IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION



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| [UNDER SEAL] | | : CIVIL ACTION NO.8:19-cv-902T35TGW |
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| | | : HON. SCRIVEN |
| | | : MAGISTRATE WILSON |
| | Plaintiff | : |
| | | : AMENDED *QUI TAM* COMPLAINT |
| | | : JURY TRIAL DEMANDED |
| | | : |
| v. | | : |
| | | : |
| [UNDER SEAL] | | : FILED UNDER SEAL |
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| | Defendants. | : DO NOT PLACE ON PACER |
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*AMENDED QUI TAM* COMPLAINT FOR VIOLATIONS OF FEDERAL AND STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL

# DO NOT FILE WITH PACER

# DO NOT SERVE ANY DEFENDANTS

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

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| UNITED STATES OF AMERICA, EX REL. DAWN BAKER and SHELDON CHO, MD, and on behalf of the STATES OF CALIFORNIA, FLORIDA, AND TEXAS | : | CIVIL ACTION NO. 8:19-cv-902T35TGW |
| PLAINTIFFS, | : | HON. SCRIVEN |
| | : | MAGISTRATE WILSON |
| V. | : | |
| PHYSICIAN PARTNERS OF AMERICA, LLC, | : | |
| | : | QUI TAM COMPLAINT |
| PHYSICIAN PARTNERS OF AMERICA HOLDINGS, LLC, | : | JURY TRIAL DEMANDED |
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| **ABRAHAM RIVERA, MD, and** | : |
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| **MEDTRONIC, PLC** | : |
| | : |
| **DEFENDANTS.** | : |
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***AMENDED QUI TAM* COMPLAINT FOR VIOLATIONS OF FEDERAL AND STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL**

## I. INTRODUCTION AND SUMMARY OF FRAUD ALLEGATIONS

1. This *qui tam* action alleges violations of the federal False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* ("FCA"), and analogous state FCAs by Defendants, Physician Partners of America, LLC ("PPOA"), and its affiliated and related entities, including its operating and holding companies, which provide pain management, and other related ancillary services, including ambulatory surgery, anesthesia, urine testing, implantation of medical devices, DNA testing, imaging, pharmacy and transportation, as well as entities related to PPOA founder, Dr. Rodolfo Gari, including, Gari Capital, LLC, and individuals related to PPOA named herein (hereafter, "the PPOA Defendants") and Defendant Medtronic PLC ("Medtronic"). The PPOA Defendants engaged in a fraud scheme to cause the submission of false claims to Government healthcare programs for medically unnecessary services and services that are and continue to be tainted by Anti-Kickback Statute and Stark Law violations related to: 1) urine toxicology testing ("UTOX"); 2) genetic testing; 3) interventional procedures; 4) laser spine surgeries; 5) anesthesia services; 6) pharmacy and specialty pharmacy services; 7) imaging; 8) durable medical equipment ("DME"); and 9) transportation services. Together with Defendant and co-conspirator Medtronic, the PPOA Defendants engaged in a fraud scheme whereby Medtronic provided inducements to PPOA physicians in exchange for using expensive Medtronic devices in interventional procedures and/or surgeries.

2. These schemes were carried out by and through the conduct of individuals, namely PPOA's corporate executives and managers who personally created, participated in, approved, and/or profited from the scheme, including, but not limited to the following PPOA-affiliated individuals: Rodolfo Gari, MD, founder and owner of the PPOA Defendants; Tracie Lawson, President, PPOA, and current or former executive of many PPOA affiliated Defendants; Samantha Dangler, Vice President of Sales and Operations – PPOA Ancillary Division; David Wood, Chief Executive Officer (CEO) and Chief Experience Officer (CXO) and Manager of multiple PPOA Defendants; Josh Helms, Chief Operating Officer (COO); James St. Louis, DO; Crystal Winkler, Vice President of Human Resources; Chris Yinger, Senior Vice President of Information Technology and Corporate Security Officer; Christina Infinger, Vice President of Business Development; William Milo, Senior Vice President of Physician Practices; and Abraham Rivera, MD, Chief Medical Officer (CMO) for PPOA.

3. During the relevant time period (late 2013 to the present), the PPOA-affiliated Defendants used PPOA patients as pawns in a well-orchestrated scheme to maximize the per-patient reimbursement from Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Plan ("FEHBP"), and the Veteran's Administration ("VA") ("Government Healthcare Programs"), as well as private insurance carriers, without regard to whether the care was medically necessary, the claim submitted was accurate, and often in clear violation of Anti-Kickback Laws, the Stark Law, and the False Claims Act.

4. The PPOA Defendants have knowingly (as that term is defined in the FCA) violated the federal and state FCAs by: 1) generating false records that were material to the payment of false or fraudulent claims for healthcare services submitted to Government healthcare programs, as described herein; 2) submitting, or causing the submission of millions of dollars' worth of false

claims to Government-funded healthcare programs for the services described herein, including confirmatory Quantitative UTOX, DNA testing, interventional procedures and laser spine surgeries, Certified Registered Nurse Anesthetist CRNA services, imaging, pharmacy, DME, and/or transportation services that were not reasonable or necessary; 3) conspiring to cause the submission of false claims by PPOA-affiliates to Government-funded healthcare programs; and 4) failing to return to Government-funded healthcare programs overpayments received by the Defendants for medically unnecessary services.

5. The PPOA Defendants have established so-called metrics for PPOA physicians, including conversion rates of patients from conservative treatments to expensive procedures and surgeries, ordering of UDT and DNA tests, and prescribing certain high-priced name brand drugs or lucrative compounding drugs. Physicians who fail to meet these quotas are reprimanded and pressured to meet PPOA's revenue-driven standards regardless of the implications for patient care and medical necessity.

6. During the relevant time period, the PPOA Defendants and Medtronic also knowingly violated the federal and state FCAs by: 1) generating false records that were material to false or fraudulent claims for healthcare services submitted to Government healthcare programs, as described herein; 2) submitting, or causing the submission of false claims to Government-funded healthcare programs for surgeries, and/or interventional procedures using Medtronic products; 3) conspiring to cause the submission of false claims to Government-funded healthcare programs for surgeries and/or interventional procedures using Medtronic products; 4) failing to return to Government-funded healthcare programs overpayments received by the Defendants for medically unnecessary services, and 5) submitting false claims to private and public insurance carriers in California.

7. During the relevant time period, Defendants' knowingly engaged in illegal conduct to carry out a carefully orchestrated, corporate-led effort to maximize reimbursements from Government healthcare programs through the following schemes:

(a) improperly steering lucrative referrals of patients covered by Government-funded healthcare programs to their affiliated Medical Tox Labs and Medical DNA Labs for unnecessary and over-utilized lab-based UTOX and DNA testing services;

(b) compelling PPOA-affiliated pain physicians to perform highly expensive and medically unnecessary interventional procedures on at least 15% of their patients;

(c) mandating that PPOA-affiliated practitioners subject every patient to a cursory psychological test – regardless of medical necessity – for the sole purpose of increasing the total billable charges per PPOA patient;

(d) pressuring physicians and mid-level providers to refer patients for medically unnecessary lab-based UTOX and DNA testing services, laser spine surgeries, and other interventional procedures, including by closely monitoring when providers did not refer patients for these services and retaliating against Physicians who did not comply with the Defendants' directives;

(e) pressuring physicians and mid-level providers to deviate from the standard of care and sign false attestations of medical necessity for lab-based UTOX and DNA testing, interventional procedures, laser spine surgeries, CRNA services, DME, imaging, pharmacy and/or transportation services in order for Defendants to either respond to and/or avoid denials of claims for these services by Government-funded healthcare programs, including Medicare;

(f) fraudulently obtaining the consent of patients, including Government healthcare program beneficiaries, for UTOX, DNA testing services, interventional procedures and

surgeries, including so-called laser spine surgeries. The latter by misrepresenting the patients that their treating physician had determined these surgeries were medically necessary, when in fact the doctor had not;

(g) overbilling for unsupervised Certified Registered Nurse Anesthetist (CRNA) services; and

(h) failing to return known overpayments when Defendants all had full knowledge that they had submitted or caused the submission of false claims to Government-funded healthcare programs.

8. Defendants also violated the federal FCA and analogous state FCAs by submitting and/or causing the submission of false claims for the following services: MedTox UTOX; Medical DNA Labs DNA testing services; laser spine surgeries; CRNA services; pharmacy services and expensive drugs and compounding products, DME, imaging, and/or transportation services that were furnished pursuant to prohibited referrals that resulted from Defendants' improper financial relationships with physicians, in violation of the physician self-referral prohibition, 42 U.S.C. 1395nn (the "Stark Law"), the federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b), and analogous state statutes.

9. In particular, the PPOA Defendants interfered with the objective medical decision-making process by adopting and making conditions of employment for PPOA's employed and affiliated pain management specialists, the use of office and ambulatory surgery center ("ASC") based procedures that resulted in the over-utilization of patients receiving UTOX and DNA testing, laser spine surgery, anesthesia (including CRNA services), pharmacy, imaging, DME, transportation, and other ancillary services because their compensation was based in part on revenues generated illegally through PPOA's ancillary services.

10. The Defendants also based their employed physicians' compensation on the volume or value of referrals of the physicians' own patients to the Defendants' wholly-owned subsidiaries, for designated health services, including, but not limited to: UTOX testing; DNA testing; laser spine surgery; implantation of medical devices, CRNA services; pharmacy services, over-utilization of anesthesia services, and transportation services.

11. All of the PPOA Defendants' pain management, ASC, spine surgery, and ancillary services were provided to beneficiaries of Government healthcare programs and claims related to these services were submitted for payment. In fact, David Wood, the Defendants' Chief Experience Officer, created an analysis of the revenue attributable to each patient through each of the PPOA affiliates including: UTOX testing; DNA testing; laser spine surgery; CRNA services; imaging; pharmacy; and transportation.

12. Together with Medtronic, the PPOA Defendants violated the Federal FCA and state FCAs through their joint efforts to violate the federal Anti-Kickback Statute ("AKS") and state analogs. Medtronic provided and PPOA accepted inducements in exchange for the PPOA Defendants recommending Medtronic products and/or the PPOA physicians referring patients to Medtronic for products to be used in procedures performed by PPOA providers.

## II. JURISDICTION AND VENUE

13. This action arises under the laws of the United States of America to redress violations of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, the physician self-referral prohibition, 34 U.S.C. 1395nn (commonly known as the "Stark Law"), and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

14. Subject-matter jurisdiction is conferred by 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331, 1345.

15. The Court has jurisdiction over all of the Defendants' violations of the False Claims Acts and Anti-Kickback Statutes of the plaintiff States of Florida, Texas, and California, as well as the California Insurance Fraud Prevention Act, pursuant to 31 U.S.C. § 3732(b), because Defendants' violations of these laws and their violations of the federal FCA arise from the same transactions or occurrences.

16. Moreover, the Court has supplemental jurisdiction over Defendants' state law violations and causes of action pursuant to 28 U.S.C. § 1367(a) because these state law violations and claims and Defendants' violations of the federal FCA arise out of a common nucleus of operative facts.

17. The Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because the Defendants have at least minimum contacts with the United States, and the Plaintiff States, and can be found in, transact or have transacted, business in the Middle District of Florida.

18. The PPOA Defendants, including the physician practices, MedTox, Medical DNA Labs, ASC, pharmacies, DME affiliates, imaging affiliates, the transportation affiliates, the CRNA subsidiaries, etc., regularly offer and perform healthcare services and submit or cause the submission of thousands of claims for payment to federal and state healthcare programs, including, but not limited to, Medicare, Medicaid, TRICARE, and the Veterans' Administration.

19. Venue lies under 28 U.S.C. § 1391(b), (c) and 31 U.S.C. § 3732(a) because the Middle District of Florida is a district in which the Defendants can be found or transact business, and acts proscribed by 31 U.S.C. § 3729 occurred within this district.

20. The specific facts, circumstances, and allegations of the Defendants' violations of the federal FCA and analogous state FCAs have not been publicly disclosed in a civil suit, criminal suit,

or administrative civil money penalty proceedings in which the Government is already a party.

## III. PROCEDURAL HISTORY

21. The Relators are the original source of all the information upon which this Amended Complaint is based, as that phrase is used in the federal FCA and analogous state FCAs. There has been no public disclosure of the allegations herein.

22. To the extent any such disclosure has been made, such disclosure is unknown to the Relators and the Relators remain "original sources" under 31 U.S.C. § 3730(e)(4), and the similar provisions of analogous state FCAs.

23. The Relators have direct and independent knowledge of the information on which the allegations herein are based and voluntarily provided all this information to the federal Government in pre-filing disclosures and during an all-day meeting with the Government in Tampa, Florida on July 23, 2019 and all relevant state Governments prior to filing this action. See 31 U.S.C. § 3730(e)(4).

## IV. THE PARTIES

### A. The Relators

#### 1. Relator Dawn Baker

24. Plaintiff/Relator Dawn Baker, a professional physician recruiter, lives in the state of Missouri, and is a resident of the United States. Ms. Baker graduated from Jackson College of Ministries. She has been a professional physician recruiter since 1995.

25. Based in St. Louis, Missouri, Ms. Baker places physicians with healthcare providers throughout the United States, including within this district.

26. Dawn Baker had a conversation with Will Milo in November 2018 where Milo shared that he wanted to replace Relator Sheldon Cho, MD, a pain management physician, with

Stanley Golovac, MD, another pain physician. Milo cited Dr. Cho's low procedure statistics, stating that Dr. Golovac "could do in one day what Dr. Cho takes all month to do."

27. In December 2018, Baker learned that PPOA was planning to hire Dr. Golovac as its Medical Director.

28. Relator Dawn Baker is aware of fraud related to UTOX testing at a prior entity, Surgery Partners, during the time that Defendants Dr. Golovac, Milo, Christina Infinger, and Winkler, as well as Durwood Thompson, worked there.

29. During the relevant time period, Ms. Baker's primary contacts at PPOA have been David Wood and Will Milo. She has also interacted directly with, among other people, Dr. Gari, Dr. Rivera, Winkler, and Infinger. With the exception of Mr. Wood, all of Ms. Baker's business contacts at PPOA were former Surgery Partners' executives or managers.

**2. Relator Sheldon Cho, MD**

30. Plaintiff/Relator Sheldon Cho, MD, a board-certified pain medicine specialist, is a resident of the state of Florida and a naturalized citizen of the United States. He graduated from Seoul National University College of Medicine in 1992, and has been practicing medicine since that time.

31. Dr. Cho is licensed to practice medicine in the states of California and Florida.

32. Before he moved to Florida in 2015, Dr. Cho had extensive experience in both pain management and addiction treatment.

33. Pursuant to a September 16, 2015, employment agreement, Dr. Cho became an employee of Tampa Pain Relief Center, Inc. Pursuant to that agreement, from November 2015 until May of 2017, Dr. Cho was in private medical practice at Surgery Partners' Florida Pain Institute (FPI) – Merritt Island, Florida. Dr. Cho also performed procedures at Surgery Partners'

Space Coast Surgery Center, which is located in the same building as FPI – Merritt Island. From time to time, Dr. Cho saw patients at Surgery Partners' FPI locations in addition to Merritt Island, including Viera, and Titusville.

34. Florida Pain Institute ("FPI") - Merritt Island was a pain management practice acquired by Surgery Partners on or about June 2015 from Dr. Stanley Golovac and Dr. Richard Gayles. At that time, Dr. Golovac became Surgery Partners' Medical Director overseeing all Surgery Partners' physician pain management practices, including those in Florida, Colorado, and North Carolina, including the Merritt Island, Florida location where Dr. Cho practiced.

35. Throughout his employment, Dr. Cho raised his concerns with the Surgery Partners' urine drug testing ("UDT") policy, which had been enforced by Dr. Golovac, and Dr. Cho made suggestions to allow practitioners to use an opioid abuse risk tool to determine the medical necessity of UDT for their patients, rather than Surgery Partners' pre-determined number of UDT episodes per patient per year.

36. Throughout his employment at Surgery Partners, Dr. Golovac made clear that he would be monitoring physician compliance with Surgery Partners' UDT policy, which required UDT screening and confirmation testing of every patient at every visit to the pain clinic. Although Surgery Partners' written policy stated that pain management physicians should use their independent judgment, Dr. Golovac told Dr. Cho that UDT was mandatory for every patient at every visit.

37. Due to ongoing fraud involving UDT at Surgery Partners, and threats from Surgery Partners executives, including Medical Director Dr. Golovac, Dr Cho left Surgery Partners in early 2017.

38. On February 3, 2017, Dr. Cho executed an Employment Agreement with the PPOA

Defendants, through Florida Pain Relief Group, PLLC ("FPRG"), effective on May 1, 2017. Dr. Cho's first day with FPRG was on or about May 6, 2017. At the time, he was subject to a non-compete agreement with Surgery Partners.

39. Upon his arrival, Dr. Cho was provided with information to establish PPOA's computer system and remote network. At that time, PPOA used Greenway (PrimeSuite). PPOA's Tricia Alvarado and Angela Leone (Gerger), IT Software Trainer, provided this information.

40. When first hired, Dr. Cho was presented with PPOA's "Affiliate Pharmacies 101." In that document PPOA made clear:

- The "importance of [PPOA's] Ancillaries," including: labs, pharmacy, clinics, ASCs. The graphic is a Jenga game, with building blocks representing PPOA's ancillary revenue sources;
- At the time, early 2017, PPOA operated pharmacies at four locations:
    1) Stonebriar in Frisco, Texas, retail and compounded medications;
    2) Patient Rx in Arlington, Texas, and Hurst, Texas, as well as Tampa, Florida ("Fletcher") with "Merritt Island coming soon;"
    3) Depending on "coverage," prescriptions were shipped to Stonebriar, then the medication was sent back to Tampa, Florida ("Fletcher") for dispensing to the patient (or shipping). In other words, all prescriptions were dispensed from Tampa, Florida.

41. When Dr. Cho arrived at PPOA, he was practicing at their Winter Haven, Florida location (in order to be compliant with the Surgery Partners' non-compete agreement). After a year, Dr. Cho moved to PPOA's Rockledge location, where he practiced for several months. In July 2018, PPOA relocated their Rockledge operations (where Dr. Cho was practicing) to their

Merritt Island Medical Pavilion in order to gain space to build an ASC. Once the Merritt Island ASC was completed (in or around January 2019), PPOA closed the procedure room at Merritt Island. All patients at PPOA's Merritt Island location were compelled to have their procedures performed at the ASC.

42. To his dismay, Dr. Cho soon realized that the PPOA defendants were engaged in the same UDT fraud as Surgery Partners, and were also perpetuating other fraudulent schemes, at the expense of their patients and payors, including Government healthcare programs, as outlined herein.

43. In fact, many of the individuals who had been involved in planning, initiating, and carrying out the fraud Dr. Cho experienced at Surgery Partners then migrated to PPOA, including:

(a) William Milo, former Vice President of Operations & Physician Services, and Vice President of Administration at Surgery Partners and Vice President of Logan Labs (Surgery Partner's toxicology arm); Milo joined PPOA in 2018 as the Senior Vice President of Physician Practices.

(b) Crystal Winkler is the Vice President of Human Resources for PPOA; prior to joining PPOA, Winkler was employed by Surgery Partners as their Regional Manager of Human Resources;

(c) Christina Infinger joined PPOA in 2018 as the Vice President of Business Development. Prior to joining PPOA, Infinger was employed as Surgery Partners' Assistant Vice President of Business Development;

(d) Durwood Thompson, who oversaw Surgery Partners' operation as Vice President, joined PPOA in early 2019; and

(e) Dr. Stanley Golovac, Surgery Partners' former Medical Director for all

physician pain management practices became the Medical Director for PPOA Defendants in late 2018 or early 2019. Dr. Golovac and Dr. Gari, PPOA's founder, have been very close personal friends for many years.

44. Dr. Cho, concerned about the fraud schemes he observed at PPOA, made the decision to leave PPOA in early 2019 shortly after Dr. Golovac's arrival. Dr. Cho tendered his resignation to PPOA on February 3, 2019, effective March 15, 2019.

45. The PPOA Defendants, through Dr. Rivera and others, immediately began retaliating against Dr. Cho. For example, they informed Dr. Cho that he could not leave PPOA before his 90-day "out" period, which would expire in May. PPOA's Dr. Rivera accused Dr. Cho of abandoning his patients. Nothing could be further from the truth.

46. Dr. Cho responded in an email dated February 10, 2019 that Dr. Fernandez had agreed to take on Dr. Cho's patients and Dr. Golovac, who had recently joined PPOA, was not seeing any patients and would be able to assist in handling Dr. Cho's patient load.

47. PPOA replied, through a letter from their outside lawyer, David Koch, dated February 14, 2019, that if Dr. Cho left before May 4, 2019, he would be in breach of his employment agreement.

48. Through emails with Dr. Rivera, and Vice President of Human Resources, Crystal Winkler, over several weeks, PPOA cut off Dr. Cho's access to the PPOA electronic medical records ("EMR") system. Ultimately, on March 11, 2019, PPOA terminated Dr. Cho's employment and released him from his clinical duties, "effective immediately."

49. After Dr. Cho left PPOA's premises on March 11, 2019, PPOA, through Dr. Rivera and through Winkler, attempted several times to have Dr. Cho sign a Termination Agreement and Release. He refused to sign PPOA's documents.

## B. The Physician Partners of America Defendants

### 1. Physician Partners of America, LLC

50. Defendant Physician Partners of America, LLC ("PPOA") is a Delaware limited liability company which is headquartered at 550 N. Reo Street, Suite 100, Tampa, FL 33609. Defendant Rodolfo Gari, MD is the founder of PPOA and the chief architect of its noxious business model.

51. The PPOA Defendants own and operate a network of physician practices, surgical facilities, and ancillary services facilities located in Florida, Texas, and since 2019, California. As a result, their operations cover the three states with the highest number of Medicare beneficiaries in the country. These states are also among the top five states (numbers one, three, and five) for Medicaid spending.

52. PPOA acquired the Regional Pain Treatment Medical Center and Alliance Surgical Center of Fullerton, California; a pain practice and related ASC, respectively. During the negotiations, the physician-owner passed away, and PPOA then purchased the practice from the physician's widow. In preparation of the acquisition, Dr. Gari became the Chief Executive Officer, Secretary, and Chief Financial Officer of Defendant Regional Pain Treatment Medical Center, Inc. ("RPTMC"), a California limited liability company headquartered at 295 Imperial Highway, Suite 100, Fullerton, CA 92835, on May 1, 2019.

53. The PPOA Defendants have staffed the California practice with coverage staff since the acquisition in June 2019. Dr. Howard Dedes, a pain management physician based in Quincy, Illinois, has been contracted to join PPOA's practice in Fullerton, California, and will start in August 2019.

54. The PPOA Defendants' physician practices include pain management specialists. The company's ancillary services include multi-specialty physician practices, ASCs, laser spine

surgeries, CRNA services, imaging services, pharmacies and laboratory services, including UTOX testing and controversial and very expensive genetic testing. The UTOX testing is provided by Defendant PPOA's affiliate, Defendant Medical Tox Labs, LLC. The genetic testing is provided by Defendant Medical DNA Labs, LLC.

55. Defendant PPOA and its affiliates were founded in 2013 by Rodolfo Gari, MD. This was not Dr. Gari's first healthcare venture. Dr. Gari had owned and operated Surgery Partners and Tampa Pain Relief, businesses which included both ASCs and related physician practices. Dr. Gari sold Surgery Partners and its affiliated physician practices at the end of 2009 for at least $120 million. After a respite (possibly related to a non-competition agreement related to the sale of Surgery Partners), in 2013, Dr. Gari founded Defendant PPOA, a Delaware corporation with headquarters in Tampa, Florida.

56. Since its founding in 2013, the PPOA Defendants, led by Dr. Gari, have established and operated multiple privately held Delaware corporations, as well as Florida and Texas subsidiaries from their Tampa, Florida headquarters. For example, in 2013, Dr. Gari also founded Defendant Texas Pain Relief Group ("TPRG").

57. Defendant David A. Wood is listed as the Manager of Defendant PPOA and many affiliated entities, including the Texas Pain Relief Group entities.

58. The PPOA Defendants' presence in Texas, through TPRG, began with one clinic in 2013. Within six months, Dr. Gari and Defendant Wood had expanded their organization to 13 multi-specialty physician practices, which focus on treating patients with chronic and acute pain. The PPOA Defendants' Texas operations now include an outpatient laser surgery center, which is serviced through referrals from the company's current 16 Texas-based multi-specialty physician practices. TPRG's physician practice expansion is ongoing.

59. In early 2016, Dr. Gari led the PPOA Defendants to expand their pain treatment operations in Florida. In less than three years, the PPOA Defendants have expanded their Florida presence to include six surgery centers and 20 multi-specialty physician clinics.

60. In all, the PPOA Defendants' Texas and Florida operations treat approximately 20,000 patients annually. The PPOA Defendants employ about 700 people nationally, with about 300 of those based in Texas. PPOA's annual revenue has exceeded $100 million.

61. Defendant Physician Partners of America Holdings, LLC ("PPOA Holdings") is a Delaware limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

62. Dr. Gari is the President of PPOA Holdings. Through Surgery Partners and PPOA, Dr. Gari has amassed a substantial fortune. His real estate holdings, held either individually or through companies he controls, alone are valued at over $70 million. Upon information and belief, much of Dr. Gari's property is owned by PPOA Holdings, and similar entities described below, including property used in the operations of PPOA and its affiliates and subsidiaries.

63. Defendant Physician Partners of America Florida Medical Holdings, LLC ("PPOA Florida Holdings") is a Delaware limited liability company which is headquartered at 550 N. Reo Street, Suite 100, Tampa, FL 33609.

64. Defendant David Wood is also listed as the Manager of PPOA Florida Holdings.

65. Defendant Physician Partners of America CRNA Operations, LLC ("PPOA CRNA OPS") is a Delaware limited liability company which is headquartered at 550 N. Reo Street, Suite 100, Tampa, FL 33609.

66. Dr. Gari is the CEO and Defendant David Wood is the Manager of PPOA CRNA OPS.

67. Defendant Physician Partners of America CRNA Holdings, LLC ("PPOA CRNA Holdings") is a Delaware limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614. Upon information and belief, PPOA CRNA Holdings owns and operates PPOA CRNA OPS.

68. In addition, in 2014, Dr. Gari formed Texas Anesthesia Group, PLLC ("Texas Anesthesia Group") located on Precinct Line Road, Hurst, TX.

69. Defendant Physician Partners of America ASC Holdings, LLC ("PPOA ASC") is a Delaware limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614. PPOA ASC is the majority owner and receives 80% – 90% of distributions from the ASCs operated throughout Texas, Florida, and California.

70. Defendant Physician Partners of America Ancillary Holdings, LLC ("PPOA Ancillary Holdings") is a Delaware limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

71. Defendant Physician Partners of America Transportation, LLC ("PPOA Physician Trans") is a Florida limited liability company which is headquartered at 550 N. Reo Street, Suite 100, Tampa, FL 33609.

72. In addition to the PPOA Defendants' domestic operations, since at least March of 2017, they have been expanding their operations internationally.

73. The above described Defendants are collectively referred to as "the PPOA Defendants."

### 2. Physician Partners of America's Pain Management Physician Practices

74. Since 2013, Defendant PPOA or an affiliate has owned and/or operated at least 33 pain management physician practices in three states, Texas, Florida, and California through a number of known and unknown subsidiaries, including Defendants TPRG, FPRG, PPOA Pain

Relief Group, and RPTMC (collectively "the PPOA Pain Management Defendants"). PPOA owns and/or operates the PPOA Pain Management Defendants through wholly-owned corporate subsidiaries.

75. From at least 2013 through the present, the PPOA Pain Management Defendants' practices located in the state of Texas and the PPOA-affiliated Defendant who owned or operated each practice included, but were not limited to:

(a) McKinney – Texas Pain Relief Group

(b) Frisco – Texas Pain Relief Group

(c) Carrolton – Texas Pain Relief Group

(d) Richardson – Texas Health & Counseling Group

(e) Richardson – Texas Pain Relief Group

(f) Keller – Texas Pain Relief Group

(g) North Dallas – Texas Pain Relief Group

(h) Hurst – PPOA Minimally Invasive Spine Clinic

(i) Hurst – Texas Health & Counseling Group

(j) Hurst - Texas Pain Relief Group

(k) PPOA – Regional Office

(l) Arlington – Texas Pain Relief Group

(m) Fort Worth – Physician Partners of America

(n) Duncanville – Physician Partners of America

(o) Desoto – Texas Pain Relief Group

(p) McKinney – Texas Health & Counseling Group

76. Dr. Gari announced in early 2016 that the PPOA Defendants were expanding into

Florida. From at least 2016 through the present, the PPOA Pain Management Defendants' practices located in the state of Florida and the owner or operator of each included, but were not limited to the following:

(a) Orange Park – PPOA Pain Relief Group

(b) Jacksonville – PPOA Pain Relief Group

(c) New Port Richey – PPOA Pain Relief Group

(d) Tampa (Westchase) – Florida Pain Relief Group

(e) Tampa (Fletcher) – Florida Pain Relief Group

(f) PPOA – Main Office

(g) Tampa (Habana) – Florida Pain Relief Group

(h) Tampa (Habana) – PPOA Personal Injury

(i) Tampa (Habana) – PPOA Orthopedic Care

(j) Tampa (Habana) – Florida Primary Care Clinics

(k) Brandon – Florida Pain Relief Group

(l) Orlando Outpatient Surgery Center

(m) Winter Haven – PPOA Pain Relief Group

(n) Merritt Island – Florida Pain Relief Group

(o) Melbourne – PPOA Pain Relief Group

(p) Wellington – PPOA Pain Relief Group

(q) Boynton Beach – PPOA Pain Relief Group

77. The PPOA Defendants announced in March 2019 that they were expanding their operations into California. The PPOA Pain Management Defendants' practices located in the state of California include, but were not limited to the following:

(a) Regional Pain Treatment Medical Center

(b) Alliance Surgical Center (ASC)

### 3. PPOA-Affiliated Testing Providers

#### a) Medical Tox Labs, LLC

78. Defendant Medical Tox Labs, LLC ("MedTox") is a Florida limited liability company which was registered in 2014, and is headquartered at 3450 Fletcher Avenue, Suite 230B, Tampa, FL 33613.

79. Defendant David Wood is also listed as the Manager of MedTox. Dr. Gari is the Chairman of MedTox.

80. MedTox is an affiliate of the PPOA Defendants through common ownership and management.

81. As alleged herein, Relators believe that virtually all of the referrals to MedTox come from the patients treated at physician practices owned by or affiliated with the PPOA Defendants.

#### b) Medical DNA Labs, LLC

82. Defendant Medical DNA Labs, LLC ("Medical DNA") is a Florida limited liability company which is headquartered at 3450 Fletcher Avenue, Suite 230A, Tampa, FL 33613.

83. Medical DNA is an affiliate of PPOA through common ownership and management. PPOA compels all of their patients to use Medical DNA for genetic testing. Medical DNA also performs UTOX tests as well, however, its focus is on exceptionally expensive DNA testing. Although not medically necessary, PPOA causes its PPOA pain management and other physician practices to refer patients to Medical DNA. PPOA and/or Medical DNA then bills the Government healthcare program or private insurer for the unnecessary tests.

84. Dr. Gari is the Chairman and Defendant David Wood is listed as the Manager of Medical DNA.

85. In 2014, Dr. Gari and David Wood established and obtained National Provider Numbers ("NPIs") for MedTox and Medical DNA Labs, but did not operate those labs until 2016, when the Defendants established PPOA-affiliated physician practices and other healthcare service providers in Florida.

86. Upon information and belief, the commencement of operations at MedTox and DNA Labs coincided with the opening of the Defendants' Florida pain management practices. MedTox and Medical DNA Labs are in the same building as Florida Pain Relief Group. Medical DNA Labs is located in the same suite as the corporate office for Florida Pain Relief Group.

87. Defendants have used the patients treated in their Florida and Texas practices to guarantee a stream of referrals for their wholly-owned ancillary lab businesses. Upon information and belief, PPOA's newer California practices have started to send referrals to these labs through the same fraudulent scheme.

#### 4. Patient Rx Solutions Pharmacy, LLC, Patient RX Solutions Pharmacy Hurst, LLC, and Patient Rx Solutions Merritt Island, LLC

88. Defendant Patient Rx Solutions Pharmacy, LLC ("Patient Rx") is a Texas limited liability company which is headquartered at 1717 Precinct Line Road, Suite 202, Hurst, TX 76054.

89. Defendant Patient RX Solutions Pharmacy Hurst, LLC ("Patient RX-Hurst") is a Texas limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614. According to PPOA documents, PPOA also operated Patient Rx Solutions in Arlington, Texas.

90. Defendant Patient Rx Solutions Merritt Island, LLC ("Patient Rx-Merritt") is a Florida limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204,

Tampa, FL 33614.

91. The PPOA Defendants' Patient Rx Solutions affiliates are or have been operated from locations in Hurst, Texas, Tampa, Florida, and Merritt Island, Florida. Collectively, these "Patient Rx Defendants" are wholly-owned by PPOA Ancillary Holdings.

92. The Patient Rx Defendants provide pharmacy services primarily to PPOA patients although they are not closed to the public at large. The Patient Rx Defendants are open only from 9:00 a.m. to 5:00 p.m., Monday to Friday. They are closed on the weekend.

93. The services provided by the Patient Rx Defendants include: medication management (focusing on drug-to-drug interactions); compounding and other topical prescription pain medications; and the delivery of services related to these prescription services.

94. The Patient Rx Defendants offer only a limited formulary of medications geared toward PPOA's preferred medications. They do not provide other aspects of retail pharmacy services such as a broad formulary or over-the-counter medications or other health and beauty products, etc.

### 5. Stonebriar Pharmaceutical Services, LLC

95. Defendant Stonebriar Pharmaceutical Services, LLC, ("Stonebriar") is a Texas limited liability company which is headquartered at 5575 Warren Parkway, Suite 216, Frisco, TX 75034. The mailing address for Stonebriar is 504 N. Reo Street, Tampa, FL 33609.

96. Stonebriar is affiliated with the PPOA Defendants.

97. Defendant David Wood is listed as one of the managers of Stonebriar, together with Rosa Bowling and Thad Johnson.

98. Although Stonebriar is arguably not closed to the public, it provides pharmacy services primarily to PPOA patients. Stonebriar is open 9:00 a.m.-5:00 p.m., Monday to Friday.

They are closed on the weekend.

99. Like the Patient Rx Defendants, Stonebriar is not set up to provide broad retail pharmacy services. Instead, Defendant Stonebriar's services are limited to: medication management (focusing on drug-to-drug interactions); compounding and other topical prescription pain medications; and related delivery services. PPOA provides all compounding services through Defendant Stonebriar to all patients in Florida and Texas.

100. As part of the medication management Defendant Stonebriar conducts laboratory tests and other studies purportedly related to the use of prescribed medications.

101. However, Stonebriar is primarily used by the PPOA Defendants to maximize revenue per patient through unnecessary compounded medications. According to PPOA documents, Stonebriar in Frisco, Texas provides limited "retail and non-sterile compounding" pharmacy services.

102. The pharmacists at Stonebriar have included Majid Jafari. PPOA's Director of Operations for its pharmacies has included Kristi Andrews, who was located in Texas.

103. PPOA's Director of Sales and Marketing for its pharmacy affiliates is Chris Gardner, who is located in Florida.

104. The logistics PPOA employs to dispense medication from its affiliated pharmacies are dictated in large part by the focus of the pharmacy. All compounded medication prescriptions are filled by PPOA's Stonebriar facility. Stonebriar then sends the prescriptions back to PPOA's Florida pharmacy for shipping. Non-compounded prescriptions are received by and dispensed by PPOA's Florida pharmacy operations.

### 6. The PPOA Imaging Affiliates

105. In addition to the above-named PPOA-affiliates, since 2015, the Defendants have

provided imaging services through Defendant Doctors Imaging, LLC, ("Doctors Imaging") which is located at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614 and has a mailing address of 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

106. The NPI for Doctors Imaging is 1487045407. Dr. Gari is also the Chairman of Doctors Imaging.

107. The PPOA Defendants also operate Partners Neurodiagnostics, LLC ("Partners Neurodiagnostics"). Partners Neurodiagnostics is located at 4726 N. Habana Avenue, Suite 100, Tampa, FL 33614 and has a mailing address of 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614. Tracie Lawson is the COO/Manager of Partners Neurodiagnostics.

### 7. The ASC Defendants

108. The Defendants own and operate a number of ASCs in Texas, Florida, and California.

109. The Texas ASC Defendants include Frisco Ambulatory Surgery Center, LLC ("Frisco ASC"), which is located at 5616 Warren Parkway, Suite 100, Frisco, TX 75034. Tracie Lawson is the COO. The mailing address is 5616 Warren Parkway, Suite 100, Frisco, TX 75034.

110. Park Ambulatory Surgery Center, LLC ("Park ASC"), is located at 550 N. Reo Street, Suite 100, Tampa, FL 33609. Tracie Lawson is the President. The mailing address for Park ASC is 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

111. Defendant Hurst Ambulatory Surgery Center, LLC ("Hurst ASC") is located at 1717 Precinct Line Road, Suite 101, Hurst, TX. Dr. Gari is the President and Chairman.

112. Defendant Bethesda Outpatient Surgery Center, LLC a/k/a Boynton Beach Ambulatory Center ("Boynton Beach ASC"), is located at 10301 Hagen Ranch Road, Suite 250,

Boynton Beach, FL 33437, and the mailing address is 504 N. Reo Street, Tampa, FL 33609. Tracie Lawson is the Chief Administrative Officer.

113. Defendant Habana Ambulatory Surgery Center, LLC ("Habana LLC") is located at 4730 N Habana Ave., Suite 204, Tampa, FL 33614. The mailing address is 4730 N Habana Ave., Suite 204, Tampa, FL 33614. Defendant David Wood is the Chief Development Officer ("CDO"). As such, he is charged with driving business growth.

114. Defendant Merritt Island Outpatient Surgery Center LLC ("Merritt Island ASC") is located at 450 E Merritt Island Cswy., Suite 400, Merritt Island, FL 32952. The mailing address is 504 N. Reo Street, Tampa, FL 33609. Deshawn Bhooshan is the Associate Director of Clinical Operations, ASC Division.

115. Defendant Orlando Outpatient Surgery Center, LLC ("Orlando ASC") is located at 1736 33rd Street, Orlando, FL 32839. The mailing address is 504 N. Reo Street, Tampa, FL 33609. Deshawn Bhooshan is the Associate Director of Clinical Operations, ASC Division.

116. Defendant West Park Surgery Center, LLC ("West Park ASC") is located at 6640 78th Avenue North, Suite B, Pinellas Park, FL 33781. The mailing address is the same.

117. As discussed above, the PPOA ASC Holdings Defendants, and their owner and founder, Dr. Gari, receive most of the revenues generated through PPOA's ASCs.

118. For example, for the quarter ending March 31, 2018, according to PPOA's quarterly "Schedule of Surgery Center Distributions," PPOA ASC Holdings would receive 83% of distributions from Park ASC (Tampa) and Frisco ASC (Texas), but 9% of distributions from Hurst ASC. The remaining 10% at Hurst ASC was earmarked for "TPRG." For Park (Tampa) and Frisco (Texas), the remaining 10% of distributions was split among "TPRG" and "outside parties."

119. In addition, the PPOA Defendants own or operate Texas Primary Care Group, LLC

("TPCG"), directed by Tracie Lawson. They also own and operate National Medical Practices of Florida, PLLC ("NMPF"), Tracie Lawson is the President.

### 8. The PPOA Durable Medical Equipment (DME) Affiliate

120. In addition to the foregoing, Dr. Gari also owns and operates Southeast Med Supplies, LLC ("SMS").

121. Dr. Gari founded SMS in late 2014. It is located at 550 N. Reo Street, Suite 100, Tampa, FL 33609, and has a mailing address of 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

### 9. National Medical Practices Affiliates of PPOA (d/b/a PPOA Minimally Invasive Spine Group)

122. National Medical Practices of Florida, PLLC d/b/a PPOA Minimally Invasive Spine Group ("PPOA Spine") is a Florida professional limited liability company which is headquartered at 550 N. Reo Street, Suite 100, Tampa, FL 33609.

123. Dr. Gari formed PPOA Spine in early 2016.

124. Dr. St. Louis is the Director of PPOA Spine.

125. Upon information and belief, all of the Defendants' Minimally Invasive Spine Group practices are owned and operated by PPOA Spine.

126. The Defendants similarly formed National Medical Practice of Texas, PLLC in 2016.

127. Defendant Wood has described the National Medical Practices Defendants as PPOA's "affiliate company" focused on providing care to patients suffering from chronic pain.

128. The individuals who operate the PPOA Defendants are also associated with the following healthcare entities which provide ancillary services on behalf of the PPOA Defendants: Genes Advice Holdings, LLC (Tracie Lawson, COO); Genes Advice, LLC (Tracie Lawson,

COO); Florida IONM, PLLC (Tracie Lawson, COO/Manager); Texas IONM, PLLC (Tracie Lawson, COO/Manager); and Urgent Care of Texas, PLLC (Rodolfo Gari, President).

**10. Gari Capital Defendants**

129. Dr. Gari owns or operates the PPOA Defendants and related entities through myriad corporate entities.

130. Defendant Gari Capital, LLC d/b/a Gari Capital Partners is a Delaware limited liability company which is headquartered at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614. Fittingly enough, Gari Capital's website states that the company is involved in business opportunities which "create[e] a referral network" in the healthcare space.

131. Defendant Gari Enterprises Investments, LLC is a Florida limited liability company which is headquartered at 550 North Reo Street, Suite 100, Tampa, FL 33609.

132. Defendant Gari Enterprises Investments, LTD is a Florida limited partnership which is headquartered at 550 North Reo Street, Suite 100, Tampa, FL 33609.

133. Dr. Gari is listed as the President of Gari Enterprises Investments, LLC.

134. Gari Enterprise Investments, LLC is listed as the general partner for Gari Enterprises Investments LTD.

135. Dr. Gari owns and operates the PPOA Defendants through other corporate entities, including, but not limited to: Tampa Medical Properties, LLC I through X.

136. The above named Defendants (collectively the "Gari Capital Defendants") have an ownership interest in the PPOA Defendants, including, but not limited to, Defendant Florida Pain Relief Group, which is identified as part of the Gari Capital Partners' portfolio.

**11. Individuals Affiliated with the PPOA Defendants**

**a) Defendant Rodolfo Gari, MD**

137. Dr. Gari currently resides at 5401 Taylor Road, Lutz, FL 33558 and 1603

Renaissance Way, Tampa, FL 33602.

138. Dr. Gari founded both PPOA and Texas Pain Relief in January of 2013. By the end of 2013, he had expanded Texas Pain Relief to three practices. By January 2015, Texas Pain relief had grown to 11 practices. Texas Pain Relief now has more than sixteen physician practices statewide.

139. After founding PPOA and Texas Pain Relief, in late 2014, Dr. Gari formed MedTox and Medical DNA. However, neither MedTox nor Medical DNA appears to have operated until approximately 2015 (for MedTox) and 2016 (for Medical DNA).

140. Dr. Gari formed the Florida Pain Relief Defendants beginning in December of 2015. The PPOA Defendants, led by Dr. Gari, have grown their presence in Florida to include at least 17 physician practices.

141. As described elsewhere herein, prior to founding PPOA, Dr. Gari was the Founder and CEO of Surgery Partners, Anesthesiology Professional Services, and Tampa Pain Relief Centers, which businesses he sold in 2009. During his time as the founder and CEO of Surgery Partners, Dr. Gari worked closely with Will Milo, Christina Infinger, and Crystal Winkler, and other individuals discussed herein, who have now reunited with Dr. Gari at PPOA.

142. More recent Surgery Partners' executive also moved to PPOA. In early 2019, PPOA hired Durwood Thompson, Surgery Partners' former Vice President, to oversee PPOA's Dallas-based physician practices. Thompson then resigned from his Texas-based position with PPOA on or about June 25, 2019. He remains involved with PPOA operations in Florida.

143. Dr. Gari, together with the executives and others discussed below, are the architects of the PPOA Defendants' fraudulent schemes detailed below.

144. In communications with Dawn Baker, Dr. Gari has represented that, although using

his Florida Pain Relief Group email (rgari@floridapainrelief.com), he was acting as a "CEO and President, Gari Enterprises Investments, LTD," or simply "Rodolfo Gari, MD."

145. In fact, at all times, Dr. Gari acted in furtherance of his scheme to maximize the revenue per patient whether billed through any Defendant, in order to benefit Dr. Gari and the other individual Defendants personally.

146. Upon information and belief, Dr. Gari, individually and/or through other corporate entities, owns the assets and real estate of the PPOA Defendants and leases these back to the PPOA Defendants to conduct their operations.

**b) Defendant David A. Wood**

147. Defendant David A. Wood currently does business at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

148. In 2013, Wood joined PPOA. Since that time, he has served as the CEO and CXO at PPOA, as well as in leadership positions for numerous PPOA-related entities. Although the internal documents usually identify Wood as PPOA's CXO, Wood identifies himself as CEO and CXO of PPOA. Available at http://www.linkedin.com/david-wood-a2400972.

149. Prior to joining PPOA, Wood served as President at LM Financial. Before that he was President/CEO of Woodco Partners. Before joining PPOA, Mr. Wood had neither medical training or experience.

150. Mr. Wood is identified as the Manager of PPOA and of both of the MedTox and Medical DNA.

151. Wood is also identified as the Manager of PPOA-affiliates that provide ancillary services.

152. Mr. Wood has been with PPOA since its inception and plays an integral part in

"physician aggregation, acquisitions and in shaping [the] business strategy and culture."

**c) Defendants James St. Louis, DO and Abraham Rivera, MD**

153. Dr. James St. Louis is an orthopedic spine surgeon who currently (since January 2018) does business at 4730 N. Habana Avenue, Suite 202 and 3450 E. Fletcher Avenue, Suite 350, both in Tampa, FL.

154. Since joining PPOA in January 2018, Dr. St. Louis has been the Director of PPOA's Minimally Invasive Spine Division.

155. Prior to joining PPOA, Dr. St. Louis was the surgical founder of the Laser Spine Institute ("LSI"), a now defunct business. Prior to its closing, both physicians and patients had complained that LSI surgeons would perform laser spine surgery without any regard for medical necessity.

156. In November 2017, Ms. Baker introduced Dr. St. Louis to Dr. Gari, founder of PPOA. At the time, Ms. Baker was unaware of any concerns regarding unnecessary laser spine procedures at LSI or the quality of medical care provided by Dr. St. Louis.

157. During his tenure as the Director of PPOA's Minimally Invasive Spine Division, physicians at PPOA practices in Florida have complained that PPOA's scheduling staff based in Tampa have called PPOA patients trying to schedule laser spine surgery consults without the PPOA treating physicians' consents.

158. In fact, Dr. Lesco Rogers complained that even Dr. St. Louis himself had posed as Dr. Rogers in an effort to convince wary patients to agree to laser spine surgery consultations.

159. Defendant Abraham Rivera, MD became the Chief Medical Officer ("CMO") of PPOA in or around May 2016.

160. Since that time, Dr. Rivera was directly involved in PPOA's UDT fraud, genetic

testing fraud, and other schemes aimed at generating fraudulent revenues for PPOA's Anesthesia and ASC operations by increasing the number of interventional procedures performed by PPOA physicians.

### d) Defendant Josh Helms

161. Defendant Josh Helms currently does business at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

162. Helms joined PPOA in 2016 as the Senior Vice President of Sales and Marketing – Business Development. Defendant Helms is currently the Chief Operating Officer ("COO") for PPOA. As the COO Helms is responsible for the strategies related to PPOA's branding initiatives, corporate messaging and operational growth. He is also responsible for creating and implementing strategy relating to customer service, patient acquisition and retention of patients.

163. Prior to joining PPOA, Helms worked for the Laser Spine Institute for eight years. During his tenure at the Laser Spine Institute, he was responsible for managing the facility's profitability, and according to his LinkedIn profile, he "delivered year-over-year revenue growth of 26% starting in 2012" Helms also implemented LSI's direct response campaigns which generated between 300 and 1300 patients monthly, and "inspired the team to increase patient visits from 6K in 2012 to an expected 15K in 2016."

164. Josh Helms brought the policies and practices that he developed with Dr. St. Louis at LSI to PPOA.

### e) Defendant William Milo

165. Milo currently resides at 12622 Stanwyck Circle, Tampa, FL 33626 and does business at 4730 N. Habana Avenue, Suite 204, Tampa, FL 33614.

166. Milo is currently the Senior Vice President of Business Development and Senior

Vice President of Physician Services for PPOA. Milo officially and publicly joined PPOA in January of 2018 after his non-compete with his former employer, Surgery Partners, expired.

167. However, Milo was working with PPOA generally, and with Dr. Gari specifically, since at least mid-2017. For example, in August 2017, Dr. Gari did not want to speak with one of Baker's physician recruits until he talked "to Will [Milo] to get his input first."

168. Prior to joining PPOA, Milo worked with Dr. Gari at Surgery Partners as Senior Vice President of Clinic Operations from 2007 until Dr. Gari sold the business in 2010. Milo stayed on at Surgery Partners until 2015. From 2007 until mid-2010, Milo served as Surgery Partners' Director of Human Resources. Thereafter he was Surgery Partners' Vice President of Operations & Physician Services, and Vice President of Administration at Surgery Partners. Milo also served as Vice President of Logan Labs from 2011 until sometime before his departure from Surgery Partners in late 2015.

169. As Vice President of Operations/Administration at Surgery Partners, Milo oversaw Surgery Partners' physician services division, including the Pain Relief Center Defendants, as well as the startup of Logan Labs. Milo was personally involved in implementing Surgery Partners' efforts to generate revenues from unnecessary UDT performed by Logan Labs.

170. At the time of the September 2015 IPO for Surgery Partners, Inc., Milo was the beneficial owner of 243,661 shares of its common stock. In December of 2015, after the Surgery Partners' IPO, Milo left Surgery Partners. At the time, Surgery Partners paid him millions of dollars for redemption of his Surgery Partners stock, plus two years' salary as part of a non-competition agreement.

171. Milo holds a bachelor's degree in Marketing from Florida State University, a master's degree in Business Administration from Hodges University, and a Senior Professional in

Human Resource (SPHR) certification from the Society for Human Resources Management.

172. Prior to Surgery Partners, Milo served as the Associate Administrator of Medical Surgical Specialists, a 70-physician group practice of Health Management Associates (HMA, now a part of CHS). He has no formal medical training or clinical experience.

173. Milo publicly joined PPOA in 2018 as the Senior Vice President of Physician Practices. When he arrived at PPOA, Milo revised the standard employment contract between PPOA and its employed physicians. One major change that Milo instituted was to incorporate the PPOA Defendants' "conversion" scheme (discussed below) into their employment contracts. Milo modified the agreement to require pain specialists to "convert" patients by performing interventional procedures on at least 15% of the pain management patients they saw in their office each month.

174. Milo was assisted as SVP Operations by: Tricia Alvarado, Director of Operations as well as Regional Clinical Supervisors Eric Alvarez, Rosaly Lawson, and Mark McKay.

175. Since joining PPOA, Milo became more focused on mergers and acquisitions. He was replaced by Tricia Alvarado, his Director of Operations, and with Chrissy Infinger, as discussed below. Since the end of 2018, Milo has tried to distance himself from direct physician contact. However, he has contacted Baker as recently as June 27, 2019.

176. As PPOA's current Vice President of Business Development, Milo oversees mergers and acquisitions involving physicians and physician practices, including the Defendants ASCs. In that capacity, he communicates with PPOA physicians by email and text messages.

### f) Defendant Tracie Lawson

177. Defendant Tracie Lawson currently resides with Dr. Gari at 5401 Taylor Road, Lutz, FL 33558, and she currently has a business address at 4730 N. Habana Avenue, Suite 204,

Tampa, FL 33614. Dr, Gari and Tracie Lawson are involved in a close relationship.

178. Lawson is involved in the ownership and/or management of many of the PPOA Defendants and their affiliates. For example, on or about January 16, 2018, Lawson was named President of PPOA. She had been the acting COO of PPOA since 2015.

179. Since 2016, Lawson has acted as the interim COO of TPRG and the COO of FPRG, as well as the Vice President of Operations for Patient Rx.

180. Although Defendant Milo informed Dawn Baker several months ago that Ms. Lawson was no longer President of PPOA, and was, instead overseeing Dr. Gari's significant real estate holdings, Ms. Lawson is still involved in PPOA operations. For example, in July 2019, Lawson had a run in with Dr. Rogers after she requested that he fill in a workers' compensation form requiring a formal functional capacity measurement (which had not been performed) and Dr. Rogers refused. Dr. Rogers sent a text to Dr. Rivera communicating his refusal to comply with Ms. Lawson's demand.

### 12. Relator Dawn Baker's Interactions with PPOA

181. Since early 2017, Ms. Baker has worked with PPOA to provide physician recruitment services. In that capacity, she has interacted with PPOA's physician recruitment executives, including: Wood; Dr. Gari; Dr. Rivera; and Milo.

182. Ms. Baker has known Dr. Gari and Milo for years. She had a business relationship with PPOA's founder, Dr. Gari in the past, before he sold Surgery Partners in 2010. She has had contact with Milo since before his time with Surgery Partners.

183. When Ms. Baker began working with PPOA, Milo was not associated with the PPOA Defendants. It is clear that Milo was working with PPOA behind the scenes since at least the summer of 2017. However, since officially joining PPOA in January 2018, Milo (along with

Chrissy Infinger) has been Baker's primary contact person for ongoing physician recruitment with PPOA.

184. When Milo left Surgery Partners in December of 2015, Chrissy Infinger, assumed physician recruitment responsibilities and became Ms. Baker's point of contact at Surgery Partners. In March of 2018, Infinger also moved from Surgery Partners to join Milo at PPOA. At that point, Infinger became more involved in PPOA's physician recruiting in Florida and Durwood Thompson did the same in Texas.

185. Since early 2017, Dawn Baker has recruited 16 providers to PPOA practices in Florida and Texas, predominantly pain management physicians and orthopedic surgeons, as follows:

| | **Physician Name -PPOA Location (Specialty) * No longer with PPOA** | **Approximate PPOA Start Date (Baker Invoice)** |
|---|---|---|
| 1 | Sheldon Cho, MD - Merritt Island* (Board Certified in Anesthesiology, sub-specialty qualifications in Pain Medicine and Substance Abuse) | 5-1-2017 |
| 2 | Jorge Fernandez-Silva, MD - Merritt Island (Board Certified in Anesthesiology, subspecialty cert. in Pain Medicine) | 6-5-2017 |
| 3 | Isabel Anyanwu, MD - Dallas* (Board Certified Anesthesiologist) | April 2017 |
| 4 | Chau Uong, DO – Hurst, TX* (Physical Medicine and Rehabilitation) | 8-29-2017 |
| 5 | Taufiq Ahmed, MD – Orlando (Pain Management, former Anesthesiologist) | 8-19-2017 |
| 6 | Ronald Stern, MD - Melbourne* (Board Certified in Pain Management) | 7-18-2017 |
| 7 | Christopher Creighton, MD -Dallas* (Board Certified in Anesthesiology and Pain Medicine) | 9-11-2017 |
| 8 | Cathie Benna-Mallette/CRNA – FL* | October 2017 |
| 9 | James St Louis, MD – ASC – Tampa (Board Certified in Orthopedic Surgery) | 1-2-2018 |

| | | |
|---|---|---|
| 10 | Harsh Dangaria, MD – Jacksonville & Orange Park, FL<br>(Board Certified in Pain Management and Physical Medicine & Rehabilitation) | 3-20-2018 |
| 11 | Demaceo Howard, MD - N. Dallas<br>(Board Certified in Anesthesia) | June 2018 |
| 12 | Anthony Clavo, MD – Arlington, TX<br>(Pain Management, former Pharmacist) | 10-22-2018 |
| 13 | G. Jason Hunt, DO – Tampa -PT<br>(Board Certified in Orthopedic Surgery) | 7-24-2018 |
| 14 | Anthony Guarino, MD - Merritt Island<br>(Pain Management) | 4-23-2019 |
| 15 | Howard Dedes, MD – Fullerton, CA<br>(Pain Management) | 8-8-2019 |
| 16 | Lesco L. Rogers, M.D - Winter Haven<br>(Board Certified in Anesthesia) | 4-9-2018 |

186. Ms. Baker receives a flat fee from PPOA for each physician she successfully places who stays with PPOA for 90 days.

### C. PPOA Creates the Pretense of Physician Ownership But Does Not Meet the In-Office Ancillary Services Exception to Stark

187. The PPOA Defendants create the appearance, but not substance, of entering into partnerships with their employed physicians. Although the employment agreement provides for employees-physicians to share in PPOA "profits," PPOA alone has the discretion to issue dividends to physician "partners." Rather than being true dividends (*i.e.*, allocated as a fixed amount per relative equity share in a company), the so-called dividends are used to reward physicians who refer procedures, surgeries, tests, drugs, and other services to PPOA-affiliated entities. These are not dividends but, rather, poorly disguised illegal kickbacks.

188. Moreover, the Stark Law's in-office ancillary services safe harbor only applies to a "group practice" and a practice is not a group practice if it pays compensation for referrals. 42 C.F.R. § 411.352(g) (a practice can only be considered a "group practice" under the safe harbors if, inter alia, "[n]o physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in §

411.352(i) [an exception which is inapplicable to PPOA's business practices]."). [1]

189. The employed physician partners do not "purchase" their interest in the PPOA Defendants' assets or operations. In fact, one of the documents PPOA demanded that Dr. Cho sign was a relinquishment of his "ownership interest," which Dr. Cho did not know even existed, which he did not pay for, and for which PPOA offered him no compensation when he left.

190. In addition, rather than buying into PPOA, the physicians who merge with or are acquired by PPOA are enticed to do so through valuable inducements. The PPOA materials provided to Dr. Cho in 2017 when he joined the company included a handbook, "Physician Partners in Health and Practice." In it, the PPOA Defendants described the benefits of "partnering" with PPOA, including:

(a) "Our acquisition and affiliate structures offer our physician partners a structured and competitive source of revenue with lower risk;"

(b) Physician partners "get all of this: Level 2- or equivalent buildout." (This means PPOA funds improvements for a revenue-producing Level-2 procedure room or equivalent value, "at no cost to" their physician "partner");

(c) PPOA provides "turnkey operations and anesthesia services;"

(d) "Share in ancillary services;"

(e) Administrative services are provided by PPOA (Physician partners provide "none of this: malpractice insurance; payroll expense; billing expense; insurance network hassles; practice management administration."

191. PPOA's incentive to provide these inducements to physicians who would become their "partners" is clear: PPOA's model requires that the physician refer patients to PPOA affiliates, and replace less invasive, lower reimbursed treatments performed under local anesthesia in a Level 1 Procedure Room, with more invasive and higher-reimbursing surgical procedures.

[1] The Anti-Kickback Statute has no such safe harbor.

This enables the PPOA Defendant to also bill for anesthesia: "more painful types of treatments such as RFA and spinal cord stimulator trials. The Level 2 procedure room enables PPOA to bill for anesthesia services ('with an affiliate model or an anesthesia contract')."

192. The Defendants also compensate physicians based, in part, on office-based Qualitative UDS and other ancillary services. Since at least 2017, the compensation paid to PPOA's employed physicians has been based on ancillary services related to the physicians' own patients. That is, the more a physician refers for ancillary services to PPOA-affiliated entities, the more a PPOA physician stands to earn in bonuses or other compensation.

193. MedTox, Medical DNA, the ASC, and anesthesia affiliates of PPOA then bill the relevant Government healthcare program or private insurer for the goods or services provided to PPOA patients, which are unnecessary and/or tainted by violations of the AKS or Stark Laws.

194. In fact, PPOA included the following standard terms in contracts with its physicians:

- "The Employee **agrees to refer patients to those ancillary businesses**, including facilities, designated in writing or verbally by the Employer to the Employee from time to time subject to applicable laws." (emphasis added).

- The potential to earn bonuses based on "**40% of the profits of Employer derived from the sale of office ancillary services or products attributable to Employee** shall be paid to Employee in a manner consistent with all applicable state and federal regulatory laws and regulations; provided, that the payment of any such bonus is subject to Employee operating on a break-even basis to Employer as it reasonably determines." [2] (emphasis added).

- "Given the high frequency of false negatives and positives from qualitative screen, and testing of additional illicit substances via quantitative testing, **all UDS [urine drug screens, i.e.**

[2] While the contract refers, vaguely, to being subject to applicable laws, the arrangement remains firmly in contravention of the Stark Laws and federal and state Anti-Kickback Statutes in that it provides substantial rewards for referrals to PPOA's "ancillary" facilities (*e.g.*, pharmacy and diagnostic testing entities).

**quantified tests] are sent for confirmation via definitive [i.e., quantitative testing] assay (GC, MS).**" (emphasis added).

195. Upon information and belief, MedTox also routinely waives any costs or co-pays to patients with Government-sponsored healthcare, including Medicare and Medicaid.

**D. Medtronic, PLC ("Medtronic")**

196. Defendant Medtronic's principal executive office for tax purposes is located at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland.

197. Medtronic's operational headquarters is located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604.

198. Medtronic reported revenues in excess of $30 billion in 2018.

199. Through its Restorative Therapies Group, Medtronic operates its Spine, Brain, Pain Therapies, and Specialty Therapies sectors. During 2018, the Restorative Therapies Group accounted for over $7.7 billion in revenue.[3]

200. According to its 10-Q as of January 25, 2019, Medtronic's Restorative Therapies Group's products "include those focused on areas of the spine, bone graft substitutes, biologic products, trauma, implantable neurostimulation therapies and drug delivery systems for the treatment of chronic pain, movement disorders, ... as well as products to treat conditions of the ear, nose, and throat (ENT), and systems that incorporate advanced energy surgical instruments."

201. Medtronic's 10-Q also notes that its Restorative Therapies Group also "manufactures and sells image-guided surgery and intra-operative imaging systems, robotic guidance systems used in robot assisted spine procedures, and therapies to treat diseases of the vasculature in and around the brain, including coils, neurovascular stents and flow diversion products."

[3] https://www.medtronic.com/us-en/about/facts-stats.html

202. Net sales growth for Medtronic's Restorative Therapies Group "for the three and nine months ended January 25, 2019 was driven by the Brain Therapies, Specialty Therapies, and Pain Therapies divisions."

203. Medtronic reported in its 10-Q for the quarter ended January 25, 2019, net sales of $942 million from its Pain Therapies sector for the nine months ended January 25, 2019, an increase of 13% over the corresponding period in the prior fiscal year. Medtronic noted in its quarterly report that the "increase in net sales was driven by our Intellis spinal cord stimulation platform which received U.S. FDA approval in September 2017 and CE Mark in November 2017. Further driving net sales growth were the Evolve workflow algorithm, Snapshot reports, and our Targeted Drug Delivery products…".

204. In its annual report, Medtronic stated that its "Restorative Therapies Group could be affected by:"

(a) "Continued market acceptance and global adoption of our Intellis spinal cord stimulator, Evolve workflow algorithm, and Snapshot reporting to treat chronic pain in major markets around the world;" and

(b) "Ongoing obligations under the U.S. FDA consent decree entered in April 2015 relating to the SynchroMed drug infusion system and the Neuromodulation quality system. The U.S. FDA lifted its distribution requirements on our implantable drug pump in October and its warning letter in November 2017." The consent decree followed problems with Medtronic's SynchroMed implantable drug infusion system (pain pump) between 2006 and 2013 led to a consent decree and half of manufacturing in April 2015.

- Problems included the deaths of 14 patients, 11 of whom died after accidentally being injected with the medication intended to refill the pump.

- Medtronic markets its pain pumps as a replacement for systemic (oral) pain medication, because the pain pump delivers the medication (opioid) directly to the spinal fluid.

- However, pain pumps such as Medtronic's are not without serious risks and complications, such as complications from surgery to implant them, reimplantation of new pumps after five years, risks of overdose, risks associated with under dosing or death during medication refill, failures of the pumps, and/or other risks related to the implanting of a medicine pump in a patient's body.

205. Medtronic offers its customers information regarding commonly billed codes for its devices so that reimbursement can be obtained from payers, including Government healthcare plans and private insurers.

## V. BACKGROUND ON FEDERAL & STATE-FUNDED HEALTH INSURANCE PROGRAMS

### A. Medicare Program: Coverage Only for Medically Necessary Services

206. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for: people age 65 or older; people under age 65 with certain disabilities; and people of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant). Medicare now has four parts: Part A (inpatient hospital treatment); Part B, Part C (managed care plans), and the Part D (prescription drug) Program.

207. Medicare Parts A and B are often referred to, collectively, as "Original Medicare."

208. Medicare Part B (Medical Insurance) covers certain medical services, such as clinical laboratory test services, physician services, CRNA services, outpatient surgery, and other outpatient care. Part B pays for covered health services and supplies only when they are medically necessary. 42 U.S.C. § 1395k(a)(2)(B). Medicare only pays for Part B services that are actually

rendered and are medically necessary. 42 U.S.C. § 395(4). Part B providers must also certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

209. Defendants submitted claims to and received payment from Medicare Part B for the healthcare services provided by PPOA's subsidiaries, including MedTox, Medical DNA, and other affiliates providing pain management, laser spine surgery, invasive pain management procedures, CRNA services, and transportation services.

210. Medicare Part C (Medicare Advantage) provides Medicare recipients with additional, private healthcare plans that provide coverage consummate with that provided in Original Medicare (Parts A and B) and may provide additional coverage as well. These private healthcare plans, referred to as Medicare Advantage plans, receive substantial federal funds. Thus, when providers submit claims to Medicare Advantage or Medicare Part C plans, they are submitting claims to Government-funded healthcare programs.

**1. Reimbursement for UTOX and DNA Testing**

211. Defendants also submitted claims to and received payment from Medicare Part C plans (Medicare Advantage) plans for the UTOX and DNA testing services provided by PPOA's affiliates, MedTox and Medical DNA.

212. Medical DNA and Medical Tox Labs have collectively billed Government payors, including Medicare, for millions of dollars under, at least, the following CPT and HCPSCS codes for their toxicology and DNA tests: 81227, 81240, 81241, 81291,81400, 81479, 82955, 83789, 83986, 83992, 84315,G0479, G0480, G0481, G0482,G0483, G6031, G6038, G6042, G6044, G6051, G6052, G6053, G6056, and G6058. By way of example, the average Medicare charge for 2017 that MedTox submitted for the confirmatory drug test with HCPCS code G0483 was $10,861 per test.

213. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

214. The Medicare Program is administered through the United States Department of Health and Human Services ("HHS") and, specifically, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal Government (particularly CMS).

215. To participate in the Medicare program as a new enrollee, the PPOA Defendants, including their clinical laboratories, such as MedTox or Medical DNA, physician practices, ASCs, imaging providers, pharmacies, CRNA practices, and transportation providers, must submit a Medicare Enrollment Application, CMS Form-855B. Laboratories also complete Form CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

216. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. §424.516(a)(1).

217. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the]supplier to all of the laws, regulations, and program instructions of the Medicare program."

218. Authorized officials for the PPOA Defendant providers were required to sign the certification statement in Section 15 of Form CMS-855B, indicating that they understood that they were required to comply with Medicare laws, regulations, and program instructions, which include, but are not limited to, the Stark Law and the Anti-Kickback Statute.

219. The National Provider Identifier ("NPI") is a standard and unique health identifier

for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

220. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent (known as the 837P form).

221. Among the information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source."

222. Each request for payment or bill submitted for an item or service payable under Medicare Part B must include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

223. To participate in Medicare, providers must assure that their services are provided economically and only when, and to the extent they are, medically necessary.

224. Sections 1814(a)(2) and 1835(a)(2) of the Social Security Act, establish that, as a condition for Medicare payment, a physician must certify the necessity of the services and, in some instances, recertify the continued need for those services. 42 C.F.R. § 424.10. Regardless of the rules governing the particular type of care, in order for the federal Government to cover services under Medicare Part A or Medicare Part B, or for a Medicare Part C plan, or for Part D prescription services, all care must be "medically necessary."

225. Medical care is "medically necessary" when it is ordered or prescribed by a licensed physician or other authorized medical provider, and Medicare (or a Medicare Part C plan or Part

D plan) agrees that the care is necessary and proper. Services or supplies that are needed for the diagnosis or treatment of a medical condition must meet the standards of good medical practice in the local area.

### 2. Medicare Reimbursement for Diagnostic Testing, Interventional Procedures, Spine Surgeries, CRNA Services, Pharmacy Services and Transportation Services

226. Government healthcare programs, including Medicare Part B, Part C, and Part D plans, provide reimbursement to healthcare providers for the services provided by the Defendants, including UTOX, DNA testing services, pharmacy services, spine laser services and other surgical procedures and transportation services.

227. However, the Medicare program covers these services only when medically necessary as determined by the independent medical judgment of the beneficiary's physician, and when the claims submitted for these services are not tainted by AKS or Stark Law violations.

## B. The Medicaid Program

228. Medicaid was created in 1965, at the same time as Medicare, when Title XIX was added to the Social Security Act. The Medicaid program aids the states in furnishing medical assistance to eligible needy persons, including indigent and disabled people. Medicaid is the largest source of funding for medical and health-related services for America's poorest people. Medicaid is a cooperative federal-state public assistance program which is administered by the states.

229. Funding for Medicaid is shared between the federal Government and those state Governments that choose to participate in the program. Federal support for Medicaid is significant. The federal Government provides greater than 50% of the funding for Medicaid programs in the plaintiff states of Florida and Texas. The remaining funds are provided by the

state. Title XIX of the Social Security Act allows considerable flexibility within the states' Medicaid plans and, therefore, specific Medicaid coverage and eligibility guidelines vary from state to state.

230. Like the Medicare Program, Medicaid only covers healthcare services or supplies that are medically necessary for the diagnosis or treatment of a medical condition, in keeping with the standards of good medical practice in the local area.

231. The PPOA physician agreements provide that physicians are required to participate in "both Medicare, Medicaid, and all third-party payor arrangements made available by or through" PPOA. Defendants advertise that their ASCs treat Medicaid, Medicare and Tricare beneficiaries.

### C. Other Federal Healthcare Programs

232. In addition to Medicaid and Medicare, the federal Government reimburses a portion of the cost of these services provided by the PPOA Defendants (including UTOX, DNA testing, other testing, and the interpretation of those results, as well as laser spine surgery and interventional pain procedures, pharmacy services, and transportation services) under several other federal healthcare programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, and the Federal Employees Health Benefit Program ("FEHBP").

233. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a healthcare program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veteran Affairs, is a healthcare program for the families of veterans with a 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for hundreds of thousands of federal employees, retirees,

and their survivors.

234. TRICARE does not pay for services that are not authorized by law or that are fraudulently billed 32 CF.R. § 199.7(i)(3).

235. Likewise, CHAMPUS and the FEHBP only pay for covered services and supplies that are medically determined to be reasonable and necessary.

## VI. APPLICABLE LAW

### A. The Federal False Claims Act

236. The federal False Claims Act ("federal FCA") provides, in pertinent part:

(a) Any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (3) conspires to commit a violation of (1) or (2) is liable to the United States Government for a statutory civil penalty, plus three times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. §3729(a)(1)(A)-(C).

(b) "[T]he terms 'knowing' and 'knowingly' (A) mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information; and require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

237. To obtain reimbursement from Government healthcare programs, providers submit a claim form, which typically is done electronically. In other words, no person from the affected payor reviews each claim before making payment.

238. For claims to Medicare and TRICARE, providers submit CMS Form 1500 and/or its electronic equivalent, known as the 837P form, which contains the following certifications:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate, and complete; 2) I have familiarized myself with all applicable laws, regulations and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were incident to my professional service by my employee under my direct supervision, except as otherwise permitted by Medicare or TRICARE...
> NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

239. To obtain TRICARE reimbursement for services from physicians or other authorized individual providers, as with Medicare, the providers must submit a claim form to TRICARE that lists the procedure code or narrative description for each procedure or service for each date of service. 32 C.F.R. § 199.7(b)(2)(ix)(B). TRICARE claim forms also must bear a signature of the participating provider certifying that the medical care billed for was actually rendered to the beneficiary. 32 C.F.R. § 199.7(c). This signature certifies that the specific medical care listed on the claim form was actually rendered to the specific beneficiary at the level indicated on the claim form. *Id.*

240. For Medicaid payments, providers also certify on Form CMS 1500 that "services were medically indicated and necessary to the health of this patient." It also contains another "NOTICE" that "the foregoing information is true, accurate and complete...and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

241. The Medicare Part B Electronic Data Interchange ("EDI") enrollment documentation, which is signed and submitted when a provider enrolls for electronic billing with a MAC, also contains an acknowledgement "that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See, e.g., Cahaba Medicare Part B EDI Application* (09/2013 v2.51); *Interactive EDI Agreement for Palmetto; EDI Enrollment for Novitas Solutions.*

242. Among the information the provider includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") Codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Chapter 23, § 20.7 *et seq.* CMS assigns reimbursement amounts to CPT and HCPCS Codes.

243. TRICARE utilizes and incorporates CPT Codes to describe the scope of allowable services. TRICARE Policy Manual 6010.60-M, Ch. 1, § 1.1, ¶ 3.4.1.2.

244. Providing accurate CPT and HCPCS Codes on claims submission forms is material to and a condition of payment for the Government healthcare programs. *See, e.g.,* Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

245. The Government healthcare programs at issue here routinely deny payment to providers who bill for codes when the criteria for those codes is not actually met, including when the services are not medically necessary.

## B. Self-Referral Prohibitions 42 U.S.C. 1395nn (the "Stark Law")

246. The federal physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law") prohibits an entity from submitting claims to Medicare for "designated health services" ("DHS"), including clinical laboratory services, if: 1) such services were referred to the entity by a physician with whom the entity had a financial relationship; and 2) the financial relationship does not fall within a statutory or regulatory exception. 42 U.S.C. §§ 1395nn; 42 C.F.R. §§ 411.351 *et seq.*

247. Because compliance with the Stark Law is a condition of payment by the Medicare program, an entity may not request or receive payment for any DHS provided in violation of the Stark Law. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1).

248. Further, federal regulations interpreting the Stark Law require that "[a]n entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis . . . ." 42 C.F.R. § 411.353(d).

249. A "financial relationship" includes a "compensation arrangement," which means any arrangement involving any "remuneration" paid to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind" by the entity furnishing the DHS. *See* 42 U.S.C. §§ 1395nn(h)(1)(A) and (h)(1)(B).

250. Effective October 1, 2008, "a physician is deemed to 'stand in the shoes' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if -- (A) The only intervening entity between the physician and the entity furnishing [DHS] is his or her physician organization; and (B) The physician has an ownership or investment interest in the physician organization." 42 C.F.R. § 411.354(c)(1)(ii).

251. Under the Stark Law, an "entity is considered to be furnishing DHS if it . . . [is the]

entity that has presented a claim to Medicare for the [DHS] . . . ." 42 C.F.R. § 411.351.

252. A "referral" includes "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any [DHS] for which payment may be made under Medicare Part B . . . ." 42 C.F.R. § 411.351.

253. The Stark Law and its interpretive regulations contain exceptions for certain compensation arrangements. The statute and regulations also exempt certain items from the definition of "remuneration," including items "used solely to (I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R.

254. The Stark Law also excepts certain ancillary services where provided for the patients of physician owners in a practice group. However, no Stark Law exception applies here.

### 1. The Federal Anti-Kickback Statute

255. Enacted in 1972, the main purpose of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), is to protect patients and federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on healthcare decisions.

256. When an entity pays kickbacks to a provider in order to induce him/her to refer or recommend patients to the entity for goods and/or services, it fundamentally compromises the integrity of the doctor-patient relationship. Government-funded healthcare programs, such as Medicare and Medicaid, rely upon providers to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by that healthcare program. As a condition of its reimbursement, Government healthcare programs require that the physicians must render their services without the conflict inherent in receipt of a kickback.

257. The federal AKS and analogous state laws make it a crime to knowingly and

willfully offer, pay, solicit or receive any remuneration to induce a person:

(1) to refer an individual to a person for the furnishing of any item or service covered under a federal healthcare program; or

(2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal healthcare program.

42 U.S.C. § 1320a-7b(b)(1) and (2).

258. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

259. Violations of the federal AKS must be knowing and willful. 42 U.S.C. § 1320a-7b(b)(1).

260. The federal AKS has been interpreted by the federal courts to cover any arrangement involving federal healthcare program funds where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Proof of an explicit *quid pro quo* is not required to show a violation of the AKS.

261. A violation of the federal AKS constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the federal AKS *must* be excluded (*i.e.*, not allowed to bill for any services rendered) from federal healthcare programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1).

262. Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the federal AKS, the Secretary may exclude that provider from federal healthcare programs for a discretionary period, and may impose administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

263. HHS has published safe harbor regulations that define practices that are not subject

to prosecution or sanctions under the federal AKS because such practices would unlikely result in fraud or abuse. *See* 42 C.F.R. § 1001.952. However, only those arrangements that precisely meet all of the conditions set forth in the safe harbor are afforded safe harbor protection.

264. Compliance with the AKS is a condition of payment under the Medicare and Medicaid programs, and that condition applies regardless of which entity is submitting the claim to the Government.

265. The AKS expressly provides that claims that arise from a kickback scheme are false and violate the False Claims Act. No further express or implied false statement is required to render such infected claims false, and none can wash the claim clean. Thus, a claim that is tainted by an AKS violation is, by its very nature, false under the FCA. 42 U.S.C. § 1320a-7b(g).

266. It is the very fact that the healthcare decision-maker has accepted a kickback that *per se* renders not payable the claims for goods or services as to which the kickback was given, not whether the decision-maker would have otherwise selected that good or service.

267. Moreover, as a prerequisite to participating in federally-funded healthcare, providers, like the various PPOA Defendants and their affiliates, must certify (expressly or, through their participation in a federally-funded healthcare program, impliedly) their compliance with the federal AKS.

268. As a prerequisite to participating in the various state Medicaid programs, providers of healthcare services must certify (expressly or, through their participation in the state-funded healthcare program, impliedly) their understanding of and compliance with both the federal AKS and applicable state anti-kickback laws. Compliance with the AKS is a precondition for payment.

269. Even in absence of an express certification of compliance, a party that submits a claim for payment impliedly certifies compliance with all conditions of payment, *i.e.*, that it is properly payable. Consequently, if a healthcare provider pays a kickback to induce the referral or recommendation of a patient for inpatient or out-patient services and related goods, it renders false the submitter's implied or express certification of compliance that the resulting claim meets the requirements of the Anti-Kickback Statute.

270. Moreover, a claim that is tainted by an Anti-Kickback Statute is otherwise, and by its very nature, a false claim under the False Claims Act. 42 U.S.C. § 1320a-7b(g).

271. Many states, including those states identified as Plaintiffs herein, have enacted similar prohibitions against the provision of illegal inducements to healthcare decision-makers.

## VII. DEFENDANTS SCHEME TO VIOLATE THE FCA THROUGH THE SUBMISSION OF CLAIMS FOR EXPENSIVE MEDICALLY UNNECESSARY SERVICES

272. PPOA and its Defendant managers and owners viewed each patient encounter as an opportunity to bilk health insurers, including Government payors, to the fullest extent possible, without regard to the clinical presentation of the patients and necessity of treatment.

273. Dr. Gari, PPOA's founder, is an entrepreneur who built his first pain management practice (Surgery Partners) into a $120 million enterprise. Dr. Gari sees PPOA as a business that generates robust revenues by over-treating patients suffering from chronic pain.

274. When PPOA held retreats for all of their physicians in Florida and Texas, Dr. Gari delivered the first presentation of the day: "PPOA Culture, Business of Medicine."

275. After growing PPOA in Texas, and expanding into Florida in 2016, PPOA began operating testing facilities in Florida, the UTOX and DNA testing Defendants.

276. PPOA also added pharmacies to its line of ancillary services, which provided

predominantly compounded creams for pain relief, and oral and other medications that were among the limited formulary preferred by PPOA's owners.

277. Once PPOA had its pain management practices, ASCs, and ancillary services in place, it set about using the "opioid crisis" as cover for its myriad schemes. In a November 2017 email, Dr. Gari described the company's opportunistic use of the opioid epidemic: "...we are looking to position ourselves as a solution to the opioid crisis."

278. Defendants' conduct has resulted in the submission of false claims by PPOA-affiliates related to unnecessary medical services. PPOA's profit over patients modus operandi infected virtually every aspect of the patient care cycle, from diagnostic testing and basic prescription protocols to surgical intervention. For example, as described herein, the PPOA Defendants adopted policies, practices, and "clinical" protocols resulting in patients being subjected to unnecessary and tainted referrals for UTOX and DNA testing, imaging services, CRNA services, invasive pain procedures, surgical procedures, and other ancillary services, including pharmacy and transportation services, all provided by affiliates of the PPOA Defendants. They also falsely solicited patients for unnecessary laser spine surgeries.

279. PPOA engaged in these myriad fraud schemes as a means to maximize the revenue that the PPOA Defendants could generate for each pain management patient treated at its facilities.

280. PPOA executives had created a spreadsheet showing the revenues that PPOA can generate from each patient. In keeping with this, PPOA's executives announced at the Florida Physician Retreat in May 2018 that one lost patient per day would cost the PPOA Defendants $1.5 million.

### A. Unnecessary UTOX Testing

281. Defendant MedTox is an affiliate of the PPOA Defendants, through which

Defendants purport to provide ancillary laboratory services. MedTox is a nation-wide provider, specifically and nearly-exclusively, of urine drug testing (referred to as "UTOX"), "urine toxicology," or "urine drug testing" ("UDT").

282. MedTox was formed in Delaware in 2014. However, MedTox did not begin operations until shortly before the PPOA Defendants expanded their operations from Texas into Florida. Thus, between 2014 and 2016, upon information and belief, there were no physicians unaffiliated with PPOA who referred their patients to MedTox for UTOX testing.

283. Since MedTox operations commenced in Tampa, Florida, it has been operated out of the same building as the PPOA's Florida Pain Relief Tampa (Fletcher) location. Upon information and belief, MedTox also began receiving referrals from the Texas-based PPOA locations after 2016 when the PPOA Defendants expanded their operations into Florida and opened the MedTox testing facility.

284. Since its founding in 2014 and the commencement of providing UTOX testing services, MedTox's primary (if not sole) source of referrals have been PPOA-affiliated physicians, including pain specialists, who practice at PPOA locations in Texas and Florida. On information and belief, PPOA's new operations in California also refer patients to Medtox as well as Medical DNA for UTOX and/or DNA testing, pursuant to the same fraudulent scheme.

285. Referrals from the PPOA Defendants' physician practices to its affiliated UTOX lab, Defendant MedTox, (as well as Medical DNA Labs), are referrals which violate the federal AKS and state analogs to the AKS, as well as the Stark Laws.

286. Defendant MedTox's business is and has been largely dependent upon referrals of beneficiaries of Government–funded healthcare programs, with a special emphasis on Medicare and Tricare beneficiaries.

### 1. UTOX Testing in the Treatment or Management of Chronic Pain

287. UTOX, when used appropriately, either detects the presence of drugs (Qualitative UTOX) or the specific amount of a particular substance in the patient's system (Quantitative UTOX).

288. Qualitative UTOX can be either point-of-care testing ("POCT"), which is performed in the physician's office, or laboratory-based, meaning it is performed at an outside laboratory.

289. In-office drug screening (a/k/a POCT) is an easy and cost-efficient method of Qualitative UTOX because it is performed to detect the presence of drugs while the patient is in the presence of the provider. The urine cup dip stick test, using immunoassay (the same technology used in home pregnancy tests) is the most common form of in-office Qualitative UTOX. It is highly affordable.

290. In order to bill for POCT, a medical facility needs a Clinical Laboratory Improvement Amendments of 1099 ("CLIA") certification or waiver. However, a medical provider can choose to perform POCT without a CLIA waiver – it just cannot bill Governments or private insurers for the test.

291. Qualitative UTOX can also be lab-based, if POCT is not available. However, in either setting, the same immunoassay technology is used (immunoassay).

292. Both types of Qualitative UTOX (in-office and lab-based) are far less expensive than Quantitative UTOX.

293. Quantitative UTOX, on the other hand, can be used to determine the specific levels of a variety of prescription or illegal substances present in a patient's body if such information is truly required. Quantitative UTOX is only performed in a laboratory using properly calibrated

equipment and appropriately qualified laboratory professionals.

294. Confirmation drug testing, through Quantitative UTOX, is medically necessary and appropriate only for specific and limited indications, including to "confirm" unexpected results of in-office drug screening. Quantitative UTOX is not medically necessary for every patient or at every clinic visit on multiple occasions during the year.

295. In the pain management setting, providers may determine that Quantitative UTOX is medically necessary to confirm a positive Qualitative UTOX, in other words, to rule out a false positive Qualitative UTOX. Quantitative UTOX may also be medically necessary in limited circumstances to rule out a false negative UTOX. In summary, Quantitative UTOX is medically indicated only for a narrow subset of patients for whom Qualitative UTOX is medically necessary.

296. Quantitative UTOX is expensive, resulting in charges by UTOX laboratories to Government healthcare programs ranging from hundreds to thousands of dollars per testing episode, depending on the number of separate tests performed and/or billed.

297. Since its founding, Defendant MedTox has generated most of its revenues from Quantitative (also called "confirmatory" ) UTOX.

298. Whatever drug testing method is used, either urine dip stick (in-office drug screening or lab-based Qualitative UTOX), or confirmatory (Quantitative) UTOX, it must be medically necessary to legally obtain reimbursement from Government-funded healthcare programs. In other words, no type of UTOX is automatically reimbursable.

299. Both pain medicine and addiction specialists prefer random in-office POC drug screening (the dip stick cup) when medically necessary, to ensure patient safety and to determine patient adherence to treatment. This provides the physician with immediate results while the patient is still in the office.

300. For the vast majority of patients, including those treated for chronic pain management by PPOA's affiliated pain specialists, laboratory-based Quantitative UTOX is not medically necessary as an initial or follow-up test. Instead, when a physician determines that any UTOX is medically necessary, the patient should receive a screening UTOX (office-based POC drug testing). If the dip stick cup results are not the expected results based on the provider's assessment of the patient, or other specific medical indications warrant it, the patient should then be referred to laboratory-based Quantitative UTOX.

### 2. The PPOA Defendants' Scheme to Generate Unnecessary UTOX Tests

301. The PPOA Defendants' profit driven fraudulent schemes viewed each PPOA patient as an opportunity to make money without regard to their individual need for treatment. This included referring them to MedTox for extensive and expensive confirmatory Quantitative UTOX. These types of tests are rarely necessary.

302. The Defendants implemented a fraudulent scheme to refer all patients of PPOA-affiliated physicians for its "clinical protocol" for UTOX, each time the patient is seen by their physician. And naturally, these highly lucrative referrals flowed to the two PPOA laboratories, MedTox and Medical DNA (which has performed both DNA and toxicology tests).

303. Medicare's Local Coverage Determination: Controlled Substances Monitoring and Drugs of Abuse Testing (L36393), applicable to Florida, recommends UDT one or two times per year for low risk patients, and every three months (four times per year) for high risk patients. *See also* L35006 (Texas-applicable LCD); L36668 (California-applicable LCD). Fittingly enough, Local Coverage Determination L36393 recognizes that "[r]outine standing orders for all patients in a physician's practice are not reasonable and necessary and the same is true of blanket orders." *See also* L35006 (Texas-applicable LCD with identical language); L36668 (California-applicable

LCD with identical language).

304. These Local Coverage Determinations (L35006, L36393; L36668) make clear that quantitative testing is only appropriate in a narrow range of case as well, further emphasizing the gross impropriety of PPOA's one-size-fits-all testing protocols which required that quantitative testing always be employed following a qualitative test. For example, L36393 states that:

> 3. Definitive [*i.e.,* quantitative] testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
>
> a. The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
>
> b. Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
>
> c. To rule out an error as the cause of a negative presumptive UDT result.
>
> 4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

L36393; *see also* L35006 (providing a narrow range of medically necessary indications); L36668 (same).

305. Moreover, Medicare requires that "[t]he clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record." *E.g.,* L36393. Yet, in the case of PPOA, given that the clinician was not ordering the testing due to *any* real rationale (but instead due to a medically unsound corporate-wide protocol), PPOA's medical records rarely, if ever, supported the medical necessity of PPOA's UTOX tests.

306. And Medicare billing data confirms not just that PPOA was billing for a grossly excessive number of drug tests, but they were billing for very expensive quantitative drug tests as

well. By way of example, in 2017, Med Tox Labs billed Medicare 14,483 times for quantitative testing, amounting to approximately $133,290,645 (and received millions in return). Medical Tox Labs billed Medicare under HCPCS codes G0481, G0482, and G0483 for those 14,483 tests. Unsurprisingly, Medical Tox Labs billings for the highly expensive G0483 22-drug panel tests (~75% of all Medicare-billed tests) dwarfed those of the substantially less expensive G0481 7-14 drug panel tests (~6%) and G0482 15-21 drug panel tests (~19%).

307. Also tellingly, in 2017, Medical Tox Labs stopped billing Medicare for the less expensive G0480 1-7 drug panel test, despite having billed Medicare for that service 737 times in 2016. In other words, by 2017, not only had PPOA succeeded in forcing its physicians to order an extraordinary volume of unnecessary quantitative drug tests, their physicians were trending toward more and more expensive versions of quantitative tests. The clinical presentation of PPOA's patient population had not changed in 2017; nor had sound medical practices. Rather, the cause for the change was, once more, purely financial. PPOA's quest to squeeze yet more money out of Medicare (and other insurers, both Governmental and private) grew unabated.

308. Medicare billing data shows the remarkable ramp up in drug (and genetic) testing over the years. From 2015 to 2016 alone, Medical Tox Labs' Medicare billings jumped over 2,163%, from approximately $3,761,572 to $85,131,610.

309. The PPOA Defendants, in contrast, adopted alleged "clinical protocols" " (*i.e.*, standing orders or blanket orders) which required both 1) the alleged use of an opioid abuse risk protocol to determine the frequency of all urine drug screening (UDS or Qualitative tests), regardless of whether there was an actual individualized need for the patient's medical management; and; 2) that "all UDS are sent for confirmation via definitive assay (GL, MS)." In

other words, all patients' urine samples were and are sent for confirmatory UTOX, regardless of medical necessity.

310. This policy was communicated frequently to PPOA providers. For example, at the May 2018 PPOA Annual Florida Physicians Meeting (discussed more fully below), Dr. Rivera discussed PPOA's Urine Drug Testing Protocol noting that PPOA required that all new patients undergo UDT (which is always followed by Quantitative confirmation testing) every visit for the first 3 months. PPOA instructed its physicians that existing patients must undergo urine drug testing "no less often than every three months."

311. Thus, PPOA required all new patients (even low risk patients) to undergo UDT 6 times during their first year with PPOA. This is excessive in light of the Medicare local coverage determination and existing laws envision that UDT only one to two times per year for low-risk patients.

312. In addition, for the vast majority of patients, PPOA did not even perform the screening (Qualitative) UTOX. In fact, PPOA did not even supply their clinics with a sufficient number, if any, inexpensive drug screening cups. Dr. Cho recalls seeing few Qualitative (screening) UTOX results during his time at PPOA. At times, Dr. Cho would buy his own inexpensive drug screening cups so he could have immediate access to the results and not have to wait for the laboratory to complete the results and have to bring the patient back in. For the vast majority of patients, he was provided only expensive Quantitative UTOX results.

313. PPOA's mandatory UTOX testing policy and related practices interfere with their treating physicians' medical judgment by requiring adherence to UDT policies that treat patients as if they are a high risk.

314. The PPOA Defendants compel all of their providers and patients to use only their

affiliated MedTox (and, to a lesser extent Medical DNA) for UTOX testing. Thus, the Defendants' excessive UTOX protocol is aimed at generally millions of dollars in revenue for the Defendants through these two affiliated laboratories.

315. To carry out this scheme, by way of example, patients' urine samples are obtained by PPOA-affiliates' employed office staff before the patient ever sees the physician, and before the physician has determined that UTOX testing is medically necessary. This is highly improper. *See, e.g.,* 42 C.F.R § 410.32(a) ("All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary. . . Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.").

316. The PPOA Defendants then create false records to create the appearance that their affiliated physicians have referred the patients to MedTox or Medical DNA for UTOX testing. In reality, the referrals are created by PPOA staff before the patient has seen their provider, and the physicians are instructed to "sign" the order only after the test results are received.

317. Virtually all UTOX testing referrals from PPOA-affiliated pain management, other specialty, or family physicians are sent to MedTox or Medical DNA.

318. When the Defendants' employed providers refuse to allow all of their patients to be referred to MedTox on each visit, the Defendants have retaliated. For example, the providers are told they have violated corporate policies or guidelines. Then, as new patients contact the Defendants to obtain pain management care, the Defendants have routed patients away from providers who refused to comply with the Defendants' fraudulent testing practices (such as Dr. Lesco Rogers). Rather than send patients to Dr. Rogers, at the PPOA Winter Haven facility, the Defendants steered patients to more "compliant" physicians in Orlando or Tampa.

319. Physicians, including Dr. Ronald Stern, have also refused to follow the PPOA-

mandated UTOX testing "protocol."

320. The Defendants have also retaliated against providers by harassing their staff who refuse to implement the fraudulent UTOX and DNA testing protocols. This retaliation happened to three of Dr. Stern's long-time employees, all mid-level providers who were pressured by PPOA to increase referrals of UTOX and DNA tests to PPOA's affiliated labs.

321. At one point, during a meeting with PPOA physicians, Dr. Rivera, PPOA's CMO, waved what he represented was a letter from the Attorney General, in support of the Defendants' protocols. The physicians were not given the opportunity to actually review the curious document.

322. The Defendants pressure their pain management providers to adhere to this mandatory UTOX Quantitative testing practice by calling it a "clinical protocol" to which providers must adhere as a term of their employment.

323. The PPOA Defendants' conduct resulted in extreme over-utilization of Government-funded healthcare program resources in light of the fact that Quantitative UTOX is medically necessary for a small subset of the patients who are treated by the PPOA Defendants' employed physicians and mid-level providers.

### 3. The PPOA Defendants Mandate Unnecessary DNA Testing

324. Defendant Medical DNA is an affiliate of PPOA through which the Defendants provide ancillary genetic testing services. Medical DNA is a nation-wide provider, specifically and nearly exclusively, of genetic testing which purports to determine the medically-appropriate pain medication for a particular patient, based on the patient's genetic makeup. Medical DNA does some toxicology testing as well. These are exorbitantly expensive tests submitted to the Governments. Conversely, Medical Tox Labs has also performed and billed Government payors for DNA tests.

325. For the vast majority of PPOA's patients, including those treated for chronic pain by PPOA's affiliated pain management specialists, DNA Tests are not medically necessary. Nonetheless, the Defendants implemented fraudulent schemes to refer patients of PPOA-affiliated physicians to Medical DNA and Medical Tox Labs for expensive DNA Tests.

326. In keeping with PPOA's strategy to bill Government healthcare programs for a multitude of expensive claims for every patient, since at least 2017, PPOA's "clinical protocols" required that "all new" patients were to be subjected to DNA testing ("pharmacogenomics"). This meant that all PPOA patients were referred to PPOA's affiliated lab, Medical DNA (or Medical Tox Labs), for a DNA test. This policy was implemented without the input of the patient's treating physician. Like the UTOX, the swab sample was obtained from the patient before they even saw their treating physician. *See, e.g.,* 42 C.F.R. § 410.32(a).

327. As noted above, not only were PPOA physicians expected to refer patients to captive PPOA laboratories like Medical DNA Labs (and could potentially receive a 40% bonus for such referrals), but PPOA's contracts with physicians further stated that "**all new patients are tested for pharmacogenomics** so that providers can obtain actionable clinical relevance from pharmacogenomics testing." (emphasis added). PPOA's mandate was clear. All patients, regardless of their clinical presentation (and, relatively, the medical necessity of such testing) would receive remarkably expensive DNA tests – tests which naturally were to be performed by PPOA's captive labs.

328. At the PPOA physician practices, non-medical personnel, including office managers and office staff, would swab the inside of the patient's cheek to obtain the DNA sample for testing. This would be done after registration, but before the patient had been seen by a

physician (thus, before the provider could make a determination if the DNA test was actually medical necessary).

329. Virtually all DNA tests performed by Medical DNA (and Medical Tox) were unnecessary. In fact, PPOA physicians did not even use the DNA tests in making clinical decisions for their patients.

330. Because physicians were not even reading the unnecessary DNA test results (much less using them in their treatment of pain management patients), on July 25, 2017, Dr. Rivera, PPOA's CMO, wrote to all PPOA providers and directed them to create false documentation setting forth that the DNA tests referred to and performed by the PPOA-affiliated lab were actually read, used in treating pain management patients, and discussed with those patients:

> A word to let you know I need you all to do a little more with the pharmacogenomics. Every time you see those results back I need you to spend some time interpreting those results, deciding the relevance of those results in the course of therapy and state for the record in a note "this is what i am doing different, now that i know this information..." I actually need those key ords [sic] in the note or something to that effect written in the chart. [...] I need you all to please look at those toxicology reports in the light of the pharmacogenomics profile. I need you to write in the record a note for each patient after you read the pharmacogenomics report and state how you interpret it and how it would change what you are doing or would do with this patient.

331. PPOA providers, and the Defendants herein, know that PPOA's DNA testing, like the vast majority of PPOA's UTOX tests, offered no actual value in the treatment of their patients, the providers rarely reviewed the results of the DNA testing, much less considered them at all in the treatment of their patient. Thus, DNA testing was not medically necessary at any point in determining the type of pain treatment or medication rendered to their patients.

332. In recognition of this reality, Dr. Rivera repeated PPOA's request for false documentation at the May 2018 PPOA Physicians Annual Meeting. At Slide 39, Dr. Rivera

highlighted a "Pivotal Article" by Andrea Trescott, he reminded the PPOA providers that genetic testing was "Part of Our [PPOA's] Protocol," and he directed the providers: "Please go over it with your patient and document doing so."

333. The articles relied upon by PPOA leaders to justify DNA testing are written by persons who themselves operate labs that preform DNA testing. For example, "Genetic Testing for Opioid Pain Management: A Primer," was written by Andrea Trescott, who also operated a DNA testing lab.

334. Other articles discuss the lack of connection or any medical necessity for expensive DNA testing in pain management. For example, the February 2016 Editor's Note in Practical Pain Management: "Pharmacogenetic Testing in Pain Management: Where Do We Stand?" notes the lack of support among medical professionals on the utility or practicality of testing for patients on opioids, including how such tests results can or should impact treatment by pain management practitioners. *Available at* https://www.practicalpainmanagement.com/resources/diagnostic-tests/pharmacogenetic-testing-pain-management-where-do-we-stand. Rather than being envisioned in the mine-run of pain management cases (as was and is envisioned by PPOA protocol), DNA testing is rarely, if ever, necessary for these patients.

335. Medicare has made clear that the DNA tests that the Defendants offer (*e.g.*, testing for the CYPC19, CYP2D6, and CYPC9 genes) are only covered and medically necessary in a very limited range of cases (if at all). By way of example, a relevant Local Coverage Determination for Florida, L35698, states that:

- "genetic testing of the CYP2C19 gene is considered medically necessary for patients with ASC undergoing PCI who are initiating or reinitiating Clopidogrel (Plavix) therapy."

- "genetic testing of the CYP2D6 gene is considered medically necessary [and is thus covered] to guide medical treatment and/or dosing for individuals for whom initial therapy is planned with: Amitriptyline or nortriptyline for treatment of depressive disorders [or] Tetrabenazine doses greater than 50 mg/day, or re-initiation of therapy with doses greater than 50 mg/day;" and
- "[c]overage for genetic testing for the CYP2C9 gene is considered investigational at this time [and is thus not covered by Medicare]"

L35698; see also L36310 (relevant LCD for California with similar limitations). PPOA's DNA testing protocols and practices were inconsistent with these LCDs, not to mention the principle of medical necessity generally. For example, most pain physicians would not be prescribing Plavix (a blood thinner used to prevent blood clots) or Amitriptyline or Nortriptyline (for depression).

336. The lack of medical necessity for PPOA's DNA testing is revealed in Dr. Rivera's own notes for his presentation during PPOA's 2018 Physician Retreat. At Slides 40 and 48, Dr. Rivera noted: "Preliminary recommendations for dose adaptations based on SNPs [single nucleotide polymorphisms] have been published, but not included here because not approved."

337. PPOA repeatedly reminded PPOA providers to, at the very least, read the DNA test results and directed them to review them with the patient for one reason: to justify the hefty claim for these unnecessary services referred to and billed by PPOA's affiliated DNA lab. The DNA tests did not change the physician's treatment protocol.

338. By way of another example, in late 2018, PPOA's COO, Josh Helms, sent an email to all PPOA office managers announcing a contest between the office managers at PPOA-affiliated practices to determine which locations could provide the most DNA testing referrals to PPOA's affiliate, Medical DNA. The PPOA manager whose office provided the most DNA test referrals

was to be rewarded with a party. The office managers involved in the contest supervised the same non-medical staff at PPOA offices who obtained DNA swabs from patients before they even saw their treating physician.

339. The PPOA Defendants' conduct resulted in extreme over-utilization of Government-funded healthcare program resources in light of the fact that the DNA testing is only medically necessary for a very narrow subset of patients (including a very narrow subset of PPOA's own patients). PPOA even created scripts for providers to read if patients received bills for these expensive tests.

340. PPOA's conduct resulted in expensive claims being submitted to Government healthcare programs (including Medicare, FEHBP, Tricare, and Medicaid) which also violated federal and state AKS and the Stark Laws. Since its founding in 2014 and commencement of business on or shortly before January 2016, the primary (if not sole) source of referrals to Medical DNA has been the physicians at practices owned, operated, and/or controlled by the PPOA Defendants.

341. The DNA test and UTOX policies were revenue-driven, and bore no relationship to medical necessity. For example, as PPOA tried to gain market share by aligning themselves with personal injury lawyers, the PPOA Defendants directed providers to cater their treatment to these patients based on the amount of coverage available and the potential settlement value of the patient's claim.

342. Tracie Lawson, PPOA's COO/CEO wrote to all PPOA providers (pain, primary care, orthopedics, rehab, wellness, and anesthesia) they did not need to prescribe DNA Tests or UTOX when treating personal injury patients. Lawson stated: "The decision about ordering pharmacogenomics is always with the provider...Urine drug screen and confirmations are again

tests that you need to decide whether you need on your patient to give the best medical care." "She added that attorneys have not wanted to send patients to PPOA because of "long wait times at the clinics, taking too long to perform procedures (meaning repetitive office appointments without treatments), pricing and not watching the limits on cases."

343. The PPOA Defendants created fraud schemes that resulted in thousands of referrals of patients treated by the physicians or mid-level providers, including pain specialists, who are employed by or affiliated with PPOA's subsidiaries and practice at PPOA locations throughout the United States to Medical Tox and Medical DNA Labs, and their fraudulent conduct included:

(a) improperly interfering in the medical decision making of their affiliated physicians by pre-selecting patients, including beneficiaries of Government-funded healthcare programs, for expensive lab-based UTOX and DNA testing services at the time the patient arrives at the PPOA practice -- before the patients were or are examined by their physician or a mid-level provider or that provider had determined such testing was medically necessary;

(b) falsely identifying UTOX as "confirmation" testing on claims submitted by or on behalf of MedTox to Government-funded healthcare programs when "confirmation" testing was not warranted. For example, when screening (Qualitative) UTOX was not requested by the physicians, when Qualitative UTOX was not performed, or there were no "unexpected" results to "confirm."

(c) fraudulently obtaining the consent of patients, including Government healthcare program beneficiaries, to lab-based UTOX by falsely representing to patients that frequent Quantitative UTOX services were required in order to comply with state and/or federal laws;

(d) fraudulently obtaining the consent of patients, including Government

healthcare program beneficiaries, to perform lab-based DNA testing by falsely representing to patients that DNA testing services enabled doctors to tailor pain medications to the individual;

(e) interfering in the medical decision making of the treating physicians after the physician or mid-level provider treated the patient by steering Government healthcare program beneficiaries to MedTox and Medical DNA and by instructing patients that they were required to use the Defendants' lab by virtue of being a patient of the clinic;

(f) implementing UTOX and DNA testing policies, including mandatory testing at each patient visit, that resulted in the creation of false electronic medical records (EMRs) in an effort to support medically unnecessary lab-based UTOX services billed by MedTox and Medical DNA Labs to Government-funded healthcare programs;

(g) causing practitioners to create false medical records (*i.e.,* including language in the record to create the appearance, but not reality, of medical necessity for UTOX and DNA tests); and

(h) causing MedTox and Medical DNA Labs to perform excessive, often untimely, medically unnecessary UTOX and DNA tests, which the Defendants billed or caused MedTox or Medical DNA Labs to bill to Government-funded healthcare programs.

344. Through the conduct described herein, Defendants knowingly submitted and/or caused the submission of false claims, created false records material to false claims, and/or conspired to submit false claims for UTOX and DNA testing services to Government-funded healthcare programs, both federal and state, including, but not limited to Medicare, Medicaid, TRICARE, FEHBP, and the VA.

345. For example, an independent auditor hired by PPOA visited PPOA practices, including the practice in Winter Haven, Florida, in late 2018 and observed that the Defendants'

testing protocols caused the submission of claims for medically unnecessary services.

346. Knowing that the claims submitted by MedTox and Medical DNA were false or fraudulent, Defendants failed to return required overpayments, and are also liable under the FCA for failure to pay a known obligation to the Government.

347. For each Quantitative UTOX episode, Defendants' conduct caused the submission of a claim to Government-funded healthcare programs of approximately $4,500, and the fraud involved multiple testing episodes per beneficiary per year. For UTOX tests, Medical Tox Labs and Medical DNA Labs bill Government payors under various CPT and HCPCS Codes, including, but not necessarily limited to, the following codes: 82955, 83789, 83986, 83992, 84315, G0479, G0480, G0481, G0482, G0483, G6031, G6038, G6042, G6044, G6051, and G6052.

348. For each DNA Test, Defendants caused the submission of a claim to Government-funded healthcare programs of approximately $6,000 to $10,000 per beneficiary. For DNA tests, Medical Tox Labs and Medical DNA Lab bill Government payors under various CPT and HCPCS Codes, including, but not necessarily limited to, the following codes: 81227, 81240, 81241, 81479, 81291, 81400, and 86225.

349. In addition, between 2015 and 2107 alone, PPOA, through its affiliates submitted over $225 million in claims to Medicare alone for UTOX and DNA testing, and received millions of dollars in payments in return.

**a) Unnecessary So-Called Laser Spine Surgeries**

350. Since at least March of 2017, the PPOA Defendants, according to Wood, were seeking "minimally invasive" (a/k/a laser) spine surgeries to fuel revenues in Florida and Texas. Laser Spine Surgery has been treated as a controversial and even dangerous treatment option for patients suffering from chronic pain.

351. Consistent with PPOA's focus on maximizing profits per patient, PPOA's addition of laser spine surgery, to its menu of services, is related directly to the fact that laser spine surgery cost about twice as much as any comparable conventional surgery.

352. For example, in 2012, news stories chronicled a 2008 laser spine surgery gone wrong at the Laser Spine Institute in Tampa. The October 2008 surgery at Laser Spine Institute cost $90,176, but left the patient incontinent with a dangerous spinal fluid leak. According to Bloomberg Businessweek, "[n]ine surgeons told Bloomberg Businessweek the company is doing surgery that is often unnecessary or inappropriate...Aetna won't cover operations at Laser Spine, citing a lack of research confirming safety and efficacy. Cigna won't pay for the laser part of surgeries done there." *Available at* https://www.bloomberg.com/news/articles/2011-05-12/patients-sue-back-surgery-company-laser-spine.

353. Just before joining PPOA, Dr. St. Louis was the surgical founder of LSI, a now defunct entity.

354. The reputation of Dr. James St. Louis, a spine surgeon, and his former practice, Laser Spine Institute, is poor at best. His reputation as a physician was well known to the Defendants. In fact, Dawn Baker, after introducing Dr. St. Louis to the PPOA Defendants in late 2017, shared with them that a Dr. Flood, who had practiced with Dr. St. Louis at LSI, would not practice with him again.

355. Despite the controversy surrounding laser spine surgery, in general, and Dr. St. Louis in particular, the PPOA Defendants set out to rapidly grow their revenues through laser spine surgery performed by Dr. St. Louis.

356. In January 2018, Dr. St. Louis joined the PPOA Defendants. According to PPOA's announcement, Dr. St. Louis focuses on minimally invasive surgical techniques for patients with degenerative disc disease, spinal and foraminal stenosis, sciatica and disc herniation. Since joining

PPOA, he practices out of a Tampa-based PPOA location, next door to the PPOA Defendant's Habana Ambulatory Surgery Center.

357. At the same time (early 2018), Phillip Kravetz, MD, whom the PPOA Defendants described as "another pioneer in the field," joined the PPOA Defendants to perform laser spine surgeries at the PPOA Defendants' Hurst, Texas Minimally Invasive Spine Clinic.

358. Since Dr. St. Louis and other laser spine surgeons joined the PPOA Defendants, there has been an ever-increasing focus by the Defendants on subjecting PPOA patients to lucrative laser spine services. For example, the PPOA website has created a banner that runs across their homepage alerting visitors: "Now accepting Laser Spine Institute Patients." Every patient calling a PPOA-affiliated office also hears a recording: "Did you know that you can have laser spine surgery?"

359. As part of their quest for laser spine surgery revenues, the PPOA Defendants have targeted Government healthcare program beneficiaries. For example, on their website, the PPOA Defendants specifically target beneficiaries with "traditional" Medicare coverage. Their website includes the following: "Does Medicare Cover Laser Back Surgery?... Good news for seniors who have put off treating neck or back pain because of cost: Physician Partners of America is one of the few healthcare providers that accepts Medicare for minimally invasive laser spine procedures." The PPOA Defendants advertise that they "accept[s] traditional Medicare for both the physician and the facility, allowing the procedure to be become more affordable for Medicare patients." PPOA notes that Dr. St. Louis is the "director of PPOA's Minimally Invasive Laser Spine Group."[4]

360. In September 2018, the PPOA Defendants sent out a press release announcing that the PPOA Defendants were accepting "Tricare, including Tricare Prime, for laser spine

[4] https://www.physicianpartnersofamerica.com/health-news/laser-spine-surgery/laser-spine-medicare-coverage.

procedures."[5] In order to attract current and former members of our Armed Forces, who are Tricare beneficiaries, the PPOA Defendants highlight that Dr. St. Louis was "a U.S. Army veteran and has been treating fellow service members for 30 years. The surgical founder of Laser Spine Institute, he is pleased to extend this groundbreaking outpatient surgical option to patients at Physician Partners of America in Florida and beyond."[6]

361. In keeping with Dr. St. Louis's arrival, physicians at PPOA-affiliated practices observed changes in PPOA policies and procedures regarding laser spine surgery.

362. For example, the PPOA Defendants, through dozens of their corporate individual managers, immediately began to pressure PPOA physicians to refer patients to Dr. St. Louis for laser spine surgery, without regard to medical necessity. The efficacy of this surgery was misrepresented to the patients.

363. Other physicians at PPOA have voiced concerns to Ms. Baker regarding the medical necessity or medical appropriateness of laser spine surgeries being performed by Dr. St. Louis. She also learned from another LSI surgeon that Dr. St. Louis himself had not been performing the actual laser procedures for some time before joining PPOA, and had not been in the Operating Room ("OR") for three years. The physicians observed that his treatment methods and surgical procedures were outdated and/or not medically appropriate. Thus, the PPOA physicians' reluctance to refer to Dr. St. Louis included that: 1) the spine surgeries were not medically necessary; and 2) even if medically necessary, the PPOA physicians would not refer their patients to Dr. St. Louis, but would refer patients to other more-qualified orthopedic spine or

[5] https://markets.businessinsider.com/news/stocks/laser-spine-surgery-now-covered-by-tricare-at-physician-partners-of-america-1027568874.

[6] *Id.*

neurosurgeons for non-laser surgery. These more qualified orthopedic spine or neurosurgeons would likely be employed by entities outside the PPOA Defendants.

364. Dr. Cho likewise has never referred a patient to Dr. St. Louis – before or after joining PPOA.

365. When the PPOA physicians resisted the PPOA Defendants' pressure to refer their patients to Dr. St. Louis for laser spine surgery (particularly because it was not medically necessary), the Defendants tried to deceive patients in order to send referrals to Dr. St. Louis and their other spine surgeons. PPOA physicians have learned that, although they did not refer patients for laser spine surgery, the PPOA Defendants were contacting patients directly and scheduling these unnecessary surgeries.

366. PPOA's Tampa-based schedulers calling patients representing (falsely) that their treating physician is calling to schedule laser spine surgery. Dr. Cho received complaints from patients who had been contacted directly by PPOA schedulers (even though Dr. Cho had not recommended them for laser spine surgery. One such patient had been victimized by Dr. St. Louis at LSI as a result of a back surgery that left her in more pain. She was offended when contacted by PPOA for another spine surgery with Dr. St. Louis.

367. For example, PPOA physicians have reported to Ms. Baker that a representative from the PPOA Defendants would directly contact patients treated by PPOA-affiliated pain management physicians and misrepresent that they were the patient's physician. The PPOA representative would also misrepresent to the patient that his or her treating PPOA physician had recommended that the patient receive laser spine surgery.

368. At least one patient, who recognized that the PPOA representative was not their treating physician (Dr. Rogers, who has a distinctive English accent), was then told that the PPOA

representative was calling on behalf of their treating physician. The PPOA Defendants engaged in this conduct in an effort to schedule PPOA patients for medically unnecessary laser spine surgeries in order to generate fraudulent revenues.

369. Patients throughout the PPOA-affiliated practices are believed to be impacted by the unnecessary spine procedures because the PPOA corporate headquarters in Tampa has been at the center of these fraudulent practices. PPPOA executives did not deny they engaged in these practices. For example, when Dr. Stern called Josh Helms, PPOA's COO, to direct him to stop calling Dr. Stern's patients to schedule laser surgery consults, there was no effort by the COO to disavow that the practice was occurring or that the COO was capable of controlling whether Dr. Stern's patients were called by the PPOA schedulers. Helms merely replied, "OK."

370. The PPOA Defendants' tactics to rapidly grow revenue through laser spine surgeries were highly successful. PPOA's campaign to send patients to Dr. St. Louis in Florida and Dr. Kravetz in Texas resulted in more than 500 laser spine procedures performed between January 16, 2018 and November 15, 2018 alone. That number jumped to 600 by December 2018.

371. The first new laser spine patient was seen on January 3, 2018 and an order for laser spine surgery was scheduled that day for January 16, 2018. In just the short time between his arrival at PPOA in January 2018 and February 2018, Dr. St. Louis performed more than 50 outpatient spine procedures.

372. In fact, by the end of February, the PPOA Defendants added Saturday office hours for Dr. St. Louis because of "high demand." Unfortunately, that demand was manufactured by PPOA's unlawful policies of pushing its practitioners to refer patients in need of conservative therapy to instead undergo expensive and unnecessary laser spine procedures and by their falsely representing to patients that their treating physician had recommended laser spine surgery. By

April 5, 2018, PPOA's efforts to feed referrals to Dr. St. Louis resulted in more than 100 laser spine surgeries.

373. On June 11, 2018, the PPOA Defendants added laser spine surgery to their Texas offerings when Dr. Philip Kravetz started practicing at their Hurst and Frisco, Texas locations. Thereafter, PPOA's ASC in Texas also instituted Saturday hours.

374. After entering into a partnership with PRC in the fall of 2018, on November 11, 2018, PPOA expanded laser spine services to Pinellas County, Florida. By November 15, 2018, the PPOA Defendants had used more than 500 PPOA patients to feed their appetite for laser spine revenues.

375. Since beginning their laser spine campaign in 2018, the PPOA Defendants have quadrupled the number of physicians performing laser spine procedures, including by bringing some of Dr. St. Louis's former colleagues from the Laser Spine Institute to PPOA. In early March 2019, the PPOA Defendants held a job fair in Tampa for former Laser Spine Institute employees. Following the job fair, the PPOA Defendants made at least 10 job offers. Dr. Stefan Prada, MD, a former Laser Spine Institute surgeon, started practicing at the PPOA Defendants' Merritt Island Outpatient Surgery Center on April 1, 2019.

376. Although PPOA actively markets laser spine surgery in Jacksonville, Florida, they do not currently have an ASC or spine surgeon in that location.

377. The PPOA Defendants often use their transportation affiliate to take patients to PPOA-affiliated ASCs hours away from the patients. For example, PPOA patients from Jacksonville are transported using PPOA's ancillary transportation provider to the PPOA-affiliated ASC in Merritt Island. Dr. Harsh Dangaria had advised Ms. Baker that the PPOA Defendants had also transported his spinal cord stimulator implant patients to that location. Dawn Baker was also

informed that PPOA transported patients to its ASC in Orlando, including patients involved in personal injury claims. Dr. Cho is aware that PPOA transported patients from Boynton Beach to their Tampa ASC.

378. The PPOA Defendants also added another interventional pain physician, Man Q. Le, MD, to practice at a new PPOA location in Boca Raton, Florida. Before joining PPOA, Dr. Le was with a Surgery Partners' affiliate, Tampa Pain Relief. The PPOA Defendants announced that Dr. Le would contribute to the expansion of their laser spine services.

379. Since 2018, the PPOA Defendants engaged in fraudulent practices to generate unlawful referrals for laser spine surgery in order to generate lucrative ASC facility charges and professional fees through (at least) two laser spine surgeons Dr. St. Louis, Dr. Prada, and Dr. Le in Florida and Dr. Kravetz in Texas, as well as other non-surgeons that PPOA "trained" to perform other unnecessary minor laser spine surgeries or other unnecessary laser procedures. The PPOA laser spine surgeons generate some of the highest revenues for all surgeons nationwide.

380. For each laser spine surgery impacted by the fraud, the PPOA Defendants caused the submission of a false claim to Government-funded healthcare programs totaling thousands of dollars in facility charges and professional fees, including anesthesia charges.

**b) <u>Unnecessary Interventional Procedures by Pain Specialists</u>**

381. Pain specialists who perform procedures in the Defendants' ASCs, or in-office procedure suite, generate revenues for PPOA through both facility charges, as well as professional fees, both of which are billed by the PPOA Defendants. The Defendants have unlawfully adopted practices to increase revenues from these interventional procedures which include implanting spinal cord stimulators or pain pumps, etc.

382. When medically necessary, the physicians would perform these procedures after

they had determined they were in the patients' best interests. PPOA Defendants, however, pressure physicians to perform interventional procedures for their patients in order to generate revenues to feed PPOA's growth strategy.

383. ASCs are expensive to build. Once PPOA complete an ASC, it must find patients to generate a return on PPOA's investment. For example, on August 8, 2017, Dr. Gari stated that PPOA's "main driver" was "interventional doctors with an existing patient base that can feed our ... ASC so that everyone benefits."

384. In keeping with PPOA's focus on procedure-related revenues, on August 21, 2017, Dr. Rivera asked Ms. Baker to provide a "case log" for the past year for a potential recruit for PPOA.

385. In order for PPOA to maximize reimbursement for a procedure, it must have been performed in PPOA Defendants' ASC or in-office procedure suite. The reimbursements from their invasive procedures, particularly those performed in an ASC, are significant. For example, implanting a spinal cord stimulator results in a Medicare reimbursement to the PPOA-affiliate of $32,800, including $5,000 for professional fees alone. Annual maintenance costs are in the thousands of dollars. The PPOA-affiliates submit claims for both the facility charge and professional fees.

386. A pain physician who performs a high volume of invasive procedures can generate millions of dollars in revenue annually for the PPOA Defendants.

**c) The PPOA Defendants Campaign to Fraudulently Grow ASC/ANA Revenues: Tripling the "Conversion Rate" from 14% to an Extraordinary 50%**

387. Sometime after Defendant Milo officially joined PPOA in January of 2018, he revised the Employment Agreement template sent to all new and incoming physician recruits to

PPOA, including the physicians practicing at the Defendants' Pain Relief practices.

388. The changes made by Milo included those in "Attachment C [to PPOA physician contracts] – Florida Pain Relief Group ("Employer") Clinical Protocols Overview." In this section Milo amended the section for "Surgery Center/Procedure Room." Milo added "as part of an interventional pain practice, [the physician] is expected to perform interventional procedures at a conversion rate of 15% or more. An 'interventional procedure' is one that qualifies for reimbursement if performed in an ambulatory surgery center/in-office procedure suite. A 'conversion rate' is the total number of interventional procedures performed monthly divided by the number of patient office visits monthly."

389. Thus, the conversion rate policy was intended to maximize revenues by requiring that a certain percentage of patients receive invasive procedures and was not based on individual patient's medical necessity. Patients were reduced to numbers that could fuel PPOA's surgical revenue engine.

390. The PPOA Defendants actual expectations for "conversion rate" by pain specialists exceeded the percentage that Milo inserted in the Employment Agreements.

391. During PPOA's 2018 Physicians Meeting, Kays Al-Ali, SVP of Operations for ASC Operations, Acquisitions, and the Anesthesia Division discussed PPOA's ASC and Anesthesia Division business. At Slide 52, he identified the PPOA executives and managers of his division as: Linda Abernathy, VP Operations, ASC/ANA Division; DeShawn Bhooshan, Director of Clinical Operations; Erida, Director of Revenue Cycle, ASC/ANA Division; Yoany Gonzalez, Associate Director of Revenue Cycle, ASC/ANA Division; Gloria (Habana ASC), Jayne (Boynton ASC); Kristy (Precinct ASC), Roxanne (Frisco ASC), and Gayle (Park ASC).

392. VP Abernathy also worked on PPOA's DNA testing and UDT operations as well.

393. At this meeting, Kays Al-Ali discussed the PPOA Defendants' "500 Cases Strategy" to grow the ASC/ANA Division. At Slide 53, Al-Ali described characteristics of the "current situation" that represented "The 'Risk'" to revenue growth, including: "Conversion rates;" and that "Habana pain case conversion was at 16%."

394. The PPOA Defendants offered no medical or clinical support for their mandate to increase the "conversion rate." Instead, at Slide 54, Al-Ali discussed the purely business means, ways, and ends of the ASC/ANA "500 Cases" growth strategy, "MEANS + WAYS = ENDS:"

- "MEANS – What are the resources related to implement the strategy?" "Our physician partners;" and "Turnover of cases;"

- "WAYS (The Strategy) – How are we going to achieve our objectives?"
  - "Goal is to achieve a 22% conversion rate;"
  - "Improve on cancellation rate;"
  - "Pre-op calls 45 days, medical clearance;"
  - M&A/ Syndication/New service lines: OPTO/SPINE/ORTHO
  - Cost of supplies % <30%
    - Vendor MEDTRONIC

- "ENDS – What are the specific objectives?"
  - "Average 500 cases per center;"
  - "Reduce SWB to 30% as percentage of top line revenue;" and
  - Clinics EBITDA as [sic] least break even point."

395. At Slide 55, PPOA illustrated for Providers the number of "conversions" over the first four months of 2018: "Jan – 381; Feb – 4--; Mar – 437; and April 440." Al-Ali included a chart depicting the CPT Code, Description, and Professional Fee for five procedures: the first three, with lower reimbursement rates ($133- $229) are injections, the bottom two procedures, which are highlighted on Slide 55, are CPT Codes for implanting stimulators and the related electrodes, with higher professional fee reimbursement rates ($377- $426).

396. At Slide 56, PPOA's SVP of Operations for ASC/Anesthesia Operations (Kays) then described PPOA's "Future Habana," includes strategy for increasing revenues will: Focus on

interventional pain procedures:

- SCS (spinal cord stimulators) on information and belief, PPOA would bill for these services under at least the following CPT Codes: 63650, 63655, and 63685. SCSs afforded the PPOA defendants two billing opportunities for each patient:
    - Trial (CPT Code 63650): Professional fee, $424, Facility Reimbursement, $5,745;
    - Permanent Placement (CPT Code 63685, IPG generator), and (CPT Code 63650, Lead electrode): Professional fees $378 and $424; Facility Charge Reimbursement (including device), $27,047. Available at: https://www.medtronic.com/content/dam/medtronic-com/professional/documents/spinal-cord-stimulation-commonly-billed-codes-2018.pdf; https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Neuromodulation/2017/NM-45908-AN%202017%20Outpatient%20Quick%20Reference%20Guide%20%20FINAL.pdf.
- Infusion Pumps (Pain Pumps) on information and belief, PPOA would bill for these services under the CPT Codes below, and also provided the PPOA defendants two billing opportunities for each patient:
    - Trial (CPT Codes 62322-62327): Professional fees $157-$251, no device fee;
    - Permanent placement (CPT Code 62362, pump placement):

Professional fee $399, Facility Reimbursement, $16,440; combined with CPT Code 62350 (catheter placement), Professional fee, $414, and Facility reimbursement $4,627. Combined, the Professional fees are $813 and the total Facility Reimbursement is $21,067 (not including separate anesthesia service). Available at https://flowonix.com/sites/default/files/hospital_coding_and_payment_guide.pdf;

- https://www.medtronic.com/content/dam/medtronic-com/professional/documents/targeted-drug-delivery-commonly-billed-codes-2018.pdf.

**d) PPOA's Fraudulent 50% Conversion Target**

397. The PPOA "Conversion Rate" real strategy was, in reality far more aggressive than demonstrated to the PPOA providers at the 2018 Physician Meeting or in the PPOA PowerPoint.

398. On December 25, 2018, Dr. Gari, the owner and founder of PPOA, wrote an email to all PPOA providers discussing the PPOA Defendants' strategy to generate revenues through spine surgeries without regard to medical necessity. The stated goal was to more than triple the "conversion rate:" "as of January 2018, 0 spine surgeries were performed per month;" "as of December 2018, 60 spine surgeries were performed per month;" "2018: Interventional techniques training increased office visits to procedures ordered ration [sic] from 14%;" "2019: Continued focus and training on interventional treatments should increase this ratio to over 50%." (*emphasis added.*)

399. Moreover, Dr. Cho was provided PPOA decisional flowcharts for converting pelvic, lower back, and neck pain (complaints which constitute a substantial portion of any pain management physician's practice) to interventional surgical procedures over more conservative

treatment modalities. These charts invariably stated that patients who responded to (or would likely respond to) far less invasive (and less inexpensive) treatment modalities should instead be referred for various invasive surgical procedures (*e.g.*, laser spine surgeries and medication pump implants) in scenarios that were remarkably inconsistent with professional norms and medical necessity.

400. The intent and effect of the PPOA decisional flowcharts was, of course, to compel PPOA physicians to refer patients for highly expensive, unnecessary, and potentially dangerous interventional procedures to be performed by providers within the PPOA network. Again, the PPOA goal was to maximize revenues per patient, rather than provide patient-specific, medically necessary care.

**e) PPOA's Physician Dashboard Reports**

401. The PPOA Defendants tracked closely their pain physicians' procedure volumes and pressured them to subject patients to more procedures in order to generate revenues for the PPOA entities. The Defendants had a regular understanding of the profit and loss of every medical provider employed by PPOA. Practitioners were routinely provided these profit report cards in order to push "underperforming" (*i.e.*, ethical) physicians to bilk insurers (and victimize patients) through more and more unnecessary services.

402. Even before the PPOA Defendants issued formal Dashboard reports in early 2019 detailing their physicians' performance in terms of procedure volumes, they were tracking this data carefully and taking steps to replace low-performing providers.

403. Milo added a minimum "conversion rate" to PPOA physician contracts by, at the latest, early 2018.

404. For example, in November 2018, Milo told Dawn Baker that he wanted to replace

Dr. Cho, who had low procedure volumes, with the infamous Dr. Golovac. Milo commented that Golovac "could do in one day what Dr. Cho takes all month to do."

405. In another conversation in December 2018, Milo complained to Dawn Baker that both Dr. Cho and Dr. Rogers "are not cutting it," and that PPOA considered both physicians to be low producers. Milo continued his discussions of his plans to replace Dr. Cho.

406. On January 1, 2019, Dr. Cho received an email from BISupport@physicianpartnersoa.com attaching the "Prior Month Physician Dashboard Metrics for Sheldon Cho." The cover email stated:

> "Attached are the physician dashboard metrics from last month. These dashboards contain an excess of information and may not all be seen on your attachments. If you'd like to review your dashboard you can access them using the link below. All data is updated as of yesterday...http://prd-zap-web01/PPA/View/Public."

407. At the bottom, the email included the following note: "This distribution was generated by the Publication Rule: Public/Resources/Automated Reports/Monthly Physician Dashboard Email/FL/Cho/Physician Dashboard – Cho."

408. PPOA's Physician Dashboard Metrics reports are comprised of four separate reports as reflected in the attachments to the email from PPOA's BI Team: Top Performing Physicians.pdf (Top Performing PPOA Physicians); Encounters.pdf (Physician Dashboard – Encounter Details –[Name of Physician]; Financial.pdf (Physician Dashboard – Financial Details – [Name of Physician]; and Services.pdf (Physician Dashboard – Additional Details – [Name of Physician].

409. The PPOA Defendants' automated reporting system generates a similar report to every PPOA physician in every state where PPOA has operations (as of 2019, this includes Florida, Texas, and California).

410. PPOA's Physician Dashboard Metrics "Top Performing PPOA Physicians" Report for December 2018 included:

- Top 10 Performing PPOA Physicians for Surgical Cases;
- Top 10 Performing PPOA Physicians for Pump/Stim[ulator]/Trial Cases;
- At the bottom of this report, PPOA provides the PPOA physician receiving the report with: "Your Surgical Rank," and
- "Your Pump/Stim/Trial Rank."

411. For the month before the PPOA Physician Dashboard Metrics report was issued (December 2018), the following providers were ranked among the top 10 for PPOA:

- Dr. Thanh Le was ranked highest among PPOA physicians for surgical cases (155);
- Medina-Sanchez (with 11) was ranked first for Pump/Stim/Trial Cases;
- Mauricio Orbegozo (112 Surgical and 9 Pump/Stim/Trial Cases);
- Chad Gorman (123 Surgical and 9 Pump/Stim/Trial Cases);
- Prasad Lakshminarasimhiah (8 Pump/Stim/Trial Cases);
- Taufiq Ahmed (108 Surgical Cases);
- Alejandro Tapia (65 Surgical and 8 Pump/Stim/Trial Cases);
- Luis Nieves (81 Surgical and 7 Pump/Stim/Trial Cases);
- Jorge Leal (78 Surgical and 8 Pump/Stim/Trial Cases); and
- Abraham Rivera (8 Pump/Stim/Trail Cases).

Dr. Cho on the other hand, was ranked 27th for surgical cases (with 14), and he failed to return any data for Pump/Stim/Trial cases.

412. According to PPOA's internal newsletter, Dr. Chad Gorman was among PPOA physicians who appeared on national and local media, ostensibly to discuss the opioid crises, but, in reality to drum up business for PPOA's interventional procedures. Dr. Gorman discussed "end-of-the-year insurance benefits and what PPOA has to offer patients on the WFTS-TV Morning Blend Show."

413. Effective December 3, 2018, PPOA entered into a partnership with Pain Relief Centers (PRC), which operated a pain management practice and ASC, West Park Surgery Center in Pinellas Park, Florida. Dr. Thanh Le was a physician at PRC who moved his pain practice to nearby St. Augustine, but continued to utilize the West Park Surgery Center after the PPOA-PRC partnership.

414. As evidenced by his appearance on the PPOA Physician Dashboard report in December 2018, Dr. Le became a PPOA physician as a result of the arrangement between PPOA and PRC. In addition to Dr. Le, PPOA hired new physicians John Keyvn Otero, M.D, Robert Guirguis, D.O., Hector Cases, MD, and nurse practitioners Linda Ngwa and Georgette Bouwhuis for the West Park Surgery Center.

415. PPOA reported in its internal newsletter, PPOA Connect, that the Pinellas Park ASC, West Park Surgery Center had been seeing 1,000 patients and performing up to 300 procedures each month (a 30% conversion rate, which is double the 15% minimum conversion rate term in PPOA's employment agreement), and that Dr. St. Louis had expanded its offerings to include spine surgery.

416. In addition to PPOA's highest ranking surgical case source, Dr. Le, and Drs. Otero and Guirguis, the West Park Surgery Center received cases from Hector Cases, MD at Sun City Center clinic in Sun City Center, FL, and John Scott Adams, MD, from the Lakewood Ranch clinic in Lakewood Ranch, FL. PPOA was in the process of opening an ASC in Sun City Center as of January 2019.

417. PPOA's Physician Dashboard - Encounter Details Report tracks Dr. Cho's patient visits for the months of August through December 2018, and compares his performance to "PRG Average Encounters" for the same months. "PRG" includes PPOA locations operated through Defendants Florida Pain Relief Group (FPRG) and Texas Pain Relief Group (TPRG).

418. PPOA also provided the encounter counts for the month and encounters per day for each of their locations (typically staffed with one pain specialist). Finally, the PPOA Defendants provided the "Physician Encounters by Type" (established versus new patients) for each month.

419. The Physician Dashboard – Financial Details" Report includes:

- Daily Cash Collected,
- Monthly Cash Collected,

- number of Unbilled Encounters and Missing Notes;
- Top 10 Billed CPT Codes, and
- Top 10 Payers.

420. For December 2018, the PPOA Defendants' Daily Cash Collected for Dr. Cho's patients included $19,932 for Established Patients; $7,780 for New patients; $4,812 for Labs; and $1,408 for Surgical.

421. For December 2018, PPOA's top 10 payors for Dr. Cho's patients included Medicare, Medicare Advantage, and Tricare. BCBS was listed as the second highest payor, and, on information and belief, includes federal employees covered by FEHBP through BCBS.

422. PPOA's "Physician Dashboard – Additional Details – Cho" report for December 2018 includes:

- Surgery Conversion Rate: None provided for Dr. Cho out of 383 office visits;
- UDS Cash Collected: $4,811.66, which matches the "Lab" collections for the month of $4,812 on the Physician Dashboard – Financial Details report for Dr. Cho;
- Average Reimbursement by Payer;
- Average Reimbursement by CPT & Payer;
- New Patients Seen with Referring Provider; and
- Patient reviews, including Overall Provider Review; Review Date, and Review Details. Dr. Cho's reviews were positive ("...by far the best doctor that ive [sic] seen..."). In contrast, Dr. Stern and Dr. Adams received poor patient reviews.

423. On February 1, 2019, Dr. Cho again received an email from BISupport@physicianpartnersoa.com attaching the "Prior Month [January 2019] Physician Dashboard Metrics." The cover email stated:

> Attached are the physician dashboard metrics from last month. These dashboards contain an excess of information and may not all be seen on your attachments. If you'd like to review your dashboard you can access them using the link below. All data is updated as of yesterday...http://prd-zap-web01/PPA/View/Public."

At the bottom, the email included the following note: "This distribution was generated by the Publication Rule: Public/Resources/Automated Reports/Monthly Physician Dashboard

Email/FL/Cho/Physician Dashboard – Cho." Again, the attachments included: Top Performing Physicians.pdf; Encounters.pdf; Financial.pdf; and Services.pdf.

424. Like the December 2018 report, PPOA's Physician Dashboard Metrics "Top Performing PPOA Physicians" Report for January 2019 included:

- Top 10 Performing PPOA Physicians for Surgical Cases;
- Top 10 Performing PPOA Physicians for Pump/Stim/Trial Cases;
- At the bottom of this report, PPOA provides the PPOA physician receiving the report with: "Your Surgical Rank," and "
- "Your Pump/Stim/Trial Rank."

425. For January 2019, the PPOA top performers were:

- Luis Nieves was ranked highest among PPOA physicians for both surgical cases (122, up from 81 in December 2018) and Pump/Stim/Trial cases (14, an increase of 7 from December 2018);
- Ronald Stern was ranked 2nd for Surgical Cases (116) and 6th for Pump/Stim/Trial Cases (6);
- Prasad Lakshminarasimhiah was ranked 4th for Surgical Cases (108, not among the top 10 in December 2018) and 3rd for Pump/Stim/Trial Cases (12, up from 8 in December 2018);
- Mauricio Orbegozo was ranked 5th for Surgical Cases (102) and tied for 1st in Pump/Stim/Trial Cases (14, up from 9 in December 2018); and
- Abraham Rivera ranked 5th (up from 8th) in 7 Pump/Stim/Trail Cases (5).

Dr. Cho on the other hand, was ranked 31st for January 2019 for surgical cases (with 15), and he failed to return any data for pump/stim/trial cases (because Dr. Cho did not perform any). Dr. Cho was earmarked by the Defendants for termination or replacement.

426. PPOA's Encounter Report detailed Dr. Cho's physician encounters with patients for the months of September 2018 through January 2019. Like the December report, PPOA compares Dr. Cho's patient visits to "PRG Average Encounters" for the same months.

427. PPOA also provided the total patient encounters for the month and patient encounters per day for Dr. Cho (each of their locations is typically staffed with one pain specialist). Both the total encounters and the encounters per day are relatively unchanged for the TPRG and FPRG locations,

except the Desoto and Fletcher locations, which increased their total encounters by about 200, and their encounters per day by three from December 2018 to January 2019. Finally, the PPOA Defendants provided the "Physician Encounters by Type" (established versus new patients) for each month.

428. The PPOA Physician Dashboard – Financial Details - Cho" report for January 2019 included:

- Daily Cash Collected, including Lab ($7,170, which corresponds with the UDS cash collections of $7,169.64), and SCS ($153). The "SCS" Column was new to the January 2019 report;
- Monthly Cash Collected,
- Top 10 Billed CPT Codes, and
- Top 10 Payers: For January 2019, the top 10 payors for Dr. Cho's patients included: Medicare; BCBS (likely includes FEHBP); Medicare Advantage; and Tricare.

429. PPOA's "Physician Dashboard – Additional Details – Cho" report for January 2019 included:

- Surgery Conversion Rate: None provided for Dr. Cho out of 377 office visits;
- UDS Cash Collected: $7,169.64, which matches the "Lab" collections for the month (discussed above);
- Average Reimbursement by Payer (including Medicare, Medicaid, Tricare, BCBS); and by CPT;
- New Patients Seen with Referring Provider; and
- Patient reviews, including Overall Provider Review; Review Date, and Review Details. Dr. Cho's reviews were positive and he received an overall provider review of five stars.

430. On March 1, 2019, Dr. Cho again received an email from BISupport@physicianpartnersoa.com attaching the "Prior Month [February 2019] Physician Dashboard Metrics." The cover email was the same as prior months. Again, the attachments included: Top Performing Physicians.pdf; Encounters.pdf; Financial.pdf; and Services.pdf.

431. Like the December 2018 and January 2019 reports, PPOA's Physician Dashboard Metrics "Top Performing PPOA Physicians" Report for February 2019 included:

- Top 10 Performing PPOA Physicians for Surgical Cases;
- Top 10 Performing PPOA Physicians for Pump/Stim/Trial Cases;
- At the bottom of this report, PPOA provides the PPOA physician receiving the report with: "Your Surgical Rank," and "
- "Your Pump/Stim/Trial Rank."

432. For February 2019, the PPOA top performers were:

- Luis Nieves was ranked highest among PPOA physicians for surgical cases (118), and ranked second for Pump/Stim/Trial cases (22, up from 14 in January 2019)
- Ronald Stern was ranked highest for Pump/Stim/Trial cases (22, up from 6 in January 2019);
- Edrick Lopez was ranked 3rd for Surgical Cases (111 – same number as January),
- Prasad Lakshminarasimhiah was ranked 4th for Surgical Cases (108 – same as January) and 4th for Pump/Stim/Trial Cases (12, same as January 2019);
- Mauricio Orbegozo was ranked 5th for Surgical Cases (103) and tied for 2nd in Pump/Stim/Trial Cases (14, same as January); and
- Abraham Rivera ranked 6th in Pump/Stim/Trail Cases (7).

Dr. Cho on the other hand, was ranked 31st again for February 2019 for surgical cases (with 15), and he failed to return any data for Pump/Stim/Trial cases (because Dr. Cho did not perform any).

433. PPOA's Encounter Report detailed Dr. Cho's physician encounters with patients for the months of October 2018 through February 2019. Like the December and January reports, PPOA compared Dr. Cho's patient visits to "PRG Average Encounters" for the same months.

434. In February 2019, PPOA provided encounter data for February only (without a comparison to January or December 2018). However, in comparing the encounters at each PPOA location to the January report, all reported locations had lower total patient encounters in February 2019 compared to January 2019.

435. The PPOA Physician Dashboard – Financial Details - Cho" report for February 2019 included:

- Daily Cash Collected, including Lab ($6,502), which corresponds with the UDS cash collections of $6,501.76), and a new "Pump" column ($394). No SCS column or data reported for February 2019;
- Monthly Cash Collected,
- Top 10 Billed CPT Codes, and

- Top 10 Payers: For January 2019, the top 10 payers for Dr. Cho's patients included: Medicare; BCBS (likely includes FEHBP); Medicare Advantage; and Tricare.

436. PPOA's "Physician Dashboard – Additional Details – Cho" report for February 2019 included:

- Surgery Conversion Rate: None provided for Dr. Cho out of 377 office visits;
- UDS Cash Collected: $6,501.76, which matches the "Lab" collections for the month (discussed above);
- Average Reimbursement by Payer (including Medicare, Medicaid, Tricare, BCBS); and by CPT;
- New Patients Seen with Referring Provider; and
- Patient reviews, including Overall Provider Review; Review Date, and Review Details.

While patient reviews for Dr. Cho were positive ("...by far the best doctor that ive [sic] seen..."), Dr. Stern and Dr. Adams, with higher procedure counts, received poor patient reviews.

437. The PPOA Defendants' focus on generating revenue through increased surgical, pump, stimulator, and trial (both stimulators and pumps) cases, without regard to medical necessity, was not limited to monthly Physician Dashboard reports. PPOA executives discussed their quest to create revenue-generating procedures constantly.

438. For example, in April of 2018, Milo told Ms. Baker that, "Dr. Ahmed did 121 procedures last month [March 2018]; Rogers did 8!"

439. When physicians failed to meet the PPOA Defendants' expectations for volume of interventional procedures, PPOA would steer their patients away from that physician to other PPOA physicians who were more amenable to PPOA's procedure requirements; these reluctant physicians faced termination and replacement by physicians who would comply with PPOA's demands. Drs. Rogers and Cho were the two lowest volume physicians for interventional procedures among those tracked by PPOA. As noted above, Dr. Cho has recently left PPOA.

### f) The PPOA Defendants Push Patients Off Maintenance Drugs for Chronic Pain in Order to Generate Revenues Through Unnecessary and Expensive Procedures

440. The PPOA Defendants also instructed their providers to stop prescribing pain medications and instead perform invasive procedures to implant pain pumps and stimulators, which generate thousands of dollars in facility charges and higher professional fees.

441. The PPOA Defendants pushed providers to perform more interventional procedures under the guise that the company is responding to the opioid epidemic. For example, during the Physicians Meeting in May 2018, Dr. Rivera discussed recent Florida opioid legislation setting limits on opioid drugs. PPOA used this legislation to segue into its mandatory UDT and DNA testing protocols, as well as mandatory highly lucrative opioid antidote and non-schedule II prescribing policies (all of which cause medically unnecessary but lucrative services to be performed by PPOA's affiliated labs and pharmacies).

442. PPOA has perversely focused on opioid abuse and legislation to deal with the opioid epidemic as a financial basis to "convert" PPOA providers from using non-invasive treatments for chronic pain (medication) to revenue-generating treatments. This message was delivered again by PPOA's CEO Dave Wood, in a January 14, 2019 email regarding the 2019 PPOA Connect Newsletter. Wood noted that PPOA Defendants orchestrated efforts to move patients to more costly invasive procedures by training PPOA physicians to perform more complex surgeries:

> Operating Room Procedural Training has been at the forefront of getting more and more of our physicians into the operating room. Dr. Rivera has taken a lead role in this training and many of our physicians are now certified in advanced levels of surgery, allowing for more interventional approaches to patient care.

Wood also discussed PPOA training "our physicians in minimally invasive sacroiliac joint fusions and laser-assisted procedures" and "[p]ivoting from opioid dependency for chronic pain treatment to interventional procedures aimed at the root cause." On that point, Wood echoed Dr. Gari's message that PPOA was focused on increasing the "conversion rate:"

> 2018: Interventional techniques training increased our office visits to procedures ordered ration from 14% in 2017 to 21% in 2018.
>
> 2019: Continued focus and training on interventional treatments should increase this ratio to over 50%.

443. The same January 2019 newsletter included other PPOA executives focusing PPOA providers on the revenues to be earned from ancillary services (testing) and surgery centers (which fuel ASC and bloated anesthesia service revenues.

(a) Josh Helms, Chief Operating Officer, describes PPOA as a "three-legged stool," including PPOA's ancillary division, physician practice division, and surgery centers.

(b) Dr Rivera, PPOA's CMA, praised PPOA efforts to train pain management specialists on interventional procedures, including laser surgery: "There is no structured training program for this anywhere in the country...We put it all together. . . After the initial training, [PPOA physicians] do a few procedures with a proctor, like me, who is there with them until they are comfortable with using it." Dr. Rivera echoed the PPOA defendants' efforts to subject patients to laser spine surgery at the hands of relative neophytes – not experienced spine surgeons.

(c) Milo, SVP of Business Development, touted the fact that Dr. St. Louis was performing spine surgery at PPOA: "Pinellas Park had never done spine at that center so it's a big success." Milo's praise for Dr. St. Louis' presence at PPOA to perform laser spine surgeries stands in stark contrast to the general opinion of the medical community, which questions the efficacy and safety of laser spine surgery in general, and Dr. St. Louis' techniques in particular. *Available at*

https://www.youtube.com/watch?v=xKjQL59UANM.

(d) Infinger, VP of Business Development, bragged that in late October 2018, PPOA acquired the practice of Richard L. Smith, MD, a retiring pain management physician. Infinger made clear that when PPOA merged with or acquired a pain management specialist's practice, their goal was to change the non-invasive treatment plans to higher revenue-generating invasive procedures. Infinger related that PPOA merged Dr. Smith's practice with the practice of Taufiq Ahmed, MD at a new Orlando location, and she boasted that PPOA had "convert[ed] a lot of the procedures Dr. Smith was doing to our interventional procedures." In fact, as illustrated above, Dr. Ahmed was among the top performers for surgical cases after he "converted" Dr. Smith's patients to expensive interventional procedures.

(e) Infinger also made clear that PPOA's strategy was to use the patients of their pain management physicians to fuel referrals and related lucrative revenues from claims for laser spine surgery performed by Dr. St. Louis and newly-trained providers who are not spine surgeons by training): "Dr. Gari is passionate about introducing the medical pavilion model: PPOA specialties and ancillary services under one roof." PPOA is "hoping to capture some of the underserved spine market there" and "get Dr. St. Louis...to go there and utilize some of the **internal referrals** . . ." (emphasis added).

444. The PPOA Defendants target lucrative Medicare referrals in particular. David Wood, Chief Experience Officer (CXO), also stated in the PPOA Connect Newsletter of January 2019:

> In January 2018, PPOA launched its Minimally Invasive Spine Group and began offering laser spine procedures. Dr. James St. Louis, surgical founder of Laser Spine Institute, was named director of the program . . . Dr. St. Louis has been busy putting on public seminars across Florida, specifically in retirement communities. **A big draw for this population is PPOA's acceptance of Medicare for laser spine**

> **procedures**, which keeps it affordable for many seniors. (emphasis added).

Wood boasted that PPOA's efforts to feed patient referrals from PPOA pain management practices to Dr. St. Louis had resulted in over 500 spine surgeries being performed between January and November of 2018 alone.

445. PPOA's software, Integrity (the result of a switch from Greenway (PrimeSuite) in late 2017 until completed in late October 2018), includes a Flowsheet "or accurate Pain Protocol tracking." The software and hardware upgrades by PPOA were directed by PPOA IT Project Manager, Nicole Vliet, and were focused on:

- Increasing interventional approach to patient care; and
- "getting more and more of our physicians into the operating room."

446. The PPOA Defendants pressure their providers to perform invasive procedures which also involve increased post-surgical pain. For example, Dr. Rivera mentioned both increased pain and prescribing opiates for surgical patients in Slides 92 and 93 of the PowerPoint from the May 2018 PPOA Physicians Meeting. Also, subjecting a patient with chronic pain to a surgical procedure does not ensure that patients will be free of pain medication in the future and inherently carries with it risks.

447. PPOA patients have complained publicly that they were taken off their prescription medication in order to force them to undergo expensive interventional procedures for pain relief.

### g) Unnecessary "Diagnostic Knee Arthroscopy" Procedures

448. One particularly insidious scheme by the PPOA Defendants was their directive to create the opportunity to bill for diagnostic knee arthroscopy procedures in place of simple knee injections performed in the provider's office for which PPOA was not able to obtain reimbursement through its ASC (but which would be reimbursed if performed in different

environments). Rather than performing the simple office procedures (which would need to occur outside PPOA's ASC), PPOA endeavored to keep their patients needlessly captive within the PPOA referral structure to capture fraudulent ASC revenues by instructing providers to perform what PPOA executives called "diagnostic knee arthroscopies."

449. On January 23, 2019, Dr. Rivera communicated this in an internal email regarding "Procedures at ASC that we will not be supporting:"

> There is [sic] a number of procedures that are being booked at the ASC with zero or no reimbursement. As much as we want to help some of these patients, the reality is that these procedures need to be done on [sic] a different environment. With few exceptions, these procedures will not be supported at any of our ASC's:
>
> 1) Bilateral procedures, with few exceptions.
>
> 2) Intraarticular joint injections. Exception, SI joint injection for diagnostic purposes.
>
> 3) Sacral radiofrequency ablation.
>
> 4) Genicular nerve blocks or RFA.

450. In response, Eric Shelton, a mid-level provider (PA) for PPOA, replied: "Are we still ordering MBB bilateral x2?" Dr. Rivera responded: "The plan is to get you an office suite to enable these procedures." Dr. Rivera then explains that because "nothing bilateral is reimbursed by just about any carrier," the providers on the email should instead perform a "viscoelastic supplementation (Hyalgen, synvisc, etc.)." Dr. Rivera directed the PPOA physicians to: "write a [sic] Rx, have the patient fill it at Walgreens...**Then the patient comes back with the drug and we book him for Diagnostic knee arthroscopy. We do the arthroscopy with our new nifty little IntraVu cameras and wash the knee then inject the joint with Hyalgen or equivalent**." Dr. Rivera continued: "Sacral RFA simply cannot be supported. Book for sacroiliac fusion. Takes 10 minutes, much better outcomes; fully reimbursed...**Genicular RFA, not reimbursed convert**

**to diagnostic arthroscopy** when appropriate."

451. IntraVu is a company that manufactures and markets. This minimally-invasive technology allows for quick, easy, and direct visualization on interior spaces. It is ideal for a multitude of current procedures as well as optically guided injections, with numerous additional application possibilities in regenerative medicine.

452. In 2018, PPOA began piloting IntraVU's endoscopic camera. In light of PPOA's strategy to use this device to fraudulently generate higher reimbursements for joint injections by fraudulently converting them to "diagnostic arthroscopy." The camera is called "MIDASVu."

453. MIDASVu is an 18-gauge needle with an endoscopic camera attached to the tip, created by IntraVu Medical, Inc. of California.

454. On its website, PPOA represents that the company is using the IntraVu camera to resolve "An age-old problem with some types of joint surgery isn't one that patients hear much about: for the surgeon, finding the target area isn't always precise." Available at https://www.physicianpartnersofamerica.com/health-news/ppoa-pilots-endoscopic-camera/ In reality, PPOA's aim was and is pure greed.

455. PPOA falsely represented to payors and patients that patients would be receiving "diagnostic" arthroscopic surgery. In keeping with their strategy to illegally maximize the PPOA revenue per patient (from all sources, particularly ancillaries) and to deceive patients, PPOA would administer anesthesia so that the patient would not be aware that they and their insurer (or the Government) was being charged for expensive arthroscopic surgery, when all the patient received was an injection.

456. Dr. Rivera was directing the PPOA physicians who had determined that patients needed only a simple knee joint injection, CPT Code 20610 (Medicare reimbursement $27.34), to

instead treat these patients as if they required a diagnostic knee arthroscopy, using the CPT code 29870 (Medicare reimbursement $1,191.94).

457. None of the providers on the email are orthopedic specialists. All are pain management, anesthesia, or rehab providers.

458. As a result of PPOA's policies for interventional procedure metrics, physicians at PPOA's pain facilities are coerced to perform thousands of unnecessary interventional procedures, which result in the submission of claims to Medicare, Medicaid, Tricare, and other Government programs for these medically unnecessary procedures.

459. PPOA leaders continue to pressure PPOA providers to discontinue oral medications and other conservative non-interventional care in order to generate revenues through procedures performed at PPOA's ASCs.

**h) PPOA Pushes Pain Management Physicians to Commit Healthcare "Robbery" Through Medically Unnecessary Sacro-Iliac Joint Fusion**

460. Conventional treatment pain related to an unstable sacro-iliac (SI) joint is to perform an injection. If that fails, then radiofrequency (RFA). Patients who get relief from these procedures can be pain free for 6-12 months.

461. If patients don't respond to these treatments, the, if indicated, the physician can recommend SI fusion, which involves stabilizing the SI joint with a titanium rod and screws. This is an invasive procedure. As traditional SI fusion requires invasive surgery to insert screws in the pelvis, and requires the skill of an orthopedic surgeon. Pain specialists do not perform SI fusions.

462. The SI fusion advocated by PPOA involves drilling a small hole and filling it with a biometric joint fusion material. It replaces traditional screws with a compound inserted in the SI space. PPOA wanted to maximize their revenue per patient by using their pain specialists, with little experience or training, to maximize revenue through unnecessary SI fusions.

463. In 2018, PPOA started pushing pain specialists to perform SI fusion for patients with lower back pain regardless of whether more conventional treatments are appropriate.

464. PPOA set about trying to get pain specialists to perform these SI fusion procedures purely for the higher reimbursement, and without regard to medical necessity. PPOA instructed physicians to stop using the conservative measures for pain related to unstable SI joints, and move immediately to spinal fusion.

465. Dr. Rivera even told Dr. Cho that any pain specialist, even those not specifically trained on the new technique, could perform SI fusions. Through Dr. Rivera, PPOA did conduct a cadaver lab in Tampa to train pain specialists on their preferred SI fusion procedure.

466. PPOA knew that its' program to subject unsuspecting patients, who could benefit from more conservative treatments, to SI fusion as a money maker was illegal. In October or November 2018, while at dinner in a Tampa restaurant attended by Dr. Cho, Dr. Rivera, Dr. Fernandez, and Dr. Leal, Dr. Rivera discussed PPOA's revenue-focused simple SI joint fusion strategy. Referring to the PainTEQ LinQ SI joint fusion, Dr. Rivera stressed that PPOA was paid the same reimbursement as traditional spinal fusion. Dr. Rivera, proudly showing those at dinner a photo on his phone depicting reimbursement check for $100,500, gloated: "You should be earning this money, like a robbery."

467. On or about February 12, 2019, while in PPOA's Merritt Island clinic, Dr. Cho met Jim Wall. Wall introduced himself as a representative of PainTEQ, a company that makes the biometric material used in the SI fusion being pushed by PPOA. Wall provided Dr. Cho with his mobile number: 813-758-0319.

468. Mr. Wall was a DME supplier, with NPI number 1013158831, which was registered in March 2009. His mailing address is 6706 SEA ROBIN PL, TAMPA, FL 33615-2548. Available

at http://www.hipaaspace.com/medical_billing/coding/national_provider_identifier/codes/npi_1013158831.aspx.

469. PainTEQ is headquartered at 3300 Henderson Blvd., Ste. 106, Tampa, FL.

470. PainTEQ manufactures a number of products tied to PPOA's scheme to maximize their profit per patient through unnecessary invasive procedures: AXLE (an interspinous process plate featured at PPOA's 2018 physician retreats) and LinQ, the SI joint fusion material referenced above. Information on AXLE is available at http://painteq.com/#1464622632018-c22679d3-ae55 and information related to LinQ is available at http://painteq.com/#1464623057260-391bf6ad-644d.

471. PainTEQ advertises that its products are "insurance and Medicare approved," and that the company: "provides coding, billing, authorization, and reimbursement support to our physicians and their offices." http://painteq.com/#1464623057260-391bf6ad-644d.

**i) <u>False Claims for Standing Order Psychological Testing</u>**

472. PPOA also implemented an illegal scheme to perform unnecessary claims for psychological testing for all patients. These patients, of course, are seeing these physicians for physical ailments and pain control, not mental health services. The purported reason was to determine if patients were at risk for addiction, depression, or suicide.

473. While in rare cases, a psychological test may be appropriate for a patient with chronic pain or similar maladies, they are wholly inappropriate and unnecessary in the vast majority of such cases.

474. PPOA's contracts with physicians stated that psychological testing was to be **"done on every visit."** (emphasis added). PPOA's mandate was in keeping with its strategy to maximize the revenue per patient.

475. Ignoring medical necessity, PPOA simply handed patients a tablet computer to fill out a useless psychological test, a test which rarely, if ever, is considered by the physician. PPOA then billed Government healthcare programs and private insurers under CPT Code 96103.

476. Prior to January 1, 2019, the PPOA Defendants billed insurers, including Government insurers, for their psychological testing under CPT Code 96103. Following January 1, 2019, changes to the psychological testing CPT Codes, on information and belief, PPOA billed (and continues to bill) insurers for such services for the test.

477. The PPOA Defendants knew or should have known that the type of "psychological testing" PPOA was performing was not reimbursable by public or private payors.

478. Government healthcare programs and private payors only reimburse for certain psychological testing that is medically necessary. PPOA's blanket requirement that all patients take a psychological test is not just inconsistent with medical necessity generally, but also at odds with explicit Medicare requirements concerning psychological tests.

479. Local Coverage Determination L34520 (applicable to Florida) sets out that such testing is not reasonable and necessary when "performed when abnormalities of brain or mental function are not suspected.... Testing conduced when no mental illness/disability is suspected would be considered screening and would not be covered."

480. Local Coverage Determination L35101 (applicable to Texas) includes similar mandates. *E.g.,* L35101 ("Testing conducted when no mental illness/disability is suspected would be considered screening and would not be covered by Medicare.").

481. Moreover, while the tests performed by PPOA were simple tablet computer tests which would take just minutes to complete and which the software itself scores, the sorts of tests expected by Medicare as separately reimbursable are far more extensive. *See* L35101 ("Brief

screening measures such as the Folstein Mini-Mental Status Exam or use of other mental status exams in isolation should not be classified separately as psychological or neuropsychological testing, since they are typically part of a more general clinical exam or interview."); L34520 ("Typically, psychological testing/neuropsychological testing may require four (4) to six (6) hours to perform (including administration, scoring, and interpretation).")

482. PPOA's psychological testing protocol is no more than another way that PPOA seeks to needlessly run up the bill for Medicare, Medicaid, other Government insurers, and private payors.

483. The vendor used by PPOA to provide the tablet-based psychological testing is assessURhealth, LLC, a Tampa, FL-based business owned and operated by Mallory Tai Taylor.

484. Taylor, cofounder, President, and COO of assessURhealth was named a finalist for EY's Entrepreneur of the Year Award in Florida.

485. Taylor's business strategy, as reflected in her marketing materials, is to entice medical practices to use the tablet-based psychological tests as a source of revenues, a strategy embraced by the PPOA Defendant.

486. The website for PPOA's vendor, assessURhealth, trumpets the revenue potential of tablet-based psychological testing to attract customers:

- "Increase ROI while gaining valuable patient health data and reducing staff resources;"
- Increase ROI… See a clear return on investment almost immediately."

Like PPOA, this tablet test vendor also touts its product as screening for "multiple mental & behavioral health categories, including:…Opioid Risk." https://assessurhealth.com/our-solution/.

487. Rather than a robust psychological assessment performed by a qualified

professional, assessURhealth's tablet-based questionnaire is nothing more than a "less than five-minute assessment in [sic] waiting room or exam room." https://assessurhealth.com/our-solution/

488. assessURhealth's website repeats the revenue potential, next to images of money bags, stating that: "providers can make more than $50,000 per year, per provider with assessURhealth." https://assessurhealth.com/tag/reporting/.

489. PPOA providers knew that there was no medical necessity for the iPad tablet tests. These screenings were never used by pain management providers to provide pain relief for their patients. Instead, pain management professionals assess their patients (who are not at PPOA for treatment for mental health issues or drug abuse).

490. Patients are also harmed by PPOA's psychological testing fraud. Dr. Cho has observed that PPOA charges a copay every time the iPad test is administered.

491. PPOA used a tablet-based (Ipad) psychological test marketed by Psych Testing.

492. On information and belief, PPOA and its Defendant executives and owners were aware of the fact that these tests were medically unnecessary. After all, PPOA operates a medical chain focused on pain management and surgical intervention, areas far afield from that of psychology.

493. This is clear from communications, between Ms. Baker and PPOA executives, including Dr. Gari, who would occasionally discuss hiring psychiatrists, who specialize in addiction. PPOA, however, only briefly employed a PhD in Dallas to provide counselling.

### j) Unnecessary Pharmacy Services

494. The Pharmacy Defendants (Patient Rx and Stonebriar) are wholly owned subsidiaries of the PPOA Defendants. The Pharmacy Defendants began operations in Texas in 2014 after the PPOA Defendants established the Texas Pain Relief Group.

495. The Pharmacy Defendants, on information and belief, were established to receive referrals from PPOA-affiliated physicians. For example, Stonebriar is affiliated with the PPOA Defendants and began operations in Texas in 2014. Defendant Pharmacy Rx Solutions is also affiliated with the PPOA Defendants and began their operations in Florida in 2016. After establishing pain management practices in Florida in 2016, the Defendants opened their Merritt Island-Patient Rx location.

496. The Pharmacy Defendants dispense only "non-controlled" substances, including topicals and expensive compounded medications "not typically available at local pharmacies." There is one exception to this practice (set forth below). PPOA's pharmacies dispense Primlev, a highly expensive formulation of oxycodone which is only medically necessary in a remarkably small number of cases.

497. The PPOA Defendants direct their pain management and other physicians to refer all of their patients' non-opioid prescriptions to the Pharmacy Defendants for expensive compounds and topical creams, but make clear that, while the "preferred pharmacy should be based on the best interest of the patient, it is good medical practice to utilize one pharmacy for all controlled substances while a different pharmacy can be utilized for non-controlled substances."

498. The PPOA Defendants' "clinical protocols" then direct the physicians to use local pharmacies for opiates, but use the PPOA "affiliate pharmacy" for "non-opiate meds."

499. Each agreement signed by a PPOA pain management physicians contains the clause that "[t]he employee physician agrees to refer patients to those ancillary businesses, including facilities, designated in writing or verbally by the Employer to the Employee from time to time subject to applicable laws." Dr. Dangaria and Dr. Rogers have reported to Ms. Baker that PPOA benefits from lucrative referrals to the PPOA-affiliated pharmacies.

500. Before joining PPOA, the pain management physicians did not typically prescribe compounds or topical creams for the treatment of pain. These medications were dispensed out of a mail order pharmacy in Texas, shipped to Florida, then mailed again from Florida.

501. PPOA's prescription policies were continually repeated and strictly enforced.

502. For example, in May 2018, during PPOA's Annual Physicians' Meetings in Florida and Texas, Dr. Rivera, the CMO, delivered the discussion of the PPOA's "Clinical Protocols: Urine Drug Testing; DNA; Pharmacogenomics; Opioid Prescribing."

503. At Slide 33 of the presentation, Dr. Rivera discusses "Wise Things We Have Implemented:"

- "Every patient RX an opiate has to be in a risk assessment and drug abuse monitoring program...risk assessment questionnaire...psych eval ...Urine drug testing...ABD monitoring and reconciliation;"
- "Every patient Rx an opiate get [sic] a [sic] Rx for antidote [*e.g.,* Evzio];"
- Every patient Rx an opiate has to be given a controlled substance prescription agreement...Example: 2 Non-controlled for every 1 controlled...Oxy 10/325 #120 with Lidocaine 5% topical, Diclofenac 3% topical."

504. Each of these policies was implemented to generate fraudulent revenues for PPOA through their ancillary businesses. They were not the standard of care, and were not required by law or any medically accepted protocol.

505. For example, although PPOA mentions risk assessment and psychological evaluations by the provider in determining the drug abuse monitoring programs for patients, its real focus was to push mandatory drug testing to benefit PPOA's wholly-owned UDT labs.

k) **Evzio**

506. In addition, the PPOA policy requiring providers who prescribed an opiate to prescribe an antidote, is related to PPOA's ability to dispense the antidote from their wholly-owned pharmacies. PPOA carefully tracked prescriptions by PPOA-affiliated providers for a particular opioid antidote, Evzio.

507. It is also particularly expensive. Although the price may have fluctuated during the relevant time period, a U.S. Senate report in November 2018 explained that: **"[t]he Medicare program was paying an average of $3,522 per EVZIO unit with Medicaid paying an average of $2,412.** At the same time, the commercial plans were only paying an average of $367 per EVZIO. Government health care programs were subsidizing the broader distribution of EVZIO." *Combatting the Opioid Crisis: the Price Increase of an Opioid Overdose Reversal Drug and the Cost to the U.S. Health Care System,* Staff Report, Permanent Subcommittee on Investigations, United States Senate, Nov. 2018, p. 5, *available at* https://www.portman.senate.gov/sites/default/files/Naloxone%20Report%20Final%20with%20Annex.pdf.

508. Relators believe that PPOA had a financial relationship with the manufacturer or marketer of this expensive drug.

509. Evzio is manufactured by Kaléo, a privately-held pharmaceutical company. Spencer Williamson is the President and CEO of Kaléo.

510. Evzio is the only FDA-approved naloxone auto-injector with voice and visual guidance that talks the user step by step through the administration of naloxone to reverse the effects of an opioid overdose. An inexpensive spray would provide the same protection to the patient.

511. PPOA claims on its website that, rather than promoting brand name EVZIO, the

company instead dispenses the less expensive version of naxolone, Narcan Nasal Spray, for more than a decade: "PPOA has written prescriptions for naloxone with every opioid prescription since 2004. Even though the medication can be free or low-cost with insurance, PPOA has discovered many patients refuse prescriptions for the antidote when they pick up their pain medication prescription." *Available at* https://www.physicianpartnersofamerica.com/health-news/surgeon-general-and-ppoa-recommend-naloxone-for-pain-patients/.

512. Of note, PPOA did not even exist in 2004.

513. Samantha Dangler, Vice president of Operations – Ancillary Division for PPOA is quoted on the PPOA website: "They feel they don't need it. As pharmacists, we try our best to stress the importance of having naloxone in the home while on opiate therapy. Dangler continued: "With the opioid crisis at an all-time high, it is imperative that when a physician writes a prescription for an opiate and an antidote, that the patient follows through and fills the prescription for the antidote." Available at https://www.physicianpartnersofamerica.com/health-news/surgeon-general-and-ppoa-recommend-naloxone-for-pain-patients/.

514. Contrary to their website, the PPOA Defendants pressure their providers to write prescriptions for brand name EVZIO alone, and that is the only opioid antidote that counts toward meeting PPOA's pharmacy utilization metrics.

515. PPOA's requirement that providers prescribe an antidote drug (Evzio) on a systematic basis does not make sense. PPOA's professed goal is to implement clinical guidelines (including genetic testing, UTOX, etc.) to reduce or even eliminate opioid abuse, and they conduct drug screens to ensure appropriate use of prescribed opioid use, all of which would render overdose only minimally likely for a large subset of their patients. PPOA's requirement that their providers write a prescription for a brand name overdose drug (as opposed to naloxone in a standard and inexpensive delivery

system) for EVERY patient is clearly excessive and not medically necessary.

516. The PPOA defendants instituted the mandatory overdose drug prescription policy and pressured prescribers to send these prescriptions for EVZIO to their affiliated pharmacies in order to benefit from the dispensing of unnecessary and expensive name brand prescriptions.

**l) Primlev**

517. The PPOA Defendants also tracked prescriptions for Primlev, a branded oxycodone-acetaminophen medication, which is typically prescribed as 5mg/300 mg or 10mg/300mg. Typical dosing is 3 to 4 times per day.

518. Primlev is manufactured, marketed and distributed by Akrimax Pharmaceuticals, LLC, based in Cranford, New Jersey. There is no generic version of Primlev.

519. Primlev is far more expensive than generic oxycodone-acetaminophen 5mg/325mg or 10mg/325mg (which differs only from Primlev in terms of the Acetaminophen component, 300mg versus 325mg). For example, Primlev #90 tablets cost $1,703 as opposed to $40 to $90 for a generic oxycodone-acetaminophen drug.

520. Primlev is rarely medically necessary. Its only substantial difference from the majority of oxycodone drugs (which are available in cheap, generic form) is that it has a slightly lower acetaminophen content (meaning that for those on exceptionally high opioid doses, a slightly lower acetaminophen dose may reduce the risk of liver damage). The current FDA recommendation is a maximum of 4,000 mg/day for acetaminophen. Thus, unless the patient takes more than 12/day (325 mgx12) of the generic version, there is no benefit from the branded Primlev (300mgx12).

521. Yet, Primlev is rarely necessary for most pain patients and its use is particularly improper at PPOA, where PPOA's stated protocol is to ensure that patients are *not on high opioid*

*doses* (*i.e.*, such patients would, invariably, have *no use* for Primlev).

522. Defendants' affiliated pharmacies perform all insurance pre-authorizations, so PPOA physicians and their staff are spared the time and resources of getting approvals for prescriptions dispensed by PPOA's pharmacy affiliates.

523. PPOA's pharmacy affiliates also advertise that they charge very low copays if the prescription is covered by insurance. The Primlev copayments for Medicare beneficiaries range from $15-106.

524. During 2017, Dr. Cho met the local sales representative for Primlev, a young woman, at PPOA's Winter Haven practice. Dr. Medina-Sanchez seemed to know her, and Dr. Cho heard that she (the Primlev sales representative) is the daughter of a physician who has a relationship with PPOA.

525. Like Medtronic, Primlev has provided inducements to PPOA. In particular, Primlev frequently sponsored PPOA dinner meetings held at Tampa-area restaurants.

526. PPOA-affiliated pharmacies dispense Primlev and the PPOA providers are tracked for the percentage of Primlev prescriptions they send to PPOA pharmacy affiliates.

**m) PPOA's 3:1 Ratio of Opioids to Non-Opioids Fuels Their Pharmacy Affiliates**

527. The PPOA Defendants' prescribing policy mandated that for every opioid prescribed, PPOA providers must also prescribe two non-opioid prescriptions. The PPOA defendants expected that these non-opioid prescriptions would be obtained from their wholly-owned pharmacies.

528. The non-controlled prescriptions listed as examples by Dr. Rivera on Slide 33 (above) are the very type of compounded prescriptions advertised as dispensed by the PPOA-affiliated pharmacies, Defendants Patient Rx and Stonebriar Defendants ("compounding and other

topical prescription pain medications"). The PPOA Defendants also touted their mail order "delivery services related to these prescription services."

529. During the 2018 PPOA Annual Physicians' Meetings in Florida and Texas, Samantha Dangler, PPOA Vice President, Sales & Operations – Ancillary Division, reiterated PPOA's expectations that providers prescribe multiple medications for each patient to be provided by PPOA's wholly-owned pharmacies.

530. As discussed below, the 3:1 ratio discussed by Dr. Rivera and Ms. Dangler was borne out of PPOA's efforts to fraudulently obtain referrals of prescriptions for predominantly compounded medications to be dispensed and billed by PPOA affiliated pharmacies.

531. Ms. Dangler had extensive experience in compounding. In addition to her position as Vice President of PPOA's Sales & Operations – Ancillary Division, since 2011, Dangler has also held the position of Vice President and Managing Partner at ROI Nutrition and Consulting. From 2013 to 2014, Dangler was also the Vice President of Sales at Wells Pharmacy Network, a national provider of compounded medications. She was also the CEO of Journey Medical Solutions, LLC from at least May 2015 until August 2017, a company which employed a sales force to sell physicians on compound medications (and other "ancillary" services) for third party compounding pharmacies and other entities.

532. At Slide 174, Dangler discussed PPOA's "Pharmacy Ratios:" "Controlled ratios for the pharmacy remain 1:3." She repeated PPOA's expectations and reiterated remarks made earlier that day by Dr. Rivera: that if an opioid was prescribed, the PPOA physician was expected to write a prescription for two additional medications that were not controlled substances.

533. At Slide 174, Dangler included a quote credited to Dr. Rivera, PPOA's CMO: "we believe that a typical pain management pharmacologic regime should address in a balanced

formulary the nociceptive, neuropathic, and musculoskeletal components of the pain. The sleep disorder, and even muscle spasms may also be addressed and certainly an opioid reversal agent should be included."

534. The PPOA prescribing policy, requiring their physicians prescribing a controlled substance to also prescribe 2 (or more) non-controlled substances to be dispensed to the patient, is a thinly veiled attempt to generate revenues for PPOA's wholly-owned pharmacies through unnecessary "pain topical" (compounded) prescriptions.

535. Contrary to PPOA's purported support for a "balanced" formulary, their policies and procedures were focused entirely on maximizing PPOA's "Best Practices" for pain specialists include: 1) using PPOA's affiliated pharmacies as the "preferred" pharmacy; 2) "split scripts," where prescriptions for "Greenway Favorites" are sent to PPOA's pharmacies. PPOA positions this as affiliated pharmacies "cater to the group" and "ensure Greenway Favorites" are stocked. PPOA references narcotics being filled "same day" and topicals being received "via free shipping," and 3) PPOA pharmacies are the default pharmacies, which require providers to "go back in and change the pharmacy" to use an independent pharmacy for revenues from each PPOA patient.

536. For example, PPOA's "Affiliate Pharmacies 101" materials devote an entire page to PPOA's "Greenway Medication Favorites." The reference to "Greenway" relates to PPOA's software. A physician using the Eprescribe method (PPOA physicians are tracked and expected to use this for 100% of prescriptions), will have limited options. PPOA programmed the Greenway software to have a limited drop-down menu based on medications carried by PPOA's affiliated pharmacies.

537. PPOA's "Greenway Favorites" included:

- MACPatch PAD .0375-5%

- Lidotral Cream 3.88%
- Lidovex Cream 3.75%
- Diclofenac Gel 3%
- Medi-10 Cap
- Lidopril Kit 2.5 – 2.5%
- Lidocaine Ointment 5%
- Evzio 2/04 ML Injector
- Pennsaid Solution 2%
- Lidocaine Pad 5%
- Diclofenac Gel 1%

538. PPOA touted its routing providers to their affiliated pharmacies as:

- "Frequently used by your peers in the group (seeing results);
- Easy of [sic] use (don't have to search through the global menu);
- "Up to 5 refills;" and
- May be used concurrent [sic] with narcotics."

539. In its mid-2017 era, "Affiliate Pharmacies 101" materials, PPOA demonstrated its real time monitoring the number and "ratio" of prescriptions written (sent) versus "filled at affiliate Dr. Rivera and Dr. Dorothy Ibasco, Jose Medina-Sanchez, and Jorge Leal were utilizing PPOA's pharmacies satisfactorily, as reflected in their ratio columns being colored green. Other providers were newer to PPOA, and thus their prescriptions were not included in PPOA's data for "Affiliate Rx's by Provider March vs. April (Projected at Current Rate).

540. Dr. Cho thwarted PPOA's efforts to generate unnecessary expenses for patients and fraudulent revenues for the PPOA Defendants by writing prescriptions for reasonable (and

affordable) medications that would actually assist the patients in their pain management, including Vitamin B and laxatives.

541. The PPOA Defendants carefully and systematically monitored (and continue to monitor) their physicians' adherence to this policy. One such means is the "Pharmacy Utilization Report" issued by the PPOA Defendants at least monthly.

542. On April 10, 2018, Dr. Cho received the PPOA March 2018 Pharmacy Utilization Report. The cover email from Abigail Francis, PPOA's Affiliate Pharmacy Liaison, to Dr. Cho, which was cc'd to Rayza Reyes, stated: Below you will find pharmacy utilization numbers for the month of March. We truly appreciate you giving us the opportunity to help round out a wonderful patient experience. We are continually working hard to meet and exceed patient and provider expectations so readily welcome all feedback...You will notice more columns on the spreadsheet below compared to previous months. The Business Intelligence team is constantly pulling more data to give all of us even more transparency into these metrics...

543. The attached March 2018 - Pharmacy Utilization Report included the following columns: Standardized name [for all prescribers, including 17 physicians and 9 Mid-Level providers]; provider category (Physician or Mid-Level); # of Rx sent; # Sent to Affiliate Pharmacy; % sent to Affiliate Pharmacy; # of Non-C2s; # of C2's; % C2s sent to Affiliate Pharmacy; Ratio Non-C2 to C2; # Pain Topical Sent; % Pain Topical to Affiliate Pharmacy; # Evzio; % Evzio to Affiliate; # Primlev sent; % Primlev to Affiliate; % of Rx E-Scribe.

544. PPOA carefully tracks revenues from its important ancillary pharmacy business.

545. In the monthly Pharmacy Utilization Report for March 2018, the PPOA Defendants tracked and reported the data related to ALL prescriptions written by PPOA-affiliated providers, including:

- the number and percentage of prescriptions each PPOA provider (both physicians and mid-level providers) sent to PPOA-affiliated pharmacies (so that the Defendants could bill Government-sponsored healthcare programs and private insurers for these prescriptions);

- the number and percentage of topical pain prescriptions sent to PPOA-affiliated pharmacies;

- the number and percentage of Evzio prescriptions sent to PPOA-affiliate pharmacies.

546. Although the names of the providers are not visible for anyone other than Dr. Cho, there are physicians and mid-level providers who capitulated to PPOA's prescribing demands, including:

- The 9th provider on the list (a physician) sent 12% of their total prescriptions and 71% of the 205 pain topical prescriptions, and 83% of Evzio and 100% of Primlev prescriptions to PPOA's affiliated pharmacies;

- The 24th provider listed (a Mid-level) sent 86% of their 1066 total prescriptions and 98% of the 659 pain topical prescriptions, and 100% of Evzio prescriptions to PPOA's affiliated pharmacies; and

- The 25th provider listed (a Physician) sent 74% of their total 709 prescriptions and 86% of the 499 pain topical prescriptions, and 100% of Evzio prescriptions and 96% of Primlev to PPOA's affiliated pharmacies.

547. Dr. Cho received a similar PPOA April 2018 Pharmacy Utilization Report on May 7, 2018, just days before the Annual PPOA Physicians' Meeting in Clearwater, Florida. The cover email from Ms. Francis to Drs. Cho and Lesco Rogers provided:

> Below you will find the Monthly Pharmacy Utilization Report for the month of April…Please note the fields in RED can be seen as areas of opportunity. As the colors shade from orange to yellow to green, those numbers that lean towards favorable in regards to CDC guidelines, PPOA initiatives, and pharmacy/prescribing regulations…**The column labeled **"Ration [sic] non C2 to C2"** is increasingly important to watch moving forward. This column shows the number of NON C2s prescribed for every 1 C2. The ideal number for this column would [sic] 3 and greater, as a ratio of 3 non C2s for every 1 C2 is the target. If the column begins with a 0, that means that more C2s were prescribed than non C2s. If you have any questions regarding your

specific numbers please let me know.

548. The attached Monthly Pharmacy Utilization Report – April – Winter Haven included the following columns: Standardized name [for all prescribers, including 19 physicians and 11 Mid-Level providers]; provider category (Physician or Mid-Level); NPI State; # of Rx sent; # Sent to Affiliate Pharmacy; % sent to affiliate pharmacy; # of Non-C2s; # of C2's; % C2s sent to Affiliate Pharmacy; Ratio Non-C2 to C2; # Pain Topical Sent; % Pain Topical to Affiliate Pharmacy; # Evzio; % Evzio to Affiliate; # Primlev sent; % Primlev to Affiliate; % of Rx E-Scribe.

549. Most (but not all) of the providers on the report used electronic prescribing at least 90% of the time. PPOA's ability to track exact percentages of electronic prescribing (E-Scribe) versus paper prescriptions shows the Defendants' effort to track and report prescribing habits in order to pressure providers to provide unnecessary prescriptions to their patients and to order these scripts electronically through PPOA-affiliated pharmacies.

550. Dr. Cho was singled out by PPOA and its affiliated pharmacies for April 2018 prescribing because, although his ratio of Non-C2 to C2 was 3.6 (exceeding PPOA's official recommendation), he sent only 1% of his prescriptions to PPOA-affiliated pharmacies, and 0% of "pain topicals" (*i.e.*, compounded creams) to PPOA-affiliated pharmacies.

551. Dr. Rogers was similarly singled out by PPOA and its affiliated pharmacies for April 2018 prescribing because, although his ratio of Non-C2 to C2 was 4.4 (exceeding PPOA's official recommendation), he sent 0% of his prescriptions to PPOA-affiliated pharmacies.

552. Although the names of the providers are not visible for anyone other than Drs. Cho and Rogers, there are physicians and mid-levels who adhered to PPOA's prescribing demands, including:

- The fourth provider on the list (a physician) sent 19% of his total prescriptions and 73% of the 115 pain topical prescriptions, and 100% of Evzio and Primlev

prescriptions to PPOA's affiliated pharmacies;

- The seventh provider listed (a physician) sent 10% of his total prescriptions and 80% of the 45 pain topical prescriptions, and 98% of Evzio and 100% of Primlev prescriptions to PPOA's affiliated pharmacies; and
- The 26th provider listed (a Mid-level) sent 63% of their total prescriptions and 92% of the 238 pain topical prescriptions, and 100% of Evzio prescriptions to PPOA's affiliated pharmacies.

553. The PPOA Defendants' corporate practice of requiring referrals to the PPOA pharmacies has resulted in extreme over-utilization of Government-funded healthcare program resources related to the over-prescribing of medically unnecessary compounds and topical creams, EVZIO prescriptions, and the expensive brand name pain medication, Primlev.

554. PPOA's conduct resulted in claims being submitted by the Pharmacy Defendants to Government healthcare programs (including Medicare, Tricare, Medicaid, etc.), which violated federal and state AKS and the Stark Laws. Since establishing the Texas PPOA Pharmacy (Stonebriar) in 2014, and then expanding in 2016 to Florida with Patient Rx, the primary (if not sole) source of referrals to the Pharmacy Defendants has been physician practices owned, operated, and/or controlled by the PPOA Defendants.

555. The PPOA Defendants created fraud schemes that resulted in thousands of referrals for compounding services to the Defendants' PPOA Pharmacies of patients treated by the physicians or mid-level providers, including pain specialists, who are employed by or affiliated with PPOA's subsidiaries and practice at PPOA locations throughout the United States.

556. Drs. Dangaria and Rogers have also reported that Dr. Rivera, PPOA's CMO, oversees compliance with PPOA corporate policies on referrals to the Defendants' affiliates and that he (Rivera) makes phone calls and sends text messages personally to physicians to compel adherence to PPOA's physician metrics.

557. For example, Dr. Rogers has received numerous emails and text messages from

Defendant Milo regarding the Defendants' practices.

**n) Unnecessary CRNA Services**

558. The PPOA Employment Agreement, Attachment C – Florida Pain Relief Group ("Employee") Clinical Protocols Overview, makes clear that PPOA was "the service of Anesthesia for all patients undergoing interventional procedures at either the ASC or procedure room."

559. PPOA's subsidiaries that provide anesthesia services include PPOA CRNA OPS and PPOA CRNA Holdings, who employ the personnel who actually provide "the service of Anesthesia."

560. For every procedure performed by a PPOA physician, whether in the office procedure room, or at the ASC, the Defendants' related CRNA entity benefits because a CRNA is present to perform and bill for the "anesthesia services."

561. The anesthesia provided may include local ("conscious") sedation, as well as general ("unconscious") anesthesia.

562. Based on Relators' experience, general anesthesia is rarely, if ever, provided for a procedure performed in an in-office setting. Thus, general anesthesia would rarely, if ever, be medically necessary for procedures performed in the Defendants' office-based procedure rooms.

563. The PPOA Defendants utilize the following personnel for their in-office procedures and ASC procedures: medical assistants, an RN, a surgeon (who is very often an anesthesiologist), and a CRNA. The CRNA is responsible for the pre-op questionnaire, intra-op notes, and handing the operative report over to the RN in recovery.

564. The Defendants instituted a policy of documenting that the CRNA provided general anesthesia services for all procedures performed in the in-office procedure room or ASC. Dr.

Rogers was present when a CRNA documented that general anesthesia was administered, when in fact conscious sedation (local anesthesia) was administered.

565. When he became aware of the false document, he confronted the CRNA. The CRNA then informed Dr. Rogers that she was following the directive of the Defendants' Vice President of Anesthesia.

566. The PPOA Defendants also submitted false claims for general anesthesia services for Dr. Cho's patients. For example, on October 23, 2018, Dr. Cho performed a procedure on Patient BB, a beneficiary of Blue Cross Blue Shield Federal Employee Program. BB received very light conscious sedation.

567. Dr. Cho recalls that Dr. Kelvin Gorrell, an anesthesiologist affiliated with the PPOA Defendants, was present at PPOA's Merritt Island in-office procedure room for each procedure that day. However, Dr. Gorrell did not administer general anesthesia to any of Dr. Cho's patients, who received nothing other than minimal conscious sedation with basic monitoring services

568. Dr. Gorrell is a member of Physician Partners of America CRNA Operations, LLC. *See* Physician Partners of America CRNA Operations LLC, *available at* https://www.healthcare4ppl.com/medical-group/florida/tampa/physician-partners-of-america-crna-operations-llc-8022239722.html.

569. When the PPOA Defendants (through PPOA CRNA) submitted the claim for anesthesia for the October 23, 2018 procedure to the Federal Employee Health Benefits program (FEHBP) for Patient BB, they falsely charged $6,324.96, as though BB received general anesthesia services, equipment, medication, and extensive monitoring was provided, In fact, she received minimal conscious sedation.

570. Dr. Cho learned that the PPOA Defendants had submitted these false charges for

general anesthesia services for ALL patients he treated that day (October 23, 2018). Dr. Cho's patients were covered by Government healthcare programs as well as commercial insurance. All of these providers received false claims for anesthesia services, equipment, and medication.

571. During a discussion with Dawn Baker, Dr. Dangaria related that the PPOA Defendants had instructed him to falsely document every patient record to support a claim for general anesthesia, and that even if patients refused anesthesia, to put a monitor on the patient to support the PPOA Defendants' false claims for anesthesia monitoring.

572. The PPOA Defendants also falsely increased utilization of anesthesia services by closing the procedure rooms at their pain management clinics, thereby forcing providers to perform what could have been in-office procedures in PPOA's ASCs.

573. The PPOA Defendants closed these procedure rooms to both increase the facility charges for the procedures performed and to create the opportunity for the PPOA Defendants to falsely submit claims for anesthesia services that were either unnecessary or not provided.

574. For example, when Dr. Cho's clinic at Rockledge was relocated to the Merritt Island Medical Pavilion in July 2018, the PPOA Defendants built an ASC at that location and closed the procedure room at Merritt Island. This left the providers (including Dr. Cho) with no alternative but to perform all procedures in the ASC.

575. Thus, the PPOA Defendants' implemented the following fraudulent practices to generate fraudulent ASC/ANA revenues:

(a) using CRNAs for every procedure (whether in the in-office procedure room or ASC), involves both unnecessary use of anesthesia services by the CRNA, but also falsely upcoding for the type of anesthesia provided;

(b) falsely billing for general anesthesia services, equipment, and medication

where only conscious sedation was provided; and

(c) closing procedure rooms at PPOA pain clinics so that PPOA-affiliated providers were forced to perform all procedures (including those which could have been performed in an in-office procedure room) are performed in PPOA's ASC.

## VIII. DEFENDANTS HAD KNOWLEDGE OF THE ILLICIT NATURE OF THE KICKBACK SCHEMES

576. At all times relevant, Defendants knew that the compensation arrangements they offered, which included bonuses paid based on the doctor's own referrals, were inducements to the PPOA physicians. These compensation arrangements violated the federal AKS and analogous state statutes.

577. Defendants' executives offered "attractive" compensation packages to physicians across the country, which included compensation based, in part, on revenues generated by referrals of the providers' own patients for ancillary services, including UTOX, DNA tests, imaging (including MRI), laser spine surgeries, pharmacy, DME, and other PPOA-affiliated services. All compensation based on PPOA's ancillary services is contingent on the profitability and PPOA's sole discretion in making disbursements to the physicians.

578. At all times relevant to this Complaint, Defendants knew that their arrangements with physicians were thinly-veiled attempts to conceal their offer of illegal inducements to referring physicians.

579. Defendants further knew that they violated the federal Anti-Kickback Statute and analogous state Anti-Kickback laws when establishing protocols requiring that PPOA-affiliated providers refer their patients to Defendants' subsidiaries for ancillary services, including UTOX, DNA testing, imaging, pharmacy services, laser spine surgeries, transportation, and other healthcare services.

580. These actions have damaged the public and the Government payors at issue in this Complaint by inducing referrals by Defendants' affiliated physicians, including pain management specialists, to refer patients to entities with whom they have a prohibited financial relationship. For example, the Defendants' Hurst, Texas location has an MRI, the most expensive imaging test.

581. Defendants have also caused these Government payors to reimburse Defendants for unnecessary ancillary services and/or laser spine surgeries that were also tainted by these improper relationships.

### A. PPOA's Compliance Program Was Not Implemented to Prevent Fraud, Waste and Abuse Related to Unnecessary Services

582. PPOA also included in the presentation their "reporting mechanisms and hotline information: Hotline telephone number (844.262.0016); and email (ComplianceOfficer@PhysicianPartenrsOA.com). There is no mention of confidential reporting.

583. In January 2019, PPOA retained Maggie Mac, a medical consultant based in Clearwater, Florida. Dr. Cho understood that Ms. Mac was retained by PPOA to conduct an audit of PPOA's compliance with Medicare guidelines, with a focus on physician documentation in the electronic medical record (EMR) to support the PPOA Defendants billing for professional fees.

584. Dr. Cho believes that Ms. Mac spent a week at his office location. Of that time, Dr. Cho met with her for approximately 30 minutes, and she met with Dr. Fernandez for approximately 30 minutes immediately before Dr. Cho. During Dr. Cho's meeting with Ms. Mac, they discussed components of Dr. Cho's physician documentation. The auditor did not find any significant deficiencies in Dr. Cho's documentation of his patient care.

### B. PPOA Ignored the Auditor's Findings of Lack of Medical Necessity for UDT, DNA Testing, and Psychological Screenings

585. The auditor did raise with Dr. Cho her concerns that there was a lack of medical

justification, documentation, and explanation for PPOA's UDT, DNA test, and psychological screening policies. Dr. Cho thanked the auditor and informed her that if she reports these findings to PPOA, he would not see her the next year (PPOA would end her contract).

586. Ms. Mac replied that she appreciated Dr. Cho's feedback and concern, but that after identifying this problem early in her reviews of PPOA practices (which began in the fall of 2018), she had promptly reported it to PPOA's medical director, Dr. Rivera and another person at PPOA. Ms. Mac shared that PPOA's response was a dismissive "we'll handle it," but she had received no further response on the issue.

587. Ms. Mac also told Dr. Cho that she had been sharing her conclusions regarding the lack of compliance with regard to UDT, DNA testing, and psychological screenings with the other PPOA physicians as well. Dr. Cho knew this to be true because he was in the same office during the time that Ms. Mac met Dr. Fernandez, and he heard the auditor share these same conclusions regarding the UDT and DNA tests with Dr. Fernandez.

## IX. DEFENDANTS' COMPENSATION ARRANGEMENT VIOLATES THE STARK LAW

588. The PPOA Defendants offered compensation to employed physicians in a position to refer patients to their affiliated companies that provided other designated healthcare services. Defendants contracts and communications to physicians provided that their compensation would be based on profits generated through referrals to their affiliated UTOX lab, DNA testing lab, imaging services (including MRI), DME provider, ASCs, pharmacy, and other health services that were ancillary to the pain management physicians and other PPOA-affiliated physicians.

589. The financial relationship does not meet the in-office ancillary services exception to the Stark Law for a number of reasons, including, but not necessarily limited to, the facts that: 1) the monies received under any group number used by the Defendants are not treated as receipts

of the group. Instead, they are treated by the Defendants as the funds of PPOA to be distributed in PPOA's sole discretion; 2) physicians at PPOA-controlled practices directly or indirectly receive compensation based on the volume or value of referrals by the physician; and 3) although there is a possibility of the pain management physicians being "eligible" for ownership in the "group" through non-voting Class B Profits Units, the issuance of these units are determined by PPOA "in its sole and absolute" discretion, rather than through vested or bona-fide ownership interests, and 4) as described above, distributions from PPOA affiliate operations are made to "outside parties," who are not "members" of the group.

590. In contrast to the actual distribution reports for PPOA's ASCs, the ASC operating agreements and their schedules show that 100% of distributions shall be made to "members."

591. Relators do not know of any physicians who are unaffiliated with PPOA who regularly refer their patients to Defendants' ancillary service providers.

592. At all times relevant to this Complaint, Defendants knew that their ancillary services incentive compensation agreements constituted an unlawful inducement in violation of the federal Stark Laws.

593. The PPOA Defendants' conduct demonstrates a knowing lack of compliance with the federal AKS and analogous state laws, the Stark Laws and federal and state FCAs, and related regulations.

594. The Defendants' knowledge of these statutes and the conduct that constitutes a violation of them is clear from the presentation made the PPOA's 2018 Annual Physicians' meetings. On the Agenda, Ms. Lawson's presentation is referred to as "Compliance and Coding." It begins on Slide 180 and is titled: "Compliance and Risk Management." The presentation was created by Rekha Rajan-Wilson, PPOA's Director of Compliance, Valerie Battle Borders, PPOA

Revenue Cycle and Physician Auditor, and Clifton Lee, PPOA's Quality Assurance Manager.

595. In the presentation, at Slide 183, PPOA's President discusses the Anti-Kickback Statute, its prohibition on the offer or receipt of remuneration, in exchange for referrals or recommending the purchase of supplies and services.

596. At Slide 184, PPOA's leader discusses Stark Law prohibitions: "a physician is unable to make referrals based on ownership arrangements of separate entities. Specifically, this means a physician owning a separate entity, such as a lab, cannot refer to that entity."

597. The Defendants knew that their pharmacies (effectuated through PPOA's policies and office procedures) was illegal. In an email dated April 13, 2017, Wood admitted that "physicians shouldn't own a pharmacy." At the time, the PPOA Defendants were already operating pharmacies whose revenues were based largely (if not exclusively) on referrals from PPOA-affiliated physicians.

598. At Slide 186, PPOA's President discussed three "Risk Areas for Physician Practices" and "OIG Compliance Guidance," each topic occupied in a separate column in a table. The first risk area, "accurate coding and billing," included "billing for non-covered services as covered;" unbundling;" "failure to use proper coding modifiers;" and "upcoding." The second risk area for compliance was "reasonable and necessary services." PPOA's President cited "medical records support appropriateness of service."

599. The third area of risk for physician practices identified by PPOA's President was "improper inducements, kickbacks and self-referrals." Under this heading, PPOA left the column blank, except for the word: "Exception." The next slide, 185, was titled: "Understanding the Physician Group Practice Exception to the Stark Law. PPOA never attempted to address how their referral arrangements would be compliant with the AKS.

600. For each patient subjected to unnecessary testing, invasive procedures, imaging, DME, CRNA services, pharmacy, or transportation charges, Defendants caused the submission of claims to Government-funded healthcare programs of hundreds to thousands of dollars in professional fees, facility charges, and/or ancillary service charges.

601. Government-funded healthcare programs have paid the PPOA Defendants for these claims on a fee-for-service basis.

### A. Medtronic and the PPOA Defendants Conspired to Violate the FCA Through Inducements Offered and Accepted by PPOA Executives In Exchange for Medtronic Being PPOA's Provider of Choice

602. During the relevant time period, Medtronic became the sole provider of devices used in procedures and surgeries for patients treated by the PPOA Defendants.

603. Medtronic became the sole supplier by providing a number of inducements to the PPOA Defendants, including, but not limited to PPOA's Annual Physician Retreat (which spouses and children also attended).

604. From May 18 through 20, 2018, PPOA held its Inaugural PPOA Physician Retreat for Florida-based PPOA providers and PPOA corporate executives at the Wyndham located in Clearwater Beach.

### B. PPOA's Physician Retreats Were Focused on Entertainment and the Referral of Business

605. At PPOA's invitation, most PPOA-affiliated physicians in Florida attended the Physician Retreat with their spouses or significant others and all of their minor children. PPOA touted the weekend as a family retreat at a luxurious resort.

606. PPOA and its Sponsor(s) covered all costs for the entire weekend for the PPOA physicians, their spouses or significant others, and their minor children, including hotel, meals, alcohol, transportation to restaurants, and entertainment.

607. Upon arrival at the Wyndham Clearwater Beach Hotel, PPOA staff helped to assign the hotel rooms and distribute welcome gift bags for each family, as well as the published Agenda for the weekend.

608. The Agenda for the Inaugural Florida PPOA Physicians Annual meeting detailed a weekend devoted largely to entertainment for the physicians' families, and included approximately 6.5 hours of PPOA business meetings:

- Friday, May 18, 2018:
  - Check-in to the Wyndham Clearwater Beach at 3 pm;
  - PPOA physicians and their families gathered in the hotel lobby to proceed to Badfins Food & Brew, Clearwater, FL, for a "Family Reception Dinner," 6 to 9:30 pm;
- Saturday, May 19, 2018: Breakfast-Presentation-Dinner from 7:30am to 9:00pm;
- Continental Breakfast/Sponsor Meet & Greet (7:30am to 8:00am);
- Break/Sponsor Meet & Greet (9:30am to 10:00am);
- Lunch/Sponsor Meet & Greet (12:00pm to 1:00pm);
- Break/Vendor Meet & Greet (3:00pm to 3:30pm);
- Family Farwell Dinner with physicians and their guests, PPOA executives and Medtronic sponsors (7:00pm to 9:00pm); and
- Sunday, May 20, 2018: Check-Out.

609. The Agenda included a 30-minute breakfast, a 30-minute morning break and a 60-minute lunch devoted to "Sponsor Meet & Greet." There was also a 30-minute afternoon break for "Vendor Meet & Greet." Thus, the PPOA business meetings took up 6.25 hours of the weekend, and the three Sponsor Meet & Greet(s) on Saturday consumed over 2 hours.

610. The PPOA physicians were not informed before they received the Agenda at the

resort that Medtronic had sponsored PPOA's Florida Physicians Annual Meeting.

611. After the event, PPOA executives reflected on the two annual meetings held for Florida and Texas PPOA physicians in their PPOA Connect publication: "Of course these events were not all work and no play; physicians joined their families at receptions both Friday and Saturday evening for nights filled with fun and relaxation!"

612. For example, during the Texas Retreat, Dr. Rogers, his girlfriend, Dr. Clavo and his wife enjoyed a high-top table and drinks. Both Dr. Howard and Dr. Clavo took photos. The Texas Retreat, like the Florida event for PPOA physicians, included PPOA's physicians, their spouse or significant other, their children and the attendees were treated to lodging, meals, activities, and entertainment. It also featured a meet-and-greet with the sponsor on Saturday evening.

613. At the Florida Physician Retreat, PPOA distributed a booklet entitled "Florida Physician Annual Meeting, Physician Partners of America, May 18-20, 2018, Clearwater Beach, Florida." (The 2018 Retreat Booklet).

614. The second page of the 2018 Retreat Booklet included the Agenda for Friday, Saturday and Sunday. The PPOA Physicians gathered in Sand Piper I and II for meetings on a variety of subjects, including:

- PPOA Culture, Business of Medicine, presented by Dr. Rodolfo Gari;
- Mission, Vision, Values, presented by Dave Wood;
- Office Operations, presented by Tricia Alvarado;
- Clinical Protocol, presented by Dr. Abraham Rivera
- ASC Operations, presented by Kays Al-Ali
- Marketing Your Practice, presented by Damon Ebanks
- Grand Rounds, presented by Dr. Abraham Rivera
- Human Resources, presented by Crystal Winkler
- IT Security, presented by Alex Gari
- Customer Service, presented by Josh Helms
- Ancillary, presented by Samantha Dangler
- Compliance / Coding, presented by Tracie Lawson

- Ultrasound Injection Presentation, presented by Dr. Chad Gorman
- PPOA Family Engagement, presented by David Wood
- Thank You & Good Night (4:30 pm), presented by Crystal Winkler, Taylor Gari

615. Pages 3-4 of the 2018 Retreat Booklet identified (with photos) the 33 PPOA physicians in Florida by practice group, which were color coded:

- 26 Physician members of the Pain Relief Group (Red): Ahmed; Boler; Cho; Crawford; Creighton; Dangaria, Fernandez-Silva, Gari, Gorman, Leal, Lakshminarasimhah; Lupi, Medina-Sanchez, Meyer, Nieves, Nocerini, Orbegozo, Racz, Rivera, Rogers, Shalev, Stern, Stone, Tapia, Uong, Wiley, Willis. The 2109 PPOA Connect Newsletter shoes that by the end of 2018, this had grown to 34 with the addition of Drs. Adams, Cases, Clavo, Ellis, Guirguis, Howard, Le, Lopez, and Otero);
- Health and Counseling Group (Purple): Michael Caruso, Ed.D.;
- Minimally Invasive Spine Group (Navy Blue): Brian McGraw, DO; James St. Louis, DO (by the end of 2018, Dr. Kravetz was providing these services in Hurst, TX);
- Personal Injury Group (Green Tab): Joseph Rashkin, MD; and
- Primary Care Clinics: Maria Del Rosario Gomez, MD; Pedmini Rajan, MD.

### C. Device and Pharmaceutical Manufacturers Sponsored PPOA's Physician Retreat Weekend

616. As reflected in the Agenda and other documents, much of PPOA's expenses for the Florida PPOA providers' retreat (and a similar retreat held in Texas) were paid by "sponsors" who manufactured devices and pharmaceuticals to whom PPOA referred or recommended patients. Sponsors provided funds for the all-day PPOA Physicians meetings (breakfast, morning break, and lunch for the PPOA physicians), as well as the hotel rooms for several days, parking fees,

food, alcohol, and entertainment expenses for the PPOA physicians' spouses and significant others, and their children. Upon information and belief, PPOA's Retreat for Florida physicians and their guests alone included 70 to 80 people including family. The cost would be in excess of $75,000 and perhaps as high as $100,000. A similar retreat for PPOA's Texas physicians, held in October 2018, had similar costs. The Florida Retreat was repeated in May 2019. Another Texas Retreat is planned for October 2019.

617. Page 1 of the 2018 Florida Physician Annual Meeting Booklet included a welcome message from Gari, PPOA's founder. Dr. Gari noted PPOA's growth over five years from 3 employees to over 600 employees at 24 clinics in two states. He also stated that PPOA physicians were "select few physicians with access to our exclusive and extensive network of corporate partners." Dr. Gari thanked "the families and sponsors supporting our meeting this weekend." He noted "We have an exciting list of activities for your families to do around Clearwater so they can enjoy themselves while you are in session." "**Also included is information about Medtronic, Flowonix, and Akrimax Pharmaceuticals – the sponsors who helped make this weekend possible**." (emphasis added).

618. Another sponsor of the 2018 PPOA meeting was Revolution Biologics, a manufacturer of stem cell products. Dr. Cho obtained the business card of their representative, Myra Hocutt.

619. Page 5 of the 2018 Retreat Booklet again extended a "Special Thanks to our sponsors... Akrimax Pharmaceuticals...Prometra II Programmable Pump System...Stop by to learn more about our micro bolus deliver...Flowonix PL-15057-00 May 2018."

620. Page 6 of the color 2018 Retreat Booklet was a full-page advertisement for Medtronic: "Medtronic. Further, Together." Medtronic is the only Sponsor identified as such in

the 2018 Retreat Agenda and PowerPoint.

621. Medtronic, the company that wants to go "further together" with PPOA, is a behomoth medical device manufacturer. Their growth, like PPOA's, is dependent on convincing providers to perform invasive procedures which require the use of devices, particularly those made by Medtronic.

622. Among the numerous devices made and marketed by Medtronic are implantable pain pumps and spinal cord stimulators (SCSs). Both of these devices are medically appropriate pain care for a small group of patients with severe pain or other grave conditions.

623. Medtronic's pain pump is properly indicated, delivers analgesic medication directly to the spinal fluid of patients with severe pain, for example cancer patients. Pain pumps carry inherent risks to patient safety. First, they require surgery to implant the device, usually in the abdomen. Pain pumps (which hold the medication reservoir and pumping mechanism) deliver the analgesic directly to the intended area, most commonly, to the spinal fluid. Pain pumps must be periodically refilled with medicines or fluids by a health care provider. Both the implanting and maintenance of pain pumps are fraught with risk. Medtronic's pumps were recalled in 2015 after 14 reported deaths. 11 of these deaths resulted from providers missing the small aperture for the needle containing the medication. The provider missed the opening, resulting in the medication being delivered directly to the patient all at once, killing the patient through overdose.

624. Pain medicines approved by FDA for delivery into the spinal fluid must meet additional safety standards because the spinal cord and brain tissue are highly sensitive to preservatives or infectious organisms such as bacteria or viruses. There are also serious health risks to patients when providers use medication not specifically approved for use in pain pumps. The FDA recently (November 14, 2018) issued a warning on this issue.

625. Pain pumps are also very costly. The procedure must be performed under general anesthesia. Reimbursement for implanting the pump is approximately $40,000. A pump lasts five years, which equates with an $8,000 annual cost for the pump. In addition, the pump must be maintained and filled at least quarterly. The provider fees for these services are approximately $100 per episode. Thus, the medical costs associated with pain pumps are significant, both for payors and for patients who have copays.

626. Pain pumps and the catheters that deliver medication, like all mechanical devices, can also fail. One of the worst complications of pain pumps is catheter tip granuloma formation, which can cause spinal cord compression, resulting in paraplegia with permanent spinal cord injury. This can happen if a high concentration of morphine is used for infusion. As a result, the patient will also require a CT scans of the spine in the event of any sign of motor weakness or severe pain. Another common complication of pain pumps is damage to the catheter during other procedures (*i.e.*, needle punctures) which can cause medication leaks, and attendant loss of pain control due to medication not being delivered to the spinal cord CSF. These are just examples of painful and/or life-threatening complications related to pain pumps.

627. Whether from use or failure, the devices need replacing. Replacement then requires another major surgery (again under anesthesia), with the attendant risks of infection, etc., to replace the device. Then the whole process of maintaining the device and refilling the medication (with attendant risks) begins anew.

628. Pain pumps, therefore, are sued as a last resort regime to treat pain that has not responded when alternative pain treatment has been attempted and failed, and the benefit to be derived outweighs the significant risk to patient health.

629. SCSs, like Medtronic's Intellis neurostimulator, interrupt pain signals that travel

between the spinal cord and brain. The SCS device, like a pacemaker, must also be surgically implanted The procedure also requires the implantation of wires to carry the signal between the device and the spine.

630. Like the pump, the stimulator is also an expensive treatment option. The procedure for the trial can cost approximately $4,450, and implanting the device can cost approximately $22,581.

631. When treating a pain patient with a pain pump or stimulator, the provider first subjects the patient to a trial, with the device attached to the outside of the body, but the catheter delivering the drug or the wire carrying the electric pulse, implanted in the body. Thus, treatment requires two surgical procedures just for the implanting phase.

632. Both pain pumps and SCSs (PPOA calls them "stims") are devices that require invasive and painful surgical procedures. Both should be used after other more conservative pain treatments have been tried and failed.

633. From 4:45 on Saturday, the PPOA physicians rejoined their families to relax and enjoy the resort and "get ready for a great night. Saturday's evening festivities included a Jolly Trolley Rides to Island Way Grill, where the Family Farewell Dinner "with physicians, their guests, PPOA executives and Medtronic sponsors" mingled before Jolley Trolley transported the physicians and their guests back to the Wyndham Resort. The PPOA physicians and their families enjoyed the resort for the remainder of Saturday evening and Sunday.

634. During the PPOA 2018 Florida Physicians' Retreat, PPOA also circulated a color photo chart identifying their Executive Leadership Team as of May 2018: Tracie Lawson, President & COO; Abraham Rivera, MD, CMO; Rodolfo Gari, MD, Founder; David Wood, Chief Experience Officer; Patrick Chunn, CFO; Kays Al-Ali, SVP of ASC Operations; William Milo,

SVP of Physician Practices; Chris Yinger, SVP of Information Technology; Josh Helms, SVP of Sales & Marketing; Robyn Suhlman, VP of Payer Relations; Linda Abernathy, VP of ASC Operations; Samantha Dangler, VP of Ancillary Products and Services; Fred Weidig, VP of Finance; Crystal Winkler, VP of Human Resources; and Chrissy Infinger, VP of Business Development. The same chart also listed PPOA's Florida Operations Team: Tricia Alvarado, Director of Operations, Practices Division Florida; Rosaly Lawson, regional Clinical Supervisor; Eric Alvarez, Regional Clinical Supervisor; Rekha Rajan-Wilson, Director of Compliance; Mary McKay, Regional Clinical Supervisor. PPOA's "Corporate contacts" included email addresses for IT Support; Credentialing; Human resources; Employee Referrals (recruiting); Benefits Questions; ADP Help; Compliance; and Marketing Requests.

**D. PPOA's Physician Retreat PowerPoint**

635. PPOA also provided physicians with an electronic version of their 224-slide PowerPoint (with speaker's notes) that was to be presented during the meeting held from 7:30 am until 4:15 pm on Saturday. The electronic version was among documents provided on a USB stick which the physicians received on arrival on Friday evening.

636. At the PPOA Physician Retreat, attendees received a color version of this PowerPoint dated 5/17/2018 with lines next to each slide for attendees to take notes.

637. Slides 75-97 of the PowerPoint, Titled "Grand Rounds," was delivered by PPOA's CMO, Defendant Abraham Rivera, MD, who highlighted Medtronic products during his presentation.

638. Dr. Rivera's presentation began with a number of slides discussing the symptoms and treatment for "acquired scoliosis" and spinal stenosis. Dr. Rivera then discussed two products. First, he discussed the Coflex device manufactured by Paradigm Spine.

639. Dr. Rivera also discussed the DIAM Spine Stabilization System, manufactured by Medtronic.

640. In February 2016, the FDA had voted against pre-market approval of Medtronic's DIAM. Dr. Harvey Smith of the University of Pennsylvania noted at the time: "I did not think there was substantial evidence to say it was definitively safe when we do not entirely understand the mechanism of the spinous process resorption, and given that it was a relatively early follow-up and the nature of the device, that was a concern from the safety perspective..." Available at https://www.massdevice.com/fda-panel-votes-against-medtronics-diam-spine-stabilization-system/.

641. Nonetheless, during the May 2018 PPOA Physician Retreat, Dr. Rivera omitted that fact from his presentation, and instead, highlighted a "recent" study conducted in Italy. Dr. Rivera noted the Italian study involved 912 patients, and showed "a significant reduction in pain and a high rate of patient satisfaction."

642. In addition, Dr. Rivera discussed interspinous process plates, including X-Stop (manufactured by Medtronic), AXLE, Minute Man, and Superion. The FDA had ceased sale and distribution of the X-Stop in 2015.

643. Dr. Rivera also presented five slides on column distraction surgery, an outpatient procedure requiring a "fully-fledged Operating Room."

644. Throughout, Dr. Rivera discussed PPOA's preference for pain specialists performing expensive invasive procedures over other less-invasive methods of treating pain patients.

645. Dr. Rivera reiterated this point in a January 23, 2019 email to all PPOA pain management providers, where he informed them that medically appropriate but poorly reimbursed

services could no longer be performed at PPOA's ASCs:

> There is [sic] a number of procedures that are being booked at the ASC with zero or little reimbursement. As much as we want to help some of these patients, the reality is that these procedures need to be done on a different environment. With few exceptions, these procedures will no longer be supported at any of our ASC's.
>
> The following list includes the most common procedures we will no longer support:
>
> 1. Bilateral procedures, with few exceptions
> 2. Intraarticular joint injections. Exception, SI joint injection for diagnostic purposes
> 3. Sacral radiofrequency ablation
> 4. Genicular nerve blocks or RFA.

646. PPOA's presentation during the Physicians Retreat, as delivered by CMO Dr. Rivera, also focused on and included images of the Medtronic Intraspinal Infusion Device: the programmable intraspinal infusion pump. In fact, the PPOA slide includes images that are marked "Copyright Medtronic, Inc." The device pictured bears the following markings: "SynchroMed® EL," "Programmable Pump," "Medtronic Inc. USA."

647. PPOA also described Medtronic as PPOA's supplier of choice, particularly for expensive implantable fusion pumps and spinal cord stimulators.

648. The Medtronic devices supplied to PPOA include SynchroMed II Drug Infusion System and Medtronic SureScan MRI System Spinal Cord Stimulation, which includes four submodels (RestoreSensor SureScan MRI Neurostimulator; RestoreUltra SureScan MRI Neurostimulator; RestoreAdvanced SureScan MRI Neurostimulator; and PrimeAdvanced SureScan MRI Neurostimulator).

649. Dr. Golovac has a long history of working as a consultant for neurostimulator therapy. For example, in 2014, Dr. Golovac contributed to a study on the benefits of

neurostimulation therapy that was partially funded by Defendant Medtronic at St. Jude Medical, Inc. ("St. Jude Medical"), another manufacturer of spinal cord stimulators. Available at https://onlinelibrary.wiley.com/doi/10.1111/ner.12204. In October 2014, Dr. Golovac contributed to "Special Report-First Comprehensive Guidelines Published for Neurostimulation Therapy." Available at https://touchneurology.com/special-report-first-comprehensive-guidelines-published-for-neurostimulation-therapy/. St. Jude Medical was sold to Abbott in 2017.

## X. CAUSES OF ACTION

### COUNT I - VIOLATION OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(A), (B) and (G)

650. Relators incorporate the averments of paragraphs 1 through 649 as if set forth in full herein.

651. Claims submitted by Defendants nationwide to federally - or state-funded health care programs, including Medicare, Medicaid, and Tricare related to professional fees, facility charges, or ancillary services that were not medically necessary or were not provided constitute violations of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

652. Claims submitted by the Defendants that violated the federal AKS or Stark Laws constitute violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

653. The Defendants knowingly made false records related to UTOX, DNA tests, imaging, laser spine surgeries, invasive procedures, CRNA services, pharmacy, DME, transportation and other ancillary services that were material to claims submitted to Government healthcare programs in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

654. The false records or statements were the patient records and bills which (a) misrepresented that UTOX, DNA tests, imaging, laser spine surgeries, invasive procedures, CRNA services, pharmacy, DME, transportation and other ancillary services were medically necessary

and/or (b) expressly or implied certified full compliance with all federal and state laws, including, but not limited to, the federal Anti-Kickback Statute and Stark Laws.

655. Moreover, Defendants, after receiving overpayments, knowingly avoided repaying Government payors for services that Defendants knew were medically unnecessary and/or tainted by Stark Law and Anti-Kickback Statute violations, in contravention of 31 U.S.C. § 3729(a)(1)(G). Defendants were required to return such overpayments within 60 days of knowingly receiving such overpayments but failed to do so. 42 C.F.R. § 401.305. Defendants, in fact, knew of the impropriety of the payments at the time they submitted the claims to Medicare and other Government payors.

656. All of Defendants' conduct described in this Complaint was knowing, as that term is used in the federal False Claims Act.

657. The FCA violations at issue here were material to the Government healthcare programs' decision to pay the affected claims. For example, the Government healthcare programs would not pay claims for unnecessary medical services and drugs, including UTOX testing, DNA testing, imaging, laser spine surgeries, interventional procedures, CRNA services, pharmacy, DME, transportation and other services described herein. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A). The Government routinely denies payment or seeks recoupment for services and drugs which are not medically necessary.

658. In addition, a violation of the federal AKS or state analog is material to the affected claims. Under the federal AKS, a violation renders the affected claims false under the federal FCA by operation of law. 42 U.S.C. § 1320a–7b(g). Likewise, the Defendants expressly or impliedly certify in submitting claims to Government healthcare programs that they are in compliance with federal laws, including the Stark Laws. Compliance with the Stark Laws is material to the payment

of claims by Government healthcare programs, including Medicare, Medicaid and Tricare. The Government routinely denies payment or seeks recoupment for services tainted by Anti-Kickback and Stark Law violations.

659. Each of the Defendants is jointly and severally liable for the damages to Government payors resulting from the conduct described in this *Qui Tam* Complaint.

**WHEREFORE**, Relators request the following relief:

A. Judgment against Defendants for three times the amount of damages the United States has sustained because of their actions, plus the maximum civil penalty allowed by law for each violation of the federal False Claims Act;

B. Twenty-five percent (25%) of the proceeds of this action if the United States elects to intervene, and thirty percent (30%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and expenses; and

D. Such other relief as the Court deems just and appropriate.

**COUNT II - VIOLATION OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3729(A)(1)(C) CONSPIRACY**

660. Relators incorporate the averments of paragraphs 1 through 659 as if set forth in full herein.

661. The PPOA Defendants, and the individual Defendants, agreed to enter into a scheme to coerce healthcare providers to refer patients, or deceive the patients themselves, in order to generate false claims for UTOX, DNA tests, imaging, laser spine surgeries, invasive procedures, pharmacy, DME, transportation and other ancillary services. They also conspired to defraud the federal Government by submitting false or fraudulent claims (including those related to unnecessary services, as well as those claims related to referrals tainted by violations of the federal

Anti-Kickback Statute and the Stark Laws) which were paid by the Government in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

662. The PPOA Defendants, the individual Defendants, and Medtronic also conspired to violate the federal FCA (and state analogs) through violations of the federal AKS and state analogs. The resulting claims, whether submitted or caused to be submitted to Government payors were false and were paid in violation of the federal FCA and state analogs.

**WHEREFORE**, Relators request the following relief:

A. Judgment against Defendants for three times the amount of damages the United States has sustained because of their actions, plus the maximum civil penalty allowed by law for each violation of the federal False Claims Act;

B. Twenty-five percent (25%) of the proceeds of this action if the United States elects to intervene, and thirty percent (30%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and expenses; and

D. Such other relief as the Court deems just and appropriate.

**COUNT III - FLORIDA FALSE CLAIMS ACT**
**Fla. Stat. §§ 68.081, *et seq.***

663. Relators incorporates Paragraphs 1 through 662 as though fully set forth herein.

664. The allegations in this count are made upon information and belief.

665. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. § 68.082(2).

666. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

667. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts to induce the Florida State Government to approve or pay such false and fraudulent claims and they conspired to violate the Florida False Claims Act.

668. By virtue of the conduct described herein, Defendants conspired to violate the Florida False Claims Act.

669. By virtue of the acts described above, Defendants have violated and continue to violate Florida law prohibiting the payment or receipt of bribes or kickbacks, namely Fla. Stat. § 456.054 and Fla. Stat. § 409.920.

670. The Florida State Government, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements.

671. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or to decrease their respective obligations to return overpayments of Florida state funds.

672. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

673. The State of Florida is entitled to a civil penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

**WHEREFORE**, Relators request the following relief:

> A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus the maximum civil penalty allowed by law for

each violation of Fla. Stat. § 68.082(2)(a), (b), (c), and (g).

B. Twenty five percent (25%) of the proceeds of this action to the Relators if the State of Florida elects to intervene, and 30% if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, the costs of the audit, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

**COUNT IV -TEXAS MEDICAID FRAUD PREVENTION ACT**
**Tex. Hum. Res. Code §§ 36.001, *et seq.***

674. Relators re-allege Paragraphs 1 through 673 as though fully set forth herein.

675. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Act.

676. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

677. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Texas State Government to approve or pay such false and fraudulent claims.

678. By virtue of the conduct described herein, the Defendants conspired to violate the Texas Medicaid Fraud Prevention Act.

679. By virtue of the acts described above, Defendants have violated and continue to violate Texas law prohibiting the payment or receipt of bribes or kickbacks, namely Tex. Occ. Code Ann. § 102.001.

680. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendants, paid and continues to pay the claims that are non-payable as a result of Defendants' illegal inducements.

681. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or to decrease their respective obligations to return overpayments of Texas state funds, and they conspired to violate the Texas Medicaid Fraud Prevention Act.

682. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

683. The State of Texas is entitled to a civil penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**WHEREFORE**, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus the maximum civil penalty allowed by law for each violation of Tex. Hum. Res. Code Ann. § 36.002(1), (4), (9), (12);

B. Twenty-five percent (25%) of the proceeds of this action to the Relators if the State of Texas elects to intervene, and thirty percent (30%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other reasonable expenses; and

D. Such other relief as the Court deems just and appropriate.

**COUNT V - (AGAINST ALL DEFENDANTS) –**
**CALIFORNIA FALSE CLAIMS ACT**
**Cal. Gov't Code §§ 12650, *et seq.***

684. Relators re-alleges Paragraphs 1 through 683 as though fully set forth herein.

685. This is a claim for treble damages and penalties under the California False Claims Act.

686. By virtue of the acts described above, during the time period relevant to the

Defendants' presence in California, the Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

687. By virtue of the acts described above, during the time period relevant to the Defendants' presence in California, the Defendants knowingly made, used, or caused to be made or used, or will make, use or cause to be made or used, false records and statements and omitted material facts to induce the California State Government to approve or pay such false and fraudulent claims, and conspired to violate the California False Claims Act.

688. The California State Government, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendants, paid and continues to pay the claims that are non-payable as a result of Defendants illegal inducements.

689. During the time period relevant to the Defendants' presence in California, by reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

690. The State of California is entitled to a civil penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

**WHEREFORE**, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus the maximum civil penalty allowed by law for each violation of Cal. Gov't Code § 12651(a)(1), (2), (3), and (7).

B. Thirty three percent (33%) of the proceeds of this action to the Relators if the State of California elects to intervene, and 50% if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

**COUNT VI (AGAINST ALL DEFENDANTS)**
**CALIFORNIA INSURANCE FRAUDS PREVENTION ACT**
**Cal. Ins. Code § 1871.7**

691. Relators re-allege Paragraphs 1 through 690 as though fully set forth herein.

692. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act.

693. By virtue of the acts described above, during the time relevant to the Defendants' presence in California, the Defendants knowingly presented, or caused to be presented, false or fraudulent claims to private health insurance companies operating in the state of California for payment or approval in violation of each patient's private health insurance contract.

694. By virtue of the acts described above, during the time relevant to the Defendants' presence in California, the Defendants knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private health insurance companies in California, or for patients in California covered by those insurers, to approve or pay such false and fraudulent claims.

695. Private insurance companies in California, or those insurers that covered patients in California, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendants, paid and continue to pay the claims that would not be paid but for Defendants' illegal conduct.

696. During the time relevant to the Defendants' presence in California, the Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their respective obligations to return overpayments to these private health insurance companies, and they conspired to do so.

697. During the time relevant to the Defendants' presence in California, by reason of the Defendants' acts, these private health insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

698. By reason of the Defendants' acts, the State of California has also been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

699. Each claim for reimbursement that was a result of the Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

700. The State of California is entitled to a civil penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

**WHEREFORE**, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages that the private insurance companies have sustained because of Defendants' actions, plus the maximum civil penalty allowed by law for each violation of Cal. Inc Code 1871.7 (a) and (b).

B. Forty percent (40%) of the proceeds of this action to the Relators if the State of California elects to intervene, and fifty percent (50%) if it does not;

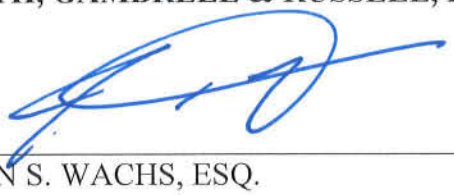
C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

Such other relief as the Court deems just and appropriate.

## DEMAND FOR JURY TRIAL

Relators request a trial by jury on all claims so triable.

**SMITH, GAMBRELL & RUSSELL, LLP**



ALAN S. WACHS, ESQ.
Florida Bar No. 980160
JOSEPH C. CRAWFORD, ESQ.
Floria Bar No. 124653
awachs@sgrlaw.com
tgreene@sgrlaw.com
dhsmith@sgrlaw.com
50 North Laura Street, Suite 2600
Jacksonville, Florida 32202
(904) 598-6110 (Telephone)
(904) 598-6300 (FASCimile)
***Counsel for Plaintiffs/Relators***

**PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP**

MARC S. RASPANTI, ESQ.
Pennsylvania Bar No. 41350
*(Pro Hac)*
MSR@Pietragallo.com
PAMELA COYLE BRECHT, ESQ.
Pennsylvania Bar No. 62249
*(Pro Hac)*
PCB@Pietragallo.com
ERIK R. GIANNITRAPANI, ESQ.
Pennsylvania Bar No. 318500
*(Pro Hac Admission Pending)*
1818 Market Street, Suite 3402
Philadelphia, Pennsylvania 19103
(215) 988-1433 (Telephone)
(215) 754-5191 (Facsimile)
***Counsel for Plaintiffs/Relators***

Date: July 30, 2019

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