patient medical history, patient diagnoses, and tried and failed medications during those calls.

CRIMINAL COUNTS

COUNT 1

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

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

192. The allegations contained in paragraphs 1 through 191 are re-alleged and incorporated herein by reference.

193. At all times relevant to the Indictment, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) LEE, and (6) ROWAN**, the co-conspirator practitioners described in paragraph 7 (“co-conspirator practitioners”), the Company, 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.

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

195. 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) LEE, and (6) ROWAN**, being persons employed by and associated with the enterprise described in paragraph 193 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).

196. The pattern of racketeering activity through which (1) **BABICH**, (2) **BURLAKOFF**, (3) **GURRY**, (4) **SIMON**, (5) **LEE**, and (6) **ROWAN**, 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 (wire fraud); and
- (c) Title 18, United States Code, § 1952 (interstate and foreign travel or transportation in aid of racketeering);

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).

197. 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
(Scheme to Defraud Patients of Honest Services)
[DEFENDANTS (1) BABICH, (2) BURLAKOFF, (4) SIMON, (5) LEE and
(6) ROWAN]**

198. The allegations contained in paragraphs 1-2, 4-56, and 69-173 are re-alleged and incorporated herein by reference.

199. From in or about June 2012 until in or about December 2015, within the District of Massachusetts and elsewhere, (1) **BABICH**, (2) **BURLAKOFF**, (4) **SIMON**, (5) **LEE**, and (6) **ROWAN**, 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 honoraria 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 honoraria 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
(Scheme to Defraud Insurers and Pharmacy Benefit Managers)
[DEFENDANTS (1) BABICH, and (3) GURRY]

200. The allegations contained in paragraphs 1, 3, 7- 32, 57-68, and 174-191 are re-alleged and incorporated herein by reference.

201. From in or about December 2012 and continuing until in or around December 2015, within the District of Massachusetts and elsewhere, (1) **BABICH** and (3) **GURRY**, 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, that is, having devised and intending to devise a scheme and artifice to defraud insurers and pharmacy benefit managers 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, transmitted and caused to be transmitted by means of wire communication in interstate commerce, writings, signs, signals, pictures, and sounds, to wit: telephone communications, 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, (4) SIMON, (5) LEE and
(6) ROWAN]**

202. The allegations contained in paragraphs 1-2, 4-56, and 69-173 are re-alleged and incorporated herein by reference.

203. From in or about June 2012 until in or around December 2015, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (4) SIMON, (5) LEE, and (6) ROWAN** 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)**

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

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

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

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 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 October 2016; and
- b. forfeiture money judgment equal to the amount of proceeds obtained as a result of the offense alleged in Count One of the Indictment;

205. If any of the property described in Paragraph 204, 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 204.

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))

206. 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 Indictment,

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

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

the Defendants herein, shall forfeit to the United States, jointly and severally as to each of Count Two and Count Three, 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. The property to be forfeited includes, but is not limited to the following:

- a. forfeiture money judgment equal to the amount of proceeds obtained as a result of the offenses alleged in Count Two and Count Three of the Indictment.

207. If any of the property described in Paragraph 206, 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 206 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))**

208. 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 Indictment,

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

the Defendants herein, shall forfeit to the United States, jointly and severally as to each of Count Four, 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. The property to be forfeited includes, but is not limited to the following:

- b. forfeiture money judgment equal to the amount of the proceeds of the offense alleged in Count Four of the Indictment.

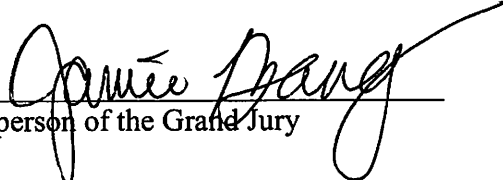
209. If any of the property described in Paragraph 208, above, as being forfeitable pursuant to Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of the defendants –

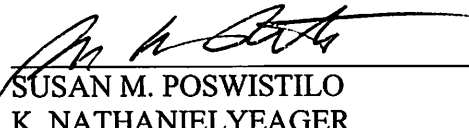
- (f) cannot be located upon the exercise of due diligence;
- (g) has been transferred or sold to, or deposited with, a third party;
- (h) has been placed beyond the jurisdiction of the Court;
- (i) has been substantially diminished in value; or
- (j) has been commingled with other property which cannot 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 208 above.

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


A TRUE BILL


Foreperson of the Grand Jury


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

DISTRICT OF MASSACHUSETTS: December 6, 2016

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


Deputy Clerk 12/6/16 @ 2:40pm