GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101

By: Kelly Elizabeth Levy (011082011)
Deputy Attorney General
Tel. (609) 433-4864
levyk@njdcj.org

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF **MUKARAM A GAZI, M.D.** **LICENSE NO. 25MA06709800** TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	Administrative Action **COMPLAINT**

GURBIR S. GREWAL, Attorney General of New Jersey, by Kelly Elizabeth Levy, Deputy Attorney General, appearing, with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, by way of Complaint, says as follows:

GENERAL ALLEGATIONS

I. Introduction.

1. This case is about a physician who allowed his treatment and prescription decisions to be influenced by improper benefits he received from the infamous and now bankrupt pharmaceutical company, Insys Therapeutics, Inc. ("Insys"). In exchange for dinners posing as "lectures," trips for "training," and payments thinly disguised as "speaker's fees," which collectively totaled about $132,000, Mukaram A. Gazi, M.D. ("Respondent") did what his meal

ticket wanted him to do: prescribe its product Subsys, a highly addictive instant release formulation of fentanyl that is fifty times more powerful than heroin, in ever increasing amounts and dosages, without regard to the medical necessity of such prescribing and in contravention of the standard of care expected to be adhered to by physicians licensed in this State.

2. Subsys is part of a special class of drugs, known as transmucosal immediate release fentanyl ("TIRF"), approved by the Food and Drug Administration ("FDA") for the single use of managing breakthrough cancer pain in patients tolerant to around-the-clock opioid therapy. The FDA's concerns about Subsys were so great that it mandated the creation of a special program for prescribers like Respondent and his patients known as Risk Evaluation and Mitigation Strategy ("REMS"). As part of his participation in the REMS program, Respondent repeatedly agreed that Subsys was only approved for use in patients suffering from breakthrough cancer pain.

3. As has been detailed in numerous state and federal civil actions and criminal prosecutions, including a pending civil action by the Attorney General in New Jersey Superior Court, Middlesex County, Insys devised a subversive and illegal plan to increase Subsys prescriptions and thereby increase profits by promoting the drug for uses beyond the sole, narrow indication for which Insys sought and received FDA approval despite the dangers its off-label use posed to patients. Among other things, Insys (i) directed its sales force to push healthcare providers like Respondent to write Subsys prescriptions for more patients and at higher doses to treat chronic pain of any type; and (ii) paid prescribers like Respondent with sham speaking and consulting fees, expensive meals, and trips to resorts for "training" sessions to induce them to write additional Subsys prescriptions.

4. Respondent willingly accepted the improper benefits Insys provided. Over time, the benefits Insys provided to Respondent continued to increase and so too did the number of Subsys prescriptions Respondent wrote.

5. As detailed in Counts I to VIII below, Respondent encouraged patients that did not have cancer or suffer from breakthrough cancer pain to fill or attempt to fill at least one prescription for Subsys. In addition, without regard for patient safety, Respondent prescribed initial dosages that exceeded the FDA mandate, likely resulting in more money for Insys as higher doses cost more. Respondent's medical records provide little or no medical justification and often no explanation at all, as to why patients were written prescriptions for Subsys or why those initial dosages exceeded the starting dosage that was mandated by the FDA. In the cases detailed below, Respondent's reckless use of Subsys placed them at risk of addiction, overdose, and death.

6. For all these reasons, as further detailed herein, Respondent has disregarded his patients' well-being and placed his interests first. In so doing he has failed to live up to the exacting standards imposed on professionals licensed to practice medicine and surgery in the State of New Jersey, and his privilege to continue to do so should be suspended or revoked.

II. Parties

7. Pursuant to N.J.S.A. 52:17A-4(h), Complainant, Gurbir S. Grewal, Attorney General of New Jersey ("Attorney General"), is charged with the duty and responsibility of enforcing the laws of the State of New Jersey, and, pursuant to N.J.S.A. 45:1-14 et seq., is empowered to initiate disciplinary proceedings against persons licensed by the New Jersey State Board of Medical Examiners ("Board").

8. Pursuant to N.J.S.A. 45:9-1 et seq., the Board is charged with the duty and responsibility of regulating the practice of medicine and surgery in the State of New Jersey.

9. Respondent is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA06709800. Respondent is Board Certified by the American Board of Urology and specializes in urology. At all times relevant hereto Respondent maintained a medical practice, University Urology Associates of New Jersey, with his main office located in Hamilton, New Jersey.

III. Fentanyl

10. Fentanyl is a synthetic opioid prescription analgesic that is fifty times more potent than heroin, and one hundred times more potent than morphine. Fentanyl use in any form can lead to severe physical and/or psychological dependence, and may result in sedation, nausea, vomiting, respiratory depression, circulatory depression, substance abuse and addiction, and/or death.

11. Based upon these dangers and the potential for abuse, the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq., classifies fentanyl as a Schedule II narcotic. See N.J.S.A. 24:21-6(d)(6); see also, N.J.A.C. 24:21-6; accord, 21 U.S.C.A. 812; 21 C.F.R. 1308.12(c)(9).

IV. "TIRF" Class of Fentanyl Substances

12. TIRF medicines are formulations of fentanyl that deliver fentanyl to their users via the oral mucosa (the mucus membrane lining the inside of the mouth) nearly instantaneously.

13. Subsys is the trade name for fentanyl sublingual spray, a TIRF substance packaged in a single-dose spray device intended for oral sublingual (under the tongue) administration. Subsys is manufactured and sold exclusively by Insys, an Arizona-based corporation, and is available in the following dosage strengths: 100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg and 1600mcg fentanyl solution.

14. Subsys was first approved for use by the FDA in January 2012.

15. At all relevant times, the only FDA-approved use for all TIRF medicines, including Subsys, has been for the management of breakthrough cancer pain in patients with cancer who are already receiving, and who are tolerant to, regular opioid therapy for their underlying persistent cancer pain.

16. In announcing the FDA's approval, Insys included the following statement in a press release from its paid spokesperson and member of its advisory Board, Dr. Jeffrey A. Gudin of Englewood Hospital and Medical Center, Englewood, NJ: "'With the early onset of action, greater bioavailability, and broadest range of approved strengths, Subsys is poised to match the onset and intensity of a breakthrough cancer pain episode.'"

V. The TIRF REMS Access Program

17. In December 2011, the FDA mandated that the manufacturers of TIRF products develop and implement a REMS program called the TIRF REMS Access Program. The TIRF REMS Access Program is designed to ensure informed risk-benefit decisions are made before initiating treatment, and also while patients are on treatment, to ensure appropriate use of TIRF medicines.

18. The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of TIRF medicines. The program is designed to achieve these goals by:

1. Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.

2. Preventing inappropriate conversion between TIRF medicines.

3. Preventing accidental exposure to children and others for whom it was not prescribed.

4. Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

19. Prescribers, including Respondent, are not eligible to prescribe TIRF medicines for outpatient use unless they are enrolled in the TIRF REMS Access Program. To successfully enroll in the Program, and thus, gain the ability to prescribe TIRF medicines to outpatients, a physician must satisfy several requirements. The physician must (a) review the TIRF REMS Access education materials, including the Program's "Education Program" and the "full prescribing information" for each TIRF medicine the physician intends to prescribe; (b) successfully complete an online "Knowledge Assessment," a quiz designed to test the physician's knowledge of TIRF medicines; and (c) complete and sign a "Prescriber Enrollment Form."

20. Upon satisfaction of these requirements, the TIRF REMS Access Program provides the physician written confirmation that he is permitted to prescribe TIRF medicines.

21. In addition, a "Patient-Prescriber Agreement Form" must be completed and signed by the physician and each patient to whom the physician seeks to prescribe a TIRF medicine before any such prescription can be given. The confirmation letter the physician receives upon enrollment in the Program reminds the physician of the Program's requirement that, before prescribing a TIRF medicine to a particular patient, he must "complete and sign a TIRF REMS Access Patient-Prescriber Agreement Form ("PPAF") with each patient that is new to the TIRF REMS Access Program."

Respondent Enrolls in the TIRF REMS Access Program

22. In or about 2013, Respondent is believed to have enrolled in the TIRF REMS Access Program. In so doing, he completed and submitted the "Prescriber Enrollment Form," read the Full Prescribing Information for all TIRF substances, including Subsys, and successfully completed the Knowledge Assessment.

23. By completing and submitting the Prescriber Enrollment Form, Respondent acknowledged, among other things:

> I understand that TIRF medicines are only available through the TIRF REMS (Risk Evaluation and Mitigation Strategy) Access Program and that I must comply with the program requirements.
>
> . . .
>
> I understand that TIRF medicines can be abused and that this risk should be considered when prescribing or dispensing TIRF medicines in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.
>
> I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer, who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent pain.
>
> I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur at any dose.
>
> I understand that TIRF medicines must not be used to treat any contraindicated conditions described in the Full Prescribing
>
> Information, such as acute or postoperative pain, including headache/migraine.
>
> . . .
>
> I understand that the initial starting dose for TIRF medicines for <u>all</u> patients is the lowest dose, unless individual product labels
>
> provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
>
> I will provide a Medication Guide for the TIRF medicine I intend to prescribe to my patient or their caregiver and review it with them.
>
> . . .

> At all follow-up visits, I agree to assess the patient for appropriateness of the dose of the TIRF medicine, and for signs of misuse and abuse.
>
> . . .
>
> I understand that TIRF medicines are only available through the TIRF REMS Access Program. I understand and agree to comply with the TIRF REMS Access program requirements for prescribers.

24. By enrolling in the TIRF REMS Access Program, Respondent acknowledged having read the Full Prescribing Information for Subsys which states, among other things:

> WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL
>
> Respiratory Depression
>
> Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS, including following use in opioid non-tolerant patients and improper dosing.
>
> . . .
>
> Medication Errors
>
> Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose. . . . When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to SUBSYS.
>
> Abuse Potential
>
> SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered

when prescribing or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

. . .

As with all opioids, the safety of patients using such products is dependent on health care professionals prescribing them in strict conformity with their approved labeling with respect to patient selection, dosing, and proper conditions for use.

. . .

The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is **always** 100 mcg.

[(Emphasis added).]

25. By enrolling in the TIRF REMS Access Program, Respondent acknowledged having read the program's "Education Program," which states, among other things:

Appropriate Patient Selection

Indication

TIRF medicines are indicated only for the management of breakthrough pain in adult patients with cancer 18 years of age and older who are already receiving and who are tolerant to regular opioid therapy for underlying persistent cancer pain.

. . .

TIRF medicines are contraindicated in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not taking chronic opioids.

Definition of Opioid Tolerance

Patients considered opioid-tolerant are those who are taking, for one week or longer, at least:

- 60 mg oral morphine/day
- 25 mcg transdermal fentanyl/hour
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day

- OR an equianalgesic dose of another oral opioid

> TIRF medicines are intended to be used only in the care of opioid-tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
>
> . . .
>
> Risk of Misuse, Abuse, Addiction, and Overdose
>
> TIRF medicines contain fentanyl, an opioid agonist and Schedule II controlled substance. TIRF medicines can be abused in a manner similar to other opioid agonists, legal and illicit.
>
> These risks should be considered when prescribing or dispensing TIRF medicines in situations where the prescriber or pharmacist is concerned about an increased risk of misuse, abuse, addiction, or overdose.
>
> Risk factors for opioid abuse include:
>
> - A history of past or current alcohol or drug abuse
> - A history of psychiatric illness
> - A family history of illicit drug use or alcohol abuse

26. As explained by Lewis S. Nelson, M.D., an addiction specialist who leads the Emergency Department at University Hospital in Newark, New Jersey, and who was consulted by the Attorney General to provide information regarding the appropriate use of TIRF medicines, in addition to TIRF medicines' "high risk for addiction, overdose, and dependence," they "have been increasingly documented to promote the development of 'opioid-induced hyperalgesia.'" Dr. Nelson clarifies that these risks "are acceptable for the management of end-of-life cancer related pain, but are not acceptable for the management of a pain syndrome expected to last decades. For these reasons, TIRF substances are not indicated for chronic pain and are only indicated for severe, breakthrough pain associated with cancer, which implies use as a palliative comfort measure for a patient with a terminal illness."

27. Dr. Nelson opines that any physician who, after completing the steps required to successfully enroll in the TIRF REMS Access Program, then proceeds to prescribe TIRF substances to patients who are not suffering from breakthrough cancer pain "act[s] with significant disregard for the well-documented risks of TIRF substances" and "exposes [those] patients to a grave risk of serious harm." As Dr. Nelson further explains, this conclusion is well founded: "[a]n individual physician's decision to prescribe a TIRF substance to a patient who does not have cancer, and his or her concomitant assessment that such a patient's supposed need for TIRF substances outweighs their well-documented grave risks, is not supported by the weight of the medical evidence."

28. The overwhelming weight of the currently available medical evidence confirms that the only safe and medically recognized use of a TIRF substance is for the management of breakthrough pain in opioid-tolerant cancer patients.

VI. Respondent's Relationship with Insys

29. In or around August 2012, Insys, the manufacturer of Subsys, launched its Insys Speaker Program ("ISP"). Prescribers who participated in the ISP were paid up to $3,000 per event in addition to meals and other expenses. The purported goal of the ISP was to increase Subsys brand awareness. However, Insys later acknowledged in various court filings that the ISP speaking fees, or "honoraria," paid to prescribers were in realty bribes used by the company to induce speaker-practitioners "to write more, medically unnecessary prescriptions" of Subsys.[1]

[1] Insys Plea Agreement filed June 5, 2019, "Statement of Facts for Insys Therapeutics, Inc. Deferred Prosecution Agreement and Insys Pharma, Inc. Plea Agreement", United States v. Insys Therapeutics, Inc., Insys Pharma, Inc., No. 1:19-cr-10191-RWZ (Dist. Ct. Mass.). See also United States v. Gurry, No. 16-cr-10343-ADB, 2019 U.S. Dist. LEXIS 205850, at *11-12 (Dist. Ct. Mass. Nov. 26, 2019).

30. Moreover, rather than serving as educational gatherings, the ISP events "often did not involve any education or presentations about [Subsys]" and frequently had no attendees at all.[2] These sham ISP events merely functioned "as bribes in the form of free dinners for speakers, friends, and, at times, family, and served as a vehicle to pay a bribe to the speaker in the disguised form of an honoraria."[3]

31. On or about November 21, 2013, Respondent was an attendee at an ISP, in which the speaker was Manoj Patharkar, M.D.[4]

32. Shortly thereafter, on or about December 13, 2013, Respondent's very first Subsys prescription was filled by a patient. About a week later, Respondent wrote two more Subsys prescriptions for two other patients. By around the end of December 2013, Insys had paid for three meals for Respondent.

33. On or about February 2014, Respondent expressed his interest to Insys regarding participation as a speaker in the ISP. Insys thereafter reviewed Respondent's nomination form and CV and accepted him into the program.

34. On or about March 2014, Respondent was included in trainings for the ISP.

35. On or about April 18, 2014, Respondent was noted to have attended his first ISP as the speaker. Insys's records also document Respondent to have been a speaker for the ISP almost three dozen more times on or about the following dates:

---

[2] Ibid.

[3] Ibid.

[4] Effective November 25, 2016, the medical license of Dr. Patharkar was permanently revoked by the Board via a Consent Order for indiscriminately prescribing Subsys to patients, among other offenses.

April 29, 2014
April 30, 2014
May 23, 2014
August 1, 2014
August 14, 2014
August 22, 2014
August 28, 2014
September 2, 2014
September 10, 2014
September 18, 2014
September 26, 2014
October 15, 2014
October 30, 2014
November 7, 2014
November 12, 2014
November 13, 2014
November 19, 2014
December 11, 2014
January 14, 2015
January 23, 2015
February 11, 2015
February 19, 2015
February 24, 2015
February 26, 2015
March 10, 2015
March 19, 2015
March 20, 2015
March 31, 2015
April 7, 2015
May 18, 2015
June 3, 2015
June 11, 2015
June 17, 2015

36. Respondent was compensated between $3,000 to $5,100 by Insys each time he was a speaker at an ISP.

37. Insys also compensated Respondent for ISP training events, as well as travel and meal related expenses.

38. Open Payments is a federal program that collects and makes information public about financial relationships between the health care industry and physicians pursuant to federal law. The Centers for Medicare & Medicaid Services ("CMS") collects information from manufacturers of drugs about payments and other transfers of value they make to physicians. Information about these payments beginning in mid-2013 is publicly available and searchable via the Internet. Prior to being made public, physicians are apprised of the payments made reported by drug manufacturers and provided the opportunity to file a dispute.

39. As reflected in Open Payments data, between in or around the end of 2013 and in or around the end of 2015, Respondent had received ongoing payments from Insys. During this same time, Respondent wrote over a hundred prescriptions for Subsys generating over $100,000 in revenue for Insys.

40. The following table illustrates Respondent's yearly prescribing of Subsys, the payments he received from Insys and the comparable amounts of all other TIRF products (Actiq (and generics), Fentora and Lazonda) he prescribed during the same years:

Year	**Subsys Prescriptions written by Respondent**	**Insys Payments to Respondent**	**All other TIRF medications prescribed**
2013	3	$123.24	0
2014	97	$70,259.48	0
2015	58	$61,982.24	0
2016	0	0	0
2017 – date	0	0	0
Total	158	$132,365.96	0

41. Respondent's payments from Insys ceased in or around the end of 2015, which was about the same time Respondent stopped writing prescriptions for Subsys for patients.

42. As detailed in the following counts, contrary to the overwhelming weight of the currently available medical evidence, the TIRF/REMS Prescriber Enrollment Form, the Knowledge Assessment, and the TIRF/REMS Patient-Prescriber Agreements, Respondent repeatedly and negligently prescribed Subsys to numerous patients under his care who were not diagnosed with cancer (and thus not complaining of breakthrough cancer pain).

COUNT I

43. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

44. D.G., a thirty-eight-year-old female, who had a history of lupus, urethral stenosis, and kidney stones, began seeing Respondent in or around March 2010.[5] In 2010, Respondent treated D.G. for complaints of frequent and painful urination, bladder outlet obstruction, urinary retention, hematuria, kidney stones, right flank pain, and a urinary tract infection. D.G. reported that she was taking one opioid, Hydrocodone – APAP and experienced pain if she waited to urinate. A bladder biopsy report at or around the end of 2010 stated that her specimen was benign and "negative for malignancy;" a urinalysis "did not support a diagnosis of a malignancy of the urinary tract;" and a CT Scan confirmed that she likely had medullary sponge kidney, a rare disorder whereby cystic malformations form in the collecting ducts of the kidneys that collect urine. Respondent started D.G. on medical therapy, Elmiron to treat bladder pain and discomfort and advised her about dietary modifications after he diagnosed her with cystitis chronic interstitial. She also underwent a urethral dilation and a cystoscopy.

[5] Pursuant to Board policy, patients are being referred to by initials to protect their privacy.

45. In 2011 and 2012, Respondent treated D.G. for urinary frequency and incontinence, incomplete emptying, and kidney stones. A CT scan of her abdomen and pelvis showed "evidence of medullary sponge kidney without evidence of collecting system or ureteral dilatation." Patient records provided by Respondent indicated that D.G. underwent surgery (Sacral neuromodulation or InterStim, whereby she received an implant that would stimulate nerves important for urinary functioning) by around the end of 2011 and InterStim reprogramming by around the end of 2012 to address her urinary issues. D.G. was noted to be taking Vicodin ES 7.5-750 mg in addition to her non-narcotic medications.

46. On or about January 16, 2014, D.G. returned to Respondent's office with complaints regarding her InterStim device, difficulty urinating, overactive bladder, and microscopic hematuria. D.G. underwent InterStim reprogramming and was referred for a series of follow-up testing. Patient records provided by Respondent reflected that D.G. continued to take Vicodin ES 7.7-750 mg in addition to her other narcotic medications.

47. On or about February 14, 2014, a CT Urogram showed that D.G. had small bilateral renal cysts.

48. On or about February 27, 2014, D.G. visited Respondent's office for a follow-up appointment. Patient records provided by Respondent stated that her "workup [was] negative for any significant renal or bladder lesions aside from bilateral renal calculi" and she would be scheduled for right extracorporeal shock wave lithotripsy, cystoscopy with hydrodistention, and InterStim reprogramming. D.G. reported that she had "right side flank pain," but was not noted to be taking any opioids at this time.

49. On or about March 7, 2014, Respondent wrote a prescription for D.G. for 120 units of Subsys, 200 mcg, which was twice the amount of the starting dosage that was mandated by the

FDA. On or about March 18, 2014, a pharmacy reported that D.G. filled her first prescription for 120 units of Subsys, 200 mcg.

50. On or about the same date, an Insys Reimbursement/Prior Authorization Request Form bearing Respondent's signature stated that D.G. needed Subsys because she suffered from lupus, although Subsys was mandated by the FDA for breakthrough cancer pain and Respondent was not treating her for lupus. The form incorrectly stated that Respondent specialized in "oncology/urology." The form also stated that D.G. tried Hydrocodone and Vicodin, but they were unsuccessful in treating her ailments, but the records provided by Respondent failed to support this assertion.

51. On or about March 11, 2014, D.G underwent cystoscopy with hydrodistention and was noted to be taking Hydrocodone/Acetaminophen by Respondent as part of her post-surgery follow-up plan. D.G. described her pain at five on a scale from zero to ten.

52. On or about April 8, 2014, D.G. underwent right extracorporeal shock wave lithotripsy and placement of a right double-J stent to treat her kidney stones. D.G. was noted to be taking Hydrocodone/Acetaminophen by Respondent as part of her post-surgery follow-up plan. D.G. described her pain at six/seven on a scale from zero to ten

53. On or about April 15, 2014, D.G. came to Respondent's office for a follow-up. D.G. reported "no new complaints at this time" and "feeling about the same as last visit." Patient records provided by Respondent for that visit lacked any documentation that D.G. was prescribed Subsys; the medication listed that she was taking the following opioids: Hydrocodone/Acetaminophen 7.5-325 mg, "1 tablet every 6 hours as needed for pain."[6]

[6] Hydrocodone/Acetaminophen 7.5-325 mg was listed twice.

54. On or about April 18, 2014, Respondent wrote a prescription for D.G. for 120 units of Subsys, 400 mcg. On or about April 18, 2014, a pharmacy reported that D.G. filled her second prescription for Subsys.

55. On or about April 30, 2014, Respondent saw D.G. for InterStim reprogramming. D.G. was being recommended for further extracorporeal shock wave lithotripsy. Patient records provided by Respondent for that visit lacked any documentation that D.G. was prescribed Subsys and her use of Hydrocodone/Acetaminophen 7.5-325 mg, "1 tablet every 6 hours as needed for pain" was noted to be discontinued as of that visit.

56. On or about May 13, 2014, D.G. underwent right extracorporeal shock wave lithotripsy. D.G. was stated to be taking Hydrocodone/Acetaminophen by Respondent as part of her post-surgery follow-up plan. D.G. described her pain at four on a scale from zero to ten. On or about May 30, 2014, she underwent left extracorporeal shock wave lithotripsy, left double-J stent placement, right stent removal, and cystoscopy. D.G. described her pain at four on a scale from zero to ten. On the post-surgery follow-up form as it related to what pain medication D.G. was taking, the following was handwritten in: "Nothing in chart."

57. On or about June 10, 2014, D.G. underwent left extracorporeal shock wave lithotripsy. D.G. was noted to be taking Hydrocodone/Acetaminophen by Respondent as part of her post-surgery follow-up plan. D.G. described her pain at zero on a scale from zero to ten.

58. On or about July 30, 2014, a radiologist reported that D.G.'s abdomen x-ray showed "stable calcifications [ ] seen in both kidneys."

59. On or about July 31, 2014, Respondent wrote a prescription for D.G. for 60 units of Subsys, 400 mcg. On or about August 8, 2014, a pharmacy reported that D.G. filled her third prescription for Subsys.

60. On or about the same date, an Insys Reimbursement Center Patient Authorization & Referral Form bearing Respondent's signature stated that D.G. needed Subsys because she was diagnosed with lupus. The form incorrectly stated that Respondent specialized in "urology/oncology" and D.G. could not tolerate medication by mouth. The form further stated that D.G. tried Oxycodone and Vicodin, but they were unsuccessful in treating her ailments, but the records provided by Respondent fail to support that statement.

61. On or about August 14, 2014, D.G. went to Respondent's office for follow-up on her kidney stones, which she reported was giving her flank pain. Months after Respondent had prescribed Subsys to D.G., patient records provided by Respondent for the first time mentioned that D.G. was taking Subsys, 400 mcg. Records also reflected she was taking the following other opioids: Hydrocodone/Acetaminophen 7.5-325 mg.[7] Records failed to explain why D.G. needed any narcotic medication, including one that was mandated to only be used for break through cancer pain, which D.G. did not have.

62. On or about August 16, 2014, Respondent wrote a prescription for D.G. for 60 units of Subsys 400 mcg. On or about August 18, 2014, a pharmacy reported that D.G. filled her fourth prescription for Subsys.

63. On or about August 22, 2014, an exam of the abdomen revealed that D.G. had renal stones. On or about the same date, she underwent left extracorporeal shock wave lithotripsy.

64. On or about September 11, 2014, D.G. visited Respondent's office for a follow-up regarding her kidney stones. D.G. reported that she felt "better compared to last visit" and her "condition has been stable since last visit," although she still had left flank pain that was

[7] Hydrocodone/Acetaminophen 7.5-325 mg was written twice.

"persistent." Patient records provided by Respondent for the second time mentioned that D.G. was taking Subsys, 400 mcg. Records also reflected that she was taking the following other opioids: Hydrocodone/Acetaminophen 7.5-325 mg.[8]

65. On or about October 2, 2014, Respondent registered D.G. for the TIRF REMS Access Program, in which Respondent and D.G.'s signatures appeared on documentation for the PPAF.[9] Patient records provided by Respondent for D.G. included a computer printout dated on or about October 2, 2014 indicating that the PPAF for D.G was submitted electronically on or about that date to the TIRF REMS Access Program. Significantly, Respondent registered D.G. for the TIRF REMS Access Program about seven months *after* issuing D.G. her first Subsys prescription in violation of the FDA rules. By around the beginning of October 2014, Respondent had written four prescriptions for Subsys for D.G. and D.G. had filled all of those prescriptions at a pharmacy.

66. On or about the same date, October 2, 2014, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the same date, a pharmacy reported that D.G. filled her fifth prescription for Subsys.

67. On or about October 14, 2014, D.G. underwent left extracorporeal shock wave lithotripsy. D.G.'s postoperative diagnosis continued to be "Medullary sponge kidney, left kidney stones and history of bilateral kidney stones."

[8] Hydrocodone/Acetaminophen 7.5-325 mg was written twice.

[9] On or about October 2, 2016, D.G.'s ability to fill TIRF prescriptions expired. There was no record that Respondent renewed the PPAF before or after the date of expiration. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

68. On or about November 13, 2014, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the next date, a pharmacy reported that D.G. filled her sixth prescription for Subsys.

69. On or about January 29, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the next date, a pharmacy reported that D.G. filled her seventh prescription for Subsys.

70. On or about February 5, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the same date, a pharmacy reported that it was provided with D.G.'s eighth written prescription by Respondent for Subsys to be filled for D.G.

71. On or about the same date, Respondent's signature appeared on a "Verbal Order Form (Oncology)" for a pharmacy to order and ship 120 units of Subsys, 400 mcg to D.G. "ASAP." The form noted that D.G. correctly was diagnosed with lupus; there was no indication that she suffered from an oncological related condition.

72. On or about February 19, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about February 24, 2015, a pharmacy reported that D.G. filled her ninth prescription for Subsys.

73. On or about March 4, 2015, D.G. went to Respondent's office for InterStim reprogramming for her urinary frequency and urgency. However, it was stated that the InterStim device was not working and could not be reprogrammed. Patient records provided by Respondent stated that D.G. was continuing to take Subsys, 400 mcg, but no explanation was provided as to why she was taking this medication and the effects of taking this medication.

74. On or about March 26, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the next date, a pharmacy reported that D.G. filled her tenth prescription for Subsys.

75. On or about April 14, 2015, Respondent operated on D.G., whereby she underwent an InterStim revision, where Respondent removed her InterStim device and replaced it with a new working one. D.G. described her pain as a three out of a scale of zero to ten. On the post-surgery follow-up form as it related to what pain medication D.G. was taking, an antibiotic was handwritten into the form.

76. On or about April 20, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about the same date, a pharmacy reported that D.G. filled her eleventh Subsys prescription.

77. On or about April 20 and 23, 2015. D.G. visited Respondent's office for follow-ups on her InterStim revision. Patient notes provided by Respondent reported that D.G. was doing well since her procedure. Subsys 400 mcg continued to be documented as part of D.G.'s medication list without any explanation, although Hydrocodone/Acetaminophen and Vicodin were noted to be discontinued at that time.

78. On or about May 12, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about May 18, 2015, a pharmacy reported that it was provided with D.G.'s twelfth written prescription by Respondent for Subsys to be filled for D.G. Patient records provided by Respondent for an office visit for D.G. on or around May 22 2015 reflected that D.G. was taking Subsys for "stone pain" and her right flank pain was "marginally controlled with Subsys." Further, comments from the visit summary stated: "Patient counseled to **absolutely avoid** taking Subsys in intervals less than every 4 hours or more than the recommended dose. I

was quite adamant about this." This counseling was noted to have taken place over a year *after* D.G. filled her first Subsys prescription.

79. On or about May 26, 2015, a CT scan of the abdomen and pelvis showed that D.G. had multiple renal stones, but no hydronephrosis. On or about the next date, D.G. went to Respondent's office for a follow-up. Patient records provided by Respondent stated that D.G. was taking Subsys, 400 mcg and D.G.'s right flank pain was "marginally well controlled with Subsys." Further, the comments included the following recommendation: "As her pain is currently resolved, I think observation is the best course of action at this time."

80. On or about June 8, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 600 mcg. On or about June 16, 2015, a pharmacy reported that it was provided with D.G.'s thirteenth written prescription by Respondent for Subsys to be filled for D.G.

81. On or about August 25, 2015, Respondent wrote a prescription for D.G. for 120 units of Subsys, 400 mcg. On or about the next date, a pharmacy reported that it was provided with D.G.'s fourteenth written prescription by Respondent for Subsys to be filled for D.G. By around the end of August 2015, Respondent had written over 150 Subsys prescriptions and received over $100,000 in payments from Insys as reflected in Insys's records.

82. On or about September 17 and November 23, 2015, D.G. saw Respondent for InterStim reprogramming. Patient records provided by Respondent continued to reflect that D.G. was taking Subsys 400 mcg, notwithstanding that FDA regulations mandated that Subsys was for the management of breakthrough pain in patients with cancer and at no point did the patient records provided by Respondent for D.G. indicate that D.G. had been diagnosed with or treated for cancer.

83. On or about December 14, 2015, Express Scripts notified Respondent that it "reviewed the information [Respondent] provided in support of [D.G.'s] request to obtain Subsys

Spray under his or her plan" and "this request [was] approved from 11/14/2015 until 12/13/2016." There was no documentation in the records provided by Respondent as to what "information" was sent to Express Scripts to support that Subsys approval.

84. On or about February 2, 2016, D.G. went to Respondent's office for a follow-up for her kidney calculi, urinary frequency, and urinary urgency. D.G. reported not having any pain as it related to her renal stones. Respondent noted that D.G. was doing well and she was recommended to make dietary modifications to prevent further kidney stone formation. Further, her medication list continued to include: Subsys, 400 mcg. On a form dated on or about February 2, 2016 corresponding to D.G.'s visit that date, it was stated that she had never had cancer.

85. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT II

86. The Attorney General repeats and re-alleges the General Allegations as if fully set forth herein.

87. J.B. was a thirty-nine-year-old female who became Respondent's patient in or around August 2011. J.B. presented with a history of kidney stones, abdominal pain, painful or difficult urination, urinary tract infections, and pelvic pain. She also had an allergy to morphine.

88. J.B. was referred to Respondent for consultation by J.B.'s primary care physician Scott Dorfner, M.D., who had been seeing J.B. since on or about December 6, 2006 for modification and control of her diet and pain in her upper thigh.[10]

89. At the time J.B. was referred to Respondent, J.B. had been experiencing flank pain, in which the "onset was new." Upon examination by Respondent, J.B. was noted to be in "mild-moderate distress," diagnosed with calculus of the kidney, and was referred for a CT scan to evaluate the kidney stone size and location. Patient records provided by Respondent did not indicate that J.B. was taking any medications at the time nor did Respondent prescribe any medication on this initial visit. Similarly, the records provided by Dr. Dorfner documented J.B.'s medication as "NONE" and the records lacked any documentation of any prescriptions by Dr. Dorfner for J.B.

90. About a week later, J.B. went to the emergency room of Lourdes Medical Center for lower abdominal and back pain, was diagnosed with diverticulitis of the colon, and was given a prescription for 20 tablets of Percocet 5/325 and directed to take two tablets orally every six hours as needed for pain. The notes provided by Respondent did not reflect any issues with J.B. taking oral opioid medications.

91. Between August 2011 and December 2013, over a span of about twenty-nine months, J.B. attended follow-up appointments with Respondent. Patient records provided by Respondent from J.B.'s visits indicated that J.B. continued to experience lower abdominal and back pain with "obvious discomfort" and "moderate to severe difficulty and pain starting the urine stream." In spite of the documented pain, patient records provided by Respondent did not list any

[10] According to patient records provided by Dr. Dorfner, J.B. worked as a billing manager for Hamilton Urology.

medications prescribed for J.B. for her pain. However, records from pharmacies reported that J.B. filled a prescription written by Respondent for 90 tablets of Oxycodone 30 mg on or about October 8, 2011. Further, J.B. continued to visit Dr. Dorfner between August 2011 and April 2013, J.B.'s last visit, and patient records provided by Dr. Dorfner documented that J.B. visited Dr. Dorfner for Behavior Modification Diet Control and J.B. was not taking any medication.

92. On or about December 10, 2013, J.B. visited Respondent complaining of stomach pain that caused burning when she urinated, abdominal and lower back pain, and nausea. Respondent noted that J.B. suffered from kidney calculi and flank pain, and had moderate to severe difficulty and pain starting the urine stream. According to patient records provided by Respondent, Respondent's care plan for J.B. determined that J.B. would be "started on fentanyl sublingual for pain control." This recommendation was not based upon a good faith assessment that J.B. had cancer, as she did not have cancer, but rather was justified by Respondent stating that J.B. was "unable to take [oral] pain medication due to GI issues and oral opioid intolerance and morphine allergy."

93. Further, the notes provided by Respondent did not elaborate on J.B.'s "oral opioid intolerance" nor did they explain why a less potent pain management regime was not recommended for J.B. Hospital records included in patient records provided by Respondent documented that Percocet was prescribed to J.B. in Lourdes Medical Center in or around August 2011. Pharmacy records reflected that Oxycodone was issued to J.B. by Respondent in or around October 2011.

94. On or about December 12, 2013, Respondent registered J.B. for the TIRF REMS Access Program, in which Respondent and J.B.'s signatures appeared on documentation for the PPAF.[11]

95. On or about the same date, Respondent wrote J.B. a prescription for 120 units of Subsys, 200 mcg, with instructions to use "1 spray 4 times daily" and "Deliver to home address". This was in spite of the documents and training Respondent underwent, whereby he acknowledged that the initial dose of Subsys should "always" be 100 mcg.

96. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Assistance/Prior Authorization Request Form for Insys to assist J.B. with obtaining her initial Subsys prescription. The form incorrectly stated that J.B. was diagnosed by Respondent with "bladder cancer," but correctly stated that Respondent's specialty was urology.

97. On or about the same date, email correspondence revealed that a manager for Insys Reimbursement Services alerted Respondent's Insys sales representative that she had received Respondent's reimbursement request for J.B. and since Respondent was a new doctor "opting in," she would assign the request for assistance to a more experienced representative to move the request forward expeditiously.

98. On or about December 13, 2013, J.B. filled Respondent's initial prescription for 120 units of Subsys, 200 mcg as reported by a pharmacy.

[11] On or about December 13, 2015, Respondent received a letter from the TIRF REMS Access Program stating that the Program required J.B. to complete a new PPAF every two years, and since J.B. had not done so, J.B. would not be able to have any TIRF medicine prescriptions filled, effective December 13, 2015. There was no evidence in the patient records provided by Respondent that J.B.'s PPAF was renewed by Respondent. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

99. On or about January 6, 2014, Respondent issued J.B. a prescription for 120 units of Subsys, 600 mcg, with instructions to use "1 spray 4 times daily." Patient records provided by Respondent are absent as to an explanation for why the dosage increased from 200 mcg to 600 mcg in such a short period.

100. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Assistance/Prior Authorization Request Form for Insys to assist J.B. with obtaining her second Subsys prescription. The form incorrectly stated that J.B. was diagnosed with "bladder cancer," but correctly stated that Respondent's specialty was urology.

101. On or about January 7, 2014, J.B. filled Respondent's second prescription for 120 units of Subsys, 600 mcg as reported by a pharmacy.

102. On or about February 19, 2014, a pharmacy reported that J.B. filled a third prescription for 120 units of Subsys, 600 mcg issued by Respondent on or about February 18, 2014.

103. On or about July 30, 2014, J.B. visited Respondent's office complaining of burning during urination. Patient records provided by Respondent stated that J.B. was suspected to have a urinary tract infection or inflammation of the kidney due to a bacterial infection and was referred for imaging studies and urine analysis and culture. Further, Respondent advised J.B. to "report to ER for intractable uncontrolled pain." The records did not state that any pain medication was prescribed to J.B. during that visit. Likewise, patient records provided by Respondent reflecting J.B.'s medication list at this time were absent of any notation about pain medication that J.B. was taking.

104. On or about November 3, 2014, Respondent saw J.B. for a follow-up visit regarding re-occurring flank pain, kidney stones, and urinary tract infections. Patient records provided by

Respondent stated that J.B. had severe lower quadrant pain with a history of ureteral/kidney stones, and Respondent suspected that she had acute diverticulitis with possible abscess and perforation, so he referred J.B. to St. Francis Medical Center for an emergent evaluation. Moreover, although patient records provided by Respondent pertaining to J.B.'s medication list at this time did not include Subsys and did not indicate that Respondent was writing J.B. a new prescription for Subsys, the notes did comment that J.B.'s pain had been managed in the past with Subsys.

105. On or about November 4, 2014, J.B. went to the emergency room at St. Francis Medical Center for complaints of pain to her left lower quadrant. On a scale from zero to ten, she self-reported a pain score of ten. According to the emergency room records from St. Francis Medical Center, J.B. underwent testing and was diagnosed with sigmoid colon diverticulosis, a condition in which small, bulging pouches develop in the digestive tract.

106. Between January 2015 and June 2015, pharmacy records reflected that Respondent wrote opioid prescriptions for J.B., all of which J.B. filled, as follows:

120 Tablets of Oxycodone HCL 15 mg on or about 1/29/2015
120 Tablets of Hydrocodone/Acetaminophen 10-325 mg on an unknown date, but filled on or about 2/25/2015
120 Tablets of Oxycodone/Acetaminophen 10-325 mg on or about 3/26/2015
120 Tablets of Oxycodone/Acetaminophen 10-325 mg on or about 4/26/2015
120 Tablets of Oxycodone 10-325 mg on or about 6/1/2015

107. Patient records provided by Respondent from between December 2013 and December 2015 did not reflect: (1) the continued use of Subsys on J.B. after in or around February 2014; (2) the initial and continued need for and effect of Subsys on J.B. between December 2013 and February 2014; (3) why Subsys was no longer being prescribed to J.B. after February 2014, even though J.B. was repeatedly issued high-dose prescriptions of Subsys between December 2013

and February 2014 and J.B. continued to suffer from kidney calculi, flank pain, difficulty and pain starting the urine stream, and urinary tract infections after February 2014; and (4) why Respondent prescribed other opioids on a monthly basis to J.B. between January and June 2015 instead of continuing to prescribe Subsys. However, patient records provided by Respondent show that J.B. was never diagnosed with cancer or, accordingly any type of associated breakthrough pain .

108. Between December 2013 and December 2015, Respondent had received more than $100,000 from Insys as reflected in Insys's records.

109. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT III

110. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

111. C.S. was a fifty-one-year-old male who became Respondent's patient in on or about May 2012. C.S. was noted to have had a history of acid reflux, GERD, anxiety, and overactive bladder.

112. C.S. was referred to Respondent for consultation by his primary care physician Vedat Obuz, M.D. During this same time, C.S. was also being treated by Shahzad Hussain, M.D. for complaints of pain in the shoulder, neck, low back, hip, elbow, and buttock area. According to patient records provided by Dr. Hussain, C.S. was diagnosed with issues, including but not limited to, rheumatoid arthritis, cervical spondylosis, lumbar spondylosis, and fibromyalgia

syndrome, and it was documented that he was taking Percocet as needed for pain at or around the time C.S. began seeing Respondent.

113. At the time of his initial visit on or about May 2012, C.S. complained of difficulty urinating, back pain, incomplete bladder emptying, dribbling when urinating, nocturia, and benign enlarged prostate. Respondent's notes documented that C.S. reported to Respondent that he was taking Oxycodone in addition to medications to treat cholesterol, GERD, blood clots, and insomnia. Respondent noted that he offered C.S. a prescription for Jalyn, a urinary retention medication that might treat an enlarged prostate, for medical therapy relating to his urinary retention issues.

114. Between June 2012 and October 2013, Respondent continued to treat C.S. for his urology issues, in which C.S. was diagnosed with kidney stones, urinary retention, urinary frequency, blood in his urine, flank and back pain, and an inguinal hernia. During this time, C.S. underwent multiple CT Scans of the abdomen and pelvis, whereby the findings noted that C.S. had non-obstructing renal calculi and renal cysts. He also had multiple bladder biopsies that were benign. Additionally, in or around August 2012, C.S. underwent lithotripsy (a treatment, typically using ultrasound shock waves, by which a kidney stone or other calculus is broken into small particles that can be passed out by the body) for his right renal calculi, in which C.S. described his pain post-procedure at seven on a scale from zero to ten and was given a prescription for Percocet 5 mg for the post-operative pain. Further, records from Robert Wood Johnson University Hospital documented that C.S. visited the emergency room on or about December 15, 2012 complaining of vomiting, nausea, and dizziness and rating his pain at zero on a scale of zero to ten, and C.S. was taking Oxycodone Hydrochloride 10-325 mg by mouth.

115. Moreover, patient records provided by Respondent stated that C.S.'s active medications included the following non-opioid medications: Nexium 40 mg, Rapaflo 8 mg, Pyridium 100 mg, Levaquin 500 mg, and Jalyn 0.5-0.4 mg. It was noted that C.S. complained in or around September 2013, that Jalyn caused him impotence.

116. On or about November 1, 2013, C.S. was seen by Respondent at his office. Patient records provided by Respondent documented that C.S. was experiencing "intermittent" pain from his kidney stones, which was rated as "moderate in severity," C.S.'s urinary frequency had increased, but he had no difficulty emptying his bladder, C.S. was dealing with sexual dysfunction as a result of his medication, and C.S.'s pain related to his impotence and hypogonadism was absent. Respondent prescribed C.S. a trial of Staxyn, a vasodilator to treat erectile dysfunction, and discussed his options for penile prosthesis insertion.

117. On or about December 3, 2013, C.S. had left extracorpeal shockwave lithotripsy after C.S. complained of flank discomfort primarily on his left side. Post-surgery follow-up documentation for C.S. indicated that C.S. was "in some pain," which he rated at five on a scale from zero to ten, and he was given Hydrocodone/Acetaminophen for the pain. A pharmacy's report confirmed that C.S. filled a prescription written by Respondent for 30 tablets of Hydrocodone/Acetaminophen 7.5-325 mg on or about December 3, 2013.

118. On or about December 20, 2013, C.S. came to Respondent's office for a follow-up appointment. Consistent with C.S.'s post-surgery follow-up paperwork, patient records provided by Respondent reflected that C.S. was taking an opioid, specifically Hydrocodone/Acetaminophen 7.5-325 mg (one tablet every six hours as needed for pain). Patient records provided by Respondent indicated that C.S. was diagnosed with "radiologically documented bilateral renal calculi," impotence, and vascular disorder of the penis.

119. On or about January 20, 2014, C.S. underwent more lithotripsy for his kidney stones.

120. On or about January 31, 2014, Respondent registered C.S. for the TIRF REMS Access Program, in which Respondent and C.S.'s signatures appeared on documentation for the PPAF.[12] Patient records provided by Respondent did not include any patient records pertaining to any visits by C.S. to Respondent's office on or about January 31, 2014.

121. On or about March 17, 2014, C.S. underwent lithotripsy. He was given Hydrocodone/Acetaminophen 7.5-325 mg for the pain resulting from the procedure. C.S. rated the pain at seven on a scale from zero to ten. On or about the same date, C.S. had a CT scan that revealed non-obstructing tiny intrarenal bilateral calculi measuring two to three mm in size.

122. On or about March 18, 2014, C.S. was admitted to Robert Wood Johnson Hospital for evaluation and pain control pertaining to a urinary tract infection and kidney stones, and was discharged on or about the next date with instructions to follow-up with outpatient treatment with Respondent.

123. On or about March 19, 2014, Respondent wrote C.S. a prescription for 120 units of Subsys, 600 mcg, with instructions to use "1 spray 4 times daily." Patient records provided by Respondent did not include an explanation for the sudden need for C.S. to take Subsys after C.S. had just been given a prescription for Hydrocodone/Acetaminophen 7.5-325 mg two days prior for post-operative pain. Respondent also did not adequately explain why C.S. was not started at a

[12] On or about January 1, 2016, Respondent received a letter from the TIRF REMS Access Program stating that the program required C.S. to complete a new PPAF every two years, and if he did not, C.S. would not be able to have any TIRF medicine prescriptions filled, effective January 31, 2016. There was no record in the patient file provided by Respondent for C.S. that Respondent thereafter renewed the PPAF for C.S., and no documentation to explain why no more prescriptions for Subsys were written for C.S. after January 2015. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

dose of 100 mcg as mandated by the FDA; C.S. was given a prescription for six times the recommended starting dose.

124. On or about the same date, a pharmacy reported that C.S. filled his initial prescription for 120 units of Subsys, 600 mcg.

125. On or about March 21, 2014, C.S. came to Respondent's office complaining of "excruciating pain" that he "couldn't tolerate" after having lithotripsy a few days prior. Patient records provided by Respondent documented that C.S. had two prescriptions for Hydrocodone/Acetaminophen 7.5-325 mg, but did not state that C.S.'s prescriptions for Hydrocodone/Acetaminophen 7.5-325 mg were insufficiently managing his pain relating to his kidney stones and post-operative pain from his kidney stone treatments.

126. On or about April 22, 2014, Respondent wrote C.S. a prescription for 120 units of Subsys, 600 mcg, with instructions to use "1 spray 4 times daily."

127. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Assistance/Prior Authorization Request for C.S. to receive assistance from Insys with a refill for Subsys, 600 mcg. Although Subsys was clearly meant to be prescribed for breakthrough pain related to cancer and not post-operative pain, the form stated that C.S. was diagnosed with acute post-operative pain, GERD, and ureteral stone. The form incorrectly reported that Respondent's specialty was "oncology" and not urology.

128. On or about the same date, a pharmacy reported that C.S. filled his second prescription for 120 units of Subsys, 600 mcg.

129. On or about April 28, 2014, C.S. visited Respondent for a follow-up appointment. Patient records provided by Respondent stated that C.S. complained of "bothersome left flank pain" and C.S. was diagnosed with microscopic blood in his urine, urinary frequency, kidney

stones, colic renal, incomplete emptying of his bladder, impotence, and enlarged benign prostate. Patient records for C.S.'s visit on or about April 28, 2014 did not reflect that C.S. was prescribed any opioids for his pain management.

130. On or about June 23, 2014, C.S. visited Respondent's office for testing pertaining to his urinary frequency, nocturia, and urinary urgency. C.S. was noted to have tolerated the procedure well. Patient records for C.S.'s visit on or about June 23, 2014 did not reflect that C.S. was prescribed any opioids for his pain management.

131. On or about July 21, 2014, C.S. came to Respondent's office for his test results from the prior month. Patient records provided by Respondent stated that C.S.'s pain relating to his kidney stones and impotence was absent, and he rated his kidney calculus, urinary frequency, and impotence as "moderate in severity." C.S. continued to complain of incomplete emptying of his bladder, frequent nighttime urination, and urinary urgency. Patient records for C.S.'s visit on or about July 21, 2014 did not reflect that C.S. was prescribed any opioids for his pain management.

132. On or about July 31, 2014, C.S. was issued another prescription by Respondent for 60 units of Subsys 600 mcg, with instructions to use "1 spray 4 times daily."

133. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Center Patient Authorization and Referral Form for C.S. to receive assistance from Insys with obtaining his Subsys prescription. The form correctly indicated that C.S. did not have cancer and that C.S. was diagnosed with other chronic pain and esophageal reflux. However, the form misrepresented that C.S. could not tolerate medication by mouth as records provided by Dr. Hussain documented that C.S. continued without any issues between May 2012 and August 2014 to take Percocet orally as needed for pain relating to his arthritis.

134. On or about August 4, 2014, Respondent saw C.S. to give him the test results of his testosterone panel that was completed on or about July 23, 2014. It was noted that C.S.'s pain relating to his impotence and kidney calculus was absent, and C.S. rated his quality of his erection as adequate, although he still continued to suffer from urinary frequency, nocturia, and incomplete bladder emptying. Patient records for C.S.'s visit on or about August 4, 2014 reflected for the first time that C.S. was prescribed Subsys 600 mcg, but the notes did not indicate why Subsys was being taken by C.S., the need for such a high dose of Subsys, and the length of time Subsys was prescribed to C.S.

135. On or about August 6, 2014, a pharmacy reported that C.S. filled his prescription for 60 units of Subsys, 600 mcg as issued by Respondent on or about July 31, 2014.

136. On or about August 7, 2014, C.S. had an MRI of the abdomen without and with contrast. According to the findings of the exam, C.S. had a renal pole lesion that had been stable in size since 2012, favoring benignity. It was also noted that he had stable benign liver lesions.

137. On or about August 18, 2014, a pharmacy reported that C.S. filled another prescription for 60 units of Subsys, 600 mcg issued by Respondent on or about August 16, 2014.

138. On or about October 14, 2014, C.S. visited Respondent for a follow-up. Although patient records stated that C.S.'s pain for his kidney calculus and impotence was "absent" and rated as "moderate in severity," C.S. was still noted to be taking Subsys, 600 mcg.

139. On or about the same date, Respondent wrote a prescription for C.S. for 120 units of Subsys, 600 mcg.

140. On or about the same date, October 14, 2014, Respondent's signature appeared on a "Verbal Order Form (Oncology)" for a pharmacy to order and ship 120 units of Subsys to C.S.

"ASAP." The form noted that C.S. was diagnosed with other chronic pain; there was no indication that he suffered from an oncological related condition.

141. On or about the same date, January 29, 2015, Respondent's signature appeared on a "Verbal Order Form (Oncology)" for a pharmacy to order and ship 120 units of Subsys to C.S. "ASAP." The form similarly noted that C.S. was diagnosed with other chronic pain; there was no indication that he suffered from an oncological related condition.

142. On or about February 2, 2015, C.S. filled a prescription for 120 units of Subsys, 600 mcg. The prescription was written by Respondent on or about January 29, 2015.

143. By on or about January 29, 2015, Respondent had received over $70,000 from Insys as reflected in Insys's records.

144. Between January 2015 and January 2016, patient records provided by Respondent did not document that C.S. was prescribed Subsys during this time and C.S.'s medication listed on patient records provided by Respondent did not include any opioids. Nonetheless, similar to the notes Respondent maintained while C.S. was known to be prescribed Subsys by Respondent, patient records for C.S. at this time stated that C.S.'s pain related to his kidney calculus and impotence was "absent" and his kidney calculus and impotence was rated as "moderate in severity." C.S. also continued to suffer from issues related to renal calculi, erectile dysfunction, urinary frequency, frequent nighttime urination, blood in his urine, urinary retention, and benign enlarged prostate, but he did not suffer from cancer.

145. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

    i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

    ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

    iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

    iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT IV

146. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

147. M.G. was a thirty-two-year-old male with a history of acid reflux, GERD, renal colic, and blood in his urine who became Respondent's patient in or around August 2014.

148. M.G. was referred to Respondent for consultation by M.G.'s primary care physician Samuel Preschel, M.D.

149. The day before his first visit with Respondent, M.G. went to the emergency room at Monmouth Medical Center and a CT scan revealed that he had a 2.3 cm stone on his left kidney. The emergency room staff administered morphine to M.G. for the pain. Emergency room records showed that M.G. had a history of kidney stones, including having had a right ureteral stone removed on or about May 22, 2007. Further, M.G. was given a prescription for Percocet for pain as needed when he was released from the emergency room and was advised to follow-up with Dr. Preschel.

150. During his initial visit with Respondent, patient records provided by Respondent revealed that M.G. presented with kidney calculi that M.G. rated as "severe," urinary frequency, microscopic hematuria, and flank pain that was deemed "persistent and required narcotic medication." Respondent referred M.G. for a series of tests to treat and further diagnose his ailments. The notes reflected that M.G. was taking Percocet 7.5-325 mg at the time, which was consistent with the emergency room records from Monmouth Medical Center.

151. On or about August 19, 2014, M.G. underwent left extracorporeal shockwave lithotripsy and stent placement as treatment for his stones. Post-surgery follow-up documentation stated that M.G. was prescribed Hydrocodone/Acetaminophen for the pain. It was noted that M.G.'s pain level was four on a scale from zero to ten, and he stated that he felt "extreme pain" and "then it would go away."

152. On or about the same date, a pharmacy reported that M.G. filled a prescription written by Respondent for 20 tablets of Hydrocodone/Acetaminophen 7.5-325 mg and 21 tablets of Phenazopyridine (also known as Pyridium) 100 mg for relief of pain related to urinary symptoms.

153. On or about August 19 and on or about 21, 2014, M.G. visited the emergency room for flank pain. He was administered morphine on the first visit and Percocet on the second visit for the pain. M.G. was diagnosed with renal colic on each visit.

154. On or about September 3, 2014, M.G. visited Respondent's office for a follow-up appointment. M.G. continued to present with the same symptoms as his initial visit and patient records provided by Respondent indicated that he was taking Percocet 7.5-325 mg.

155. Less than a month after M.G.'s initial visit, Respondent registered M.G. for the TIRF REMS Access Program, in which Respondent and M.G.'s signatures appeared on documentation for the PPAF.[13]

[13] On or about August 6 and September 6, 2016, Respondent received letters from the TIRF REMS Access Program stating that the program required M.G. to complete a new PPAF every two years, and since M.G. had not done so, M.G. would not be able to have any TIRF medicine prescriptions filled, effective September 6, 2016. Patient records for M.G. provided by Respondent did not have any evidence of a subsequent PPAF being completed by M.G. and Respondent, in order to enable Respondent to continue to prescribe Subsys to M.G. after September 6, 2016. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

156. On or about September 5, 2014, Respondent wrote M.G. a prescription for 120 units of Subsys, 600 mcg, with instructions to use "1 spray 4 times daily." The record was unclear as to why M.G. was started on dosage six times the starting amount mandated by the FDA; the recommended initial dose for Subsys should "always" be 100 mcg. However, the record was clear that M.G. was not diagnosed with cancer at this time or a later date and that the FDA mandated that Subsys be used only "for the management of breakthrough cancer pain in patients with cancer who are already receiving, and who are tolerant to, regular opioid therapy for their underlying persistent cancer pain."

157. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Center Patient Authorization and Referral Form for M.G. to obtain assistance from Insys with his Subsys prescription. The form stated that M.G. had difficulty swallowing, could not tolerate medication by mouth, and generic was not reliable for him. On the contrary, patient records provided by Respondent failed to document any issues that this thirty-two-year-old patient experienced with swallowing or an inability to take medication by mouth, although it was well-documented that M.G. had previously taken oral pain medications and continued to take oral pain medications without incident at the time of his Subsys prescription.

158. By on or about September 5, 2014, the date on which M.G. was first prescribed Subsys, Respondent had received over $25,000 from Insys, including a payment of $3,000 two days prior to the initial prescription date of Subsys to M.G., as reflected in Insys's records.

159. On or about September 23, 2014, M.G. underwent left extracorporeal shockwave lithotripsy and stent placement for his stones. It was noted that M.G.'s shockwave lithotripsy and stent placement procedures in or around August and in or around September 2014 were "effective at decreasing the stone burden tremendously."

160. On or about the same date, a pharmacy reported that M.G. filled a prescription for 30 units of Subsys, 600 mcg. Insys's records showed that M.G.'s private insurance denied coverage for 120 units of Subsys, 600 mcg on or about September 12, 2014, but Insys representatives were able to cover a prescription for M.G. for 30 units of Subsys at zero cost.

161. By around the end of September 2014, Respondent had received over $35,000 from Insys as reflected in Insys's records.

162. On or about October 3, 2014, a KUB (a radiographic examination to determine the location, size, shape, and malformation of the kidneys, ureters, and bladder, including detecting stones and calcified areas) was completed for M.G. The results showed no evidence of new calcifications in the abdomen or pelvis.

163. On or about October 15, 2014, at an office visit with M.G., Respondent noted that M.G.'s tests reflected "no evidence of stones" because they had been eradicated by his surgical procedures. Moreover, patient records provided by Respondent showed that M.G.'s use of Subsys was discontinued, but offered no explanation for the one-time Subsys prescription. Similarly, his opioid medications for Hydrocodone-Acetaminophen 7.5-325 mg (one tablet by mouth every six hours for pain) and Percocet 7.5-325 mg (one tablet by mouth every three hours as needed) were documented to be discontinued. At the time, M.G. was not noted to be taking any opioid medication.

164. On or about December 1, 2014, M.G. underwent a cystoscopy and stent removal. The post-surgery follow-up documentation stated that M.G. felt "slight burning" and described his pain at two on a scale from zero to ten. M.G. was prescribed Hydrocodone/Acetaminophen and Pyridium (an analgesic for urinary problems) for the pain. Patient records provided by Respondent stated that M.G.'s flank pain had been stable since his surgery in or around September 2014.

165. On or about the same date, it was reported that a pharmacy filled a prescription written by Respondent for M.G. for 20 tablets of Hydrocodone/Acetaminophen 7.5-325 mg. There was no corresponding documentation provided by Respondent noting that M.G. was having issues with orally consuming this opioid or explaining why Subsys was no longer the provider-preferred option for pain relief, as it had been noted to be a few months prior.

166. On or about the same date, a pharmacy reported that M.G. filled a prescription written by Respondent for 21 tablets of Pyridium 100 mg.

167. On or about January 6, 2015, M.G. had a CT Scan of the abdomen and pelvis and the findings revealed that M.G. had a four mm obstructing stone in the midureter and a one mm non-obstructing stone in the mid-to-lower pole region of the right kidney.

168. On or about April 21, 2015, M.G. visited Respondent for an office visit. Patient records provided by Respondent documented that M.G. complained of abdominal pain and underwent updated imaging in January 2015 that demonstrated that he still had issues with kidney stones, but noted that M.G. did not have any updated procedures to address these new kidney stones and had been "taking Percocet since January 2015." Further, M.G. was counseled on dietary modifications that might decrease the likelihood of urinary stone formation and additional urinary analysis tests were ordered to rule out infection secondary to obstruction.

169. On or about May 12, 2015, M.G. had a follow-up appointment with Respondent to review his lab and imaging results. Patient records indicated that M.G.'s updated imaging from April 2015 showed that M.G. had a three mm stone with moderate left excess fluid and one mm non-obstructing right renal stone. Respondent discussed surgical treatment options with M.G., including ureteroscopy and laser lithotripsy to treat the stones. Further, it was documented that

M.G. continued to take one tablet of Hydrocodone/Acetaminophen 7.5-325 mg every six hours as needed for pain.

170. On or about June 2, 2015, patient records provided by Respondent documented that M.G. called Respondent's office to cancel his scheduled surgical appointment for on or about June 4, 2015, stating that his wife was having a baby and he would not be able to return for a few months.

171. On or about October 7, 2016, Respondent's office documented that M.G. called to schedule an appointment, but would call back after the holidays to do so. It was noted that M.G. had last visited Respondent's office on or about May 12, 2015.

172. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT V

173. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

174. L.L., a male with a history of acid reflux, gastrointestinal problems, and arthritis was referred to Respondent for a consultation by his primary care physician Martin Riss, D.O. at the age of sixty-four.

175. At the time of his initial visit with Respondent on or about June 12, 2013, L.L. complained of back pain for several days. L.L.'s noted medications were Celebrex, Aspirin, Nexium, and Pravastatin Sodium. After examining him, Respondent diagnosed L.L. with

microscopic blood in his urine, unspecified abdominal pain, frequent nighttime urination, and age-associated prostate gland enlargement that might cause urination difficulty, although no difficulty or pain starting his urinary stream was noted. L.L. was referred for follow-up testing by Respondent.

176. On or about August 7, 2013, Respondent advised L.L. that he had atypical cytology results and had a bilateral inguinal hernia. Respondent referred L.L. to his primary care physician to consider a surgical referral.

177. On or about August 31, 2013, Michael M. Schulman, M.D. evaluated L.L.'s hernia. Dr. Schulman noted that the hernia had been present for years and had not bothered L.L., except that it was getting bigger. L.L. advised that he would like his hernia removed.

178. On or about September 24, 2013, L.L. underwent surgical removal of the hernia.

179. Between October 2013 and March 2014, patient records provided by Respondent indicated that L.L. continued to follow-up with Respondent and underwent additional tests for his issues relating to microscopic blood in his urine, frequent urination, urinary urgency, and an enlarged prostate that obstructed his urinary tract system. These tests included a cystoscopy and bladder biopsy, which revealed no evidence of masses or tumors. Further, it was noted that L.L. was prescribed Hydrocodone/Acetaminophen and had requested a prescription for Vicodin, and also that L.L. was experiencing pain associated with his inguinal hernia and its repair surgery.

180. On or about March 20, 2014, a pharmacy reported that L.L. filled a prescription written by Respondent for 20 tablets of Hydrocodone/Acetaminophen 7.5-325 mg.

181. On or about the same date, a pharmacy reported that L.L. filled a prescription written by Respondent on or about March 20, 2014 for 21 tablets of Pyridium 100 mg.

182. On or about March 24, 2014, Respondent registered L.L. for the TIRF REMS Access Program, in which Respondent and L.L.'s signatures appeared on documentation for the PPAF.[14]

183. On or about the same date, Respondent wrote L.L. a prescription for 120 units of Subsys, 600 mcg, with instructions to use "1 spray 4 times daily." Patient records provided by Respondent did not adequately explain why L.L. was not started at a dose of 100 mcg as mandated by the FDA, but was issued a dosage six times the mandated amount. Also, the records were void of any complaints of breakthrough pain by L.L. and L.L. was at no point diagnosed with cancer.

184. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Assistance/Prior Authorization Request Form for Insys to assist L.L. in obtaining 120 units of Subsys, 600 mcg. The form stated that L.L. was diagnosed with acute post-operative pain (from his inguinal hernia surgery) and GERD, had previously tried/failed in taking Hydrocodone, and had difficulty swallowing medication by mouth. On the contrary, the Prescriber Enrollment Form signed by Respondent stated that Respondent understood that TIRF medications "must not be used to treat any contraindicated conditions . . . such as [ ] postoperative pain." Moreover, pharmacy records reflected that L.L. filled a prescription for Hydrocodone about four days prior to Respondent writing a prescription for L.L. for Subsys and there was no indication in the records that Hydrocodone was inadequate or unsuitable. Further, this one prescription for Hydrocodone written by Respondent did not establish that L.L. was opioid tolerant.

[14] On or about February 23 and on or about March 25, 2016, Respondent received letters from the TIRF REMS Access Program stating that the program required L.L. to complete a new PPAF every two years, and since L.L. had not done so, L.L would not be able to fill any TIRF medicine prescriptions, effective March 25, 2016. Subsequently, Respondent did not submit a second PPAF for L.L. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

185. On or about the next date, March 25, 2014, a pharmacy reported that L.L. had filled his prescription for 120 units of Subsys, 600 mcg.

186. About a month later, L.L. visited Respondent's office for a follow-up and it was noted that L.L. suffered from frequent nighttime urination, an inflamed prostate, and urinary retention. At this time, L.L. underwent transurethral microwave thermotherapy to address his inflamed prostate and had a urethral catheter inserted. Although patient records provided by Respondent stated that L.L. tolerated the thermotherapy well, it was noted that L.L. complained of pain with the associated catheter and Respondent prescribed Subsys "for break through pain on opioid therapy." Nevertheless, Subsys was not intended to be used for temporary pain caused by routine insertion of a catheter; it was intended for breakthrough cancer pain, which L.L. did not have.

187. By around the end of April 2014, Respondent had received over $3,000 from Insys as reflected in Insys's records.

188. On or about April 21, 2014, a pharmacy reported that L.L. filled a prescription written by Respondent for 21 tablets of Pyridium 100 mg.

189. Between April 2014 and May 2016, L.L. had follow-up appointments with Respondent and was seen for issues of impotence, day and nighttime urinary frequency, urinary retention, microscopic hematuria, and a benign enlarged prostate. Follow-up testing on or about January 9, 2016 indicated that L.L. had no masses, lesions, diverticula, or trabeculation. Indeed, at no point during this time did L.L. receive a cancer diagnosis. Patient records provided by Respondent did not provide any explanation as to why Respondent wrote a Subsys prescription for L.L. in March 2014 and then continued to treat L.L for the same urological issues at least two more years without writing any further Subsys prescriptions.

190. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT VI

191. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

192. M.A., a thirty-nine-year-old male, who had a history of diabetes, was referred to Respondent by his primary care physician Sanjay Kumar, M.D. in or around July 2011. M.A. advised Respondent that he was interested in getting a circumcision. Patient records provided by Respondent diagnosed M.A. with phimosis, a narrowing of the opening of the foreskin of the penis that prevents the penis from retracting properly. After being advised of the risks and benefits, M.A. expressed a desire to proceed with circumcision.

193. On or about July 26, 2011, M.A. underwent a circumcision as performed by Respondent.

194. On or about the same date, M.A. filled a prescription for 60 tablets of Hydrocodone/APAP 7.5-750 mg. Respondent wrote the prescription on or about the same date with instructions for M.A. to take one tablet every six hours for pain as needed.

195. On or about December 7, 2011, M.A. visited Respondent's office for a follow-up on his circumcision. It was noted that he was doing well. According to patient records provided by Respondent, M.A. was taking Vicodin ES 7.5-750 mg and had been prescribed a vasodilator to treat issues M.A. was having with erectile dysfunction.

196. About six months later, M.A. visited Respondent complaining of issues with impotence and hypogonadism. He complained of having no energy. Respondent referred M.A. for follow-up testing.

197. Between June and September 2012, M.A. was seen by Respondent for continuous erectile dysfunction issues, including penile fibrosis, and a penile prosthesis was implanted. He complained of excruciating pain in the pelvic area. Records provided by Respondent stated that M.A. took Endocet 7.5-325 mg and Vicodin 7.5-325 mg for pain as needed about every four to six hours.

198. Documentation of Respondent's post-procedure telephone call to M.A. after his penile prosthesis surgery in or around July 2012 stated that M.A. was prescribed Vicodin for his pain related to the procedure. Pharmacy records confirmed that during this time M.A. filled the following opioid prescriptions as prescribed by Respondent: 80 tablets of Endocet 7.5-325 mg on or about July 13; 60 tablets of Oxycodone/APAP 7.5-325 mg on or about July 20; 30 tablets of Oxycodone/APAP 10-325 mg on or about July 25; 60 tablets of Oxycodone/APAP 5-325 mg on or about August 8; 60 tablets of Oxycodone/APAP 5-325 mg on or about August 23; 90 tablets of Acetaminophen/Codeine 300-30 mg on or about August 30; 90 tablets of Acetaminophen/Codeine 300-30 mg on or about September 12; and 90 tablets of Acetaminophen/Codeine 300-30 mg and 30 tablets of Hydrocodone/APAP on or about September 24, 2012.

199. On or about September 20, 2012, M.A. came to Respondent's office for an emergency visit due to an abscess on the upper part where his penile prosthesis placement was positioned. Patient records provided by Respondent stated that M.A. complained of "excruciating pain, swelling, [and] soreness." M.A. was thereafter scheduled for additional testing and incision and drainage of his abscess.

200. On or about October 1, 2012, M.A. filled a prescription written by Respondent for 30 tablets of Hydrocodone/APAP 7.5-750 mg.

201. On or about October 3, 2012, M.A. visited Respondent's office to have staples removed. It was noted that M.A. felt a lot better and was healing appropriately. Patient records provided by Respondent indicated that M.A. was taking Vicodin ES 7.5-750 mg for pain every four to six hours as needed. Pharmacy records revealed that M.A. filled a prescription on the same date for 90 tablets of Endocet 7.5-325 mg.

202. On or about October 10, 2012, Respondent issued a prescription to M.A. for 60 tablets of Percocet 10/325 mg to be taken orally every six hours. Pharmacy records stated that M.A. filled a prescription on the same date for 60 tablets of Endocet 10-325 mg.

203. On or about October 17, 2012, M.A. came for an emergency visit to Respondent's office complaining of severe pain and a wish to have a refill on his medication. Patient records provided by Respondent reflected that Respondent advised M.A. to seek pain management consultation for his chronic pain. In addition, Respondent noted that the penile prosthesis was in a good position and appeared to be intact and functional.

204. On or about October 22, 2012, M.A. filled a prescription written by Respondent for 30 tablets of Hydrocodone/APAP 7.5-750 mg.

205. On or about October 25, 2012, M.A. filled prescriptions written by Respondent for 60 tablets of Endocet 10-325 mg and 60 tablets of Tramadol HCL 50 mg.

206. Between November 2012 and October 2013, M.A. continued to visit Respondent's office complaining of constant pain that he believed was associated with his prosthesis. Respondent continued to check and monitor M.A.'s prosthesis and scheduled M.A. for prosthesis revisions and repairs, and follow-up appointments. During this time, M.A. was reported by

pharmacies to have filled the following pain management prescriptions written by Respondent: 80 tablets of Endocet 10-325 mg on or about November 8 and 80 tablets of Endocet 10-325 mg on or about November 21, 2012; and 30 tablets of Oxycodone/Acetaminophen 10-325 mg on or about January 2, 30 tablets of Hydrocodone/Acetaminophen 7.5-750 mg on or about January 12, and 80 tablets of Oxycodone/Acetaminophen 10-325 mg on or about January 19, 2013.

207. On or about March 24, 2014, M.A. saw Teresa Thomas, M.D. for issues related to carbon monoxide poisoning he experienced about three weeks prior. According to patient records provided by Dr. Thomas, it was noted that M.A. suffered residual dizziness from the carbon monoxide poisoning and continued to have insulin dependent diabetes. M.A. was documented to have taken opioids, including Oxycodone, Hydrocodone, and Tramadol in 2012, but was not prescribed any opioids at the time of that visit with Dr. Thomas.

208. On or about August 20, 2014, M.A. returned to Respondent's office for a consultation as recommended by Dr. Kumar. It was noted that M.A. complained of issues of impotence and Respondent directed M.A. to be evaluated. Patient records provided by Respondent noted that in addition to taking anti-inflammatory medication, testosterone, antibiotics and medication for diabetes and high blood pressure, M.A. was taking the following opioids at the time: Endocet 7.5-325 mg, Vicodin ES 7.5-300 mg, and Percocet 10-325 mg. In or around August 2014, M.A. was admitted to Monmouth Medical Center for a penile shaft infection.

209. On or about August 21, 2014, Respondent’s signature appeared on an Insys Reimbursement Center Patient Authorization and Referral Form for M.A. to obtain assistance from Insys for a prescription for Subsys. Notwithstanding that, Subsys was only permitted to be prescribed for patients with breakthrough cancer pain, the form correctly stated that M.A. was diagnosed with other chronic pain, other complications due to genitourinary device, implant, and

graft, and chronic pain due to trauma. The form also stated that M.A. had difficulty swallowing/tolerating medication by mouth, although patient records provided by Respondent did not document that M.A. had any difficulty taking medication orally. The form further stated that Respondent was "ordering 15 day supply twice" of 120 units total of Subsys, 600 mcg, which was contrary to the recommendations that the initial prescription of Subsys is "always" supposed to be 100 mcg.

210. On or about the same date, Respondent's signature appeared on an "Oncology Referral Form" for a pharmacy stating that an "order for 15 day supply X2" for 120 Subsys, 600 mcg needed to be shipped to M.A. "ASAP." The form stated that M.A. was diagnosed with other complications due to genitourinary device, implant, and graft, and chronic pain due to trauma. The record did not explain why M.A.'s current opioid prescriptions were inadequate to address his pain. Insys's records reflect that attached to the "Oncology Referral Form" were copies of two prescriptions for M.A. for Subsys 600 mcg, 60 units written by Respondent, one dated August 21 and the other dated September 5, 2014. 600 mcg was six times the starting dosage for Subsys that was mandated by the FDA. On the top of each copy of the two prescriptions appeared the date August 21, 2014 and "From:6095815900". The number 609-581-5900 is the telephone number for Respondent's office.

211. On or about the same date, August 21, 2014, M.A. underwent an MRI of the pelvis and the findings noted that M.A. was stable "post penile prosthesis implant placement," and there were no defects or masses in the urinary bladder, no evidence of inguinal hernia, hematoma, or lymphadenopathy, and no fluid collection or abscess formation in the pelvis or scrotum.

212. On or about September 5, 2014, Respondent wrote a prescription for M.A., for 60 units of Subsys, 600 mcg, with instructions for a "15 day supply" and "1 spray 4x daily." On or

about October 1, 2014, a pharmacy reported that M.A. filled his prescription for 60 units of Subsys, 600 mcg.

213. On or about September 3 and 17, 2014, M.A. went to Respondent's office complaining of purulent drainage of his penis after scratching himself profusely. Respondent instructed M.A. to keep the prosthesis deflated for two weeks and scheduled M.A. for penile prosthesis removal. Patient records provided by Respondent noted that M.A. was taking Subsys 600 mcg, "1 spray sub lingual every 4-6 hours," Endocet 7.5-325 mg, Vicodin ES 7.5-300 mg, and Percocet 10-325 mg for pain. However, the notes reflected that M.A.'s pain was "intermittent."

214. On or about October 14, 2014, Respondent registered M.A. for the TIRF REMS Access Program, in which Respondent and M.A.'s signatures appeared on documentation for the PPAF. According to patient records provided by Respondent, Respondent received confirmation from the TIRF REMS Access Program that the PPAF was successfully submitted on this date.[15] Contrary to the requirements that physicians register a patient for the TIRF REMS Access Program *prior* to writing an initial prescription for a patient, M.A. was first registered about two months *after* Respondent wrote M.A.'s initial prescription for Subsys, and M.A. filled his initial Subsys prescription about two weeks before Respondent and M.A.'s signatures appeared on documentation for the PPAF.

215. On or about the same date, Respondent wrote a prescription for 120 units of Subsys, 600 mcg with instructions for "1 spray 4x daily."

[15] On or about October 14, 2016, M.A.'s ability to fill TIRF prescriptions expired. There was no record that Respondent and M.A. renewed M.A.'s PPAF before or after this date. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

216. On or about the same date, Respondent's signature appeared on an Insys Reimbursement Center Patient Authorization and Referral Form for M.A. to obtain assistance from Insys for a prescription for Subsys. "Corrected Order" was handwritten on the top of the form. The form stated that M.A. was diagnosed with other complications due to genitourinary device, implant, and graft, and chronic pain due to trauma. Insys's records reflected that attached to the form was a prescription dated on or about October 14, 2014 written by Respondent for Subys 600 mcg, 120 units. The words "correction order" was handwritten on top of the prescription.

217. On or about October 24, 2014, a pharmacy reported that M.A. filled his prescription for 60 units of Subsys, 600 mcg.

218. On or about November 7, 2014, M.A. underwent removal of his penile prosthesis. It was noted that M.A. had evidence of erosion of the prosthesis cylinder to the glans, since M.A. had "not been compliant as far as deflating the prosthesis." Respondent's post-surgery follow-up notes indicated that M.A. was taking Subsys for pain, which M.A. rated at five on a scale from zero to ten.

219. On or about November 12, 2014, M.A. visited Respondent for his impotence issues and a follow-up on his penile prosthesis removal. Patient records provided by Respondent stated that M.A.'s pain associated with his impotence was "intermittent" and he was taking Subsys 600 mcg, Endocet 7.5-325 mg, Vicodin ES 7.5-300 mg, and Percocet 10-325 mg. However, the notes did not outline any dates or explain the effects, need, and use for all the opioids listed under M.A.'s medication. On or about November 13, 2014, Respondent wrote M.A. a prescription for 120 units of Subsys, 600 mcg with instructions to use "1 spray 4x daily."

220. On or about December 9, 2014, a pharmacy reported that M.A. filled his prescription for 120 units of Subsys, 600 mcg.

221. On or about December 16, 2014, Respondent wrote M.A. a prescription for 120 units of Subsys 600 mcg with instructions to use "1 spray 4x daily."

222. On or about December 18, 2014, a pharmacy reported that M.A. filled his prescription for 120 units of Subsys, 600 mcg.

223. The patient records provided by Respondent from between November 2014 and May 2015 did not document that M.A. had any visits with Respondent nor that M.A. received any medical care from Respondent. Records provided by Dr. Thomas indicated that M.A. visited Dr. Thomas's office on or about January 7, 9, and 14, 2015 during this time for follow-up appointments. The records provided by Dr. Thomas listed M.A.'s current opioid medication as Fentanyl 600 mcg sublingual spray, which she started taking on or about October 1, 2014; Dr. Thomas did not document that M.A. was taking any other opioid medication at this time.

224. On or about May 19 and June 16, 2015, M.A. visited Respondent and presented with impotence. The notes provided by Respondent reflected that M.A. had his prosthesis removed in November 2014, and since that time, had difficulty urinating, mild painful urination, and a weak stream, and experienced penile and left testicle pain, but no abdomen or perineal pain. According to the unexplained medication lists incorporated in patient records for M.A. from his visits on or about May 19 and on or about June 16, 2015, M.A.'s medication list included Subsys 600 mcg (one spray sublingual every six hours as needed), Subsys 600 mcg (one spray sublingual every four to six hours), and Endocet 7.5-325 mg. However, pharmacy records did not confirm that M.A. was taking Endocet any time in 2015, though they did reference M.A. taking Subsys 600 mcg between November 2014 and February 2015.

225. By around the end of 2015, Respondent had received over $100,000 from Subsys.

226. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

    i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

    ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

    iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

    iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT VII

227. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

228. W.R. was a thirty-eight-year-old male, who had a history of erectile dysfunction, right lower abdominal pain with dysuria and microscopic hematuria, overactive bladder, kidney stones, and impotence, an allergy to Vicodin, and a family history of prostate cancer (father, brother, and grandfather). Patient records from W.R.'s prior urologist showed that he was taking Tramadol HCL 50 mg and Acetaminophen/Tramadol Hydrochloride 37.5-325 mg in and around February 2012.

229. On or about June 18, 2012, W.R. had an initial visit at Respondent's office for complaints of burning sensation while urinating and microscopic hematuria with "persistent and mild" pain that was "too painful when walking or sitting." W.R. reported that he was taking Celebrex 200mg and Tramadol HCL/APAP 37.5 mg for pain. W.R. was thereafter scheduled for follow-up tests.

230. On or about July 9, 2012, W.R had a follow-up visit. He presented showing signs of dysuria and impotence and complained of pain while urinating. Patient records provided by Respondent did not indicate that W.R. was taking any opioids, but requested that his Pyridium (an analgesic for urinary problems) be renewed for his urinary frequency.

231. On or about August 10, 2012, W.R. visited Respondent's office for his dysuria and impotence. When Respondent asked W.R. about the Naproxen Sodium 550 mg (a nonsteroidal anti-inflammatory drug (NSAID)) he had prescribed, W.R. stated: "I can now pee without much pain at all."

232. On or about August 31, 2012, W.R. visited Respondent for a follow-up on his Naproxen. W.R. reported that he finished taking the medication and was "doing much better." However, he complained of nocturia and indicated he was being tested for diabetes.

233. On or about November 5, 2012, W.R. underwent a cystoscopy to further evaluate his bladder function. Patient records provided by Respondent indicated that the cystoscopy showed no bladder or kidney lesions and W.R. was recommended for therapy regarding the timing of his voiding and dietary modification, and prescribed Naproxen 500 mg.

234. Between January and April 2013, Respondent treated W.R. for bladder outlet obstruction, dysuria, urinary frequency, impotence, and nocturia, and W.R. continued to complain of a "burning" pain when urinating that was "rated as 3/10 in severity." In or around the end of March 2013, W.R. underwent surgery for urethral dilation, urethrectomy, and cystoscopy, and reported in or around April 2013 that he could completely empty his bladder and his dysuria was resolved, but still had issues with nocturia. Patient records provided by Respondent did not document that W.R. was taking any opioids.

235. On or about March 19, 2013, W.R. filled a prescription written by Respondent for 30 units of Hydrocodone/APAP 7.5-325 mg as reported by a pharmacy.

236. On or about July 16, 2013, W.R. went to Respondent's office to have a uroflow exam as it related to his treatment for his incomplete voiding. Patient records provided by Respondent stated that W.R. was "feeling significantly better since his last visit," his condition

had "been mostly well controlled since surgery," and he was "experiencing no pain." As it related to his continued issues with impotence, it was noted that W.R did not have painful erections. In addition, the medication section stated that W.R. was taking Hydrocodone/Acetaminophen 5-500 mg and Tramadol Hydrochloride/Acetaminophen 37.5-325 mg, but the documentation was unclear as to when and why he started taking these opioids.

237. On or about November 22 and December 9 and 20, 2013, W.R. visited Respondent's office for urinary frequency, incomplete voiding, and impotence. W.R. stated that he was experiencing burning while urinating and frequent nighttime urination. Although patient records provided by Respondent indicated W.R. was not experiencing any pain, the notes continued to show that W.R. was taking Hydrocodone/Acetaminophen 5-500 mg and Tramadol Hydrochloride/Acetaminophen 37.5-325 mg.

238. On or about January 17, 2014, W.R. underwent a CT urography and the results stated that he had a "normal urographic exam" and there was no "abnormality to explain the hematuria." On or about three days later, W.R. underwent a cystoscopy; the exam indicated that he had a urethral stricture, which was restricting the flow of urine from the bladder, and a "markedly enlarged prostate." Patient records provided by Respondent documented that W.R. had "intermittent" pain related to the urethral stricture and microscopic hematuria, and he was taking Hydrocodone/Acetaminophen 5-500 mg and Tramadol Hydrochloride/Acetaminophen 37.5-325 mg. Further, the records indicated that a new medication – Hydrocodone/Acetaminophen 7.5-325 mg – was added to W.R.'s list as needed for any post-operative pain, despite W.R. rating his pain as zero out of a ten. Respondent scheduled W.R. for transurethral microwave therapy to address his urinary issues.

239. On or about February 17, 2014, W.R. underwent transurethral microwave therapy, in which he received a catheter. He reported experiencing a two out of a ten on the pain scale and was given Hydrocodone/Acetaminophen and Pyridium for pain. Patient records provided by Respondent reported that W.R. was seen for benign prostatic hypertrophy, he felt the "same compared to last visit," and he tolerated the therapy well. On or about four days later at his follow-up appointment, W.R. was "experiencing no pain" related to the urethral stricture and had "burning" related to his enlarged prostate. Patient records provided by Respondent listed without explanation the following opioids: Hydrocodone/Acetaminophen 5-500 mg, Tramadol Hydrochloride/Acetaminophen 37.5-325 mg, and Hydrocodone/Acetaminophen 7.5-325 mg.

240. On or about February 19, 2014, W.R. filled a prescription written by Respondent for 20 units of Hydrocodone/APAP 7.5-325 mg as reported by a pharmacy.

241. On or about February 24, 2014, W.R. visited Respondent's office for a urinary tract infection, enlarged prostate, and urinary retention. Patient records provided by Respondent documented that W.R. had to be rushed to the hospital after his catheter was removed, so it had to be put back in. On or about two days later, Respondent removed W.R.'s catheter at an office visit.

242. On or about March 7, 2014, W.R. came to the office complaining of pain while urinating; the pain was documented to be "significant" and "persistent" ("rated as 7/10 in severity") and he was "feeling worse compared to last visit." Patient records provided by Respondent as to that office visit indicated that W.R. was given two new medications – Naproxen 500mg as needed for pain and Bactrim DS 800-160 mg for treatment of his prostatitis – and urinalysis was needed for his continued urinary tract infection. Hydrocodone/Acetaminophen 5-500 mg, Tramadol

Hydrochloride/Acetaminophen 37.5-325 mg, and Hydrocodone/Acetaminophen 7.5-325 mg[16] remained on W.R.'s medication list as continuing medication with no further explanation. The documentation lacked any mention of Subsys and it being prescribed to W.R. at that visit.

243. On or about the same date, Insys's records reflected that Respondent registered W.R. for the TIRF REMS Access Program, in which Respondent and W.R.'s signatures appeared on documentation for the PPAF.[17]

244. On or about the same date, an Insys Reimbursement/Prior Authorization Request Form bearing Respondent's signature stated that W.R. required Subsys because he was diagnosed with pain in his thoracic spine. The form incorrectly stated that Respondent specialized in "oncology/urology" and that W.R. had tried and failed Hydrocodone, Oxycodone, Vicodin, and Conzip (Tramadol). On the top of the form was the date March 7, 2014 and "From:6095815900". The number 609-581-5900 is the telephone number for Respondent's office.

245. On or about the same date, Insys and pharmacy records showed that Respondent wrote a prescription for W.R for 120 units of Subsys, 600 mcg. The initial Subsys prescription was six times the amount mandated by the FDA. Patient records provided by Respondent did not document why W.R. needed to be started on a Subsys dose that was substantially above the mandated FDA amount or that Respondent wrote this prescription for W.R.

[16] Hydrocodone/Acetaminophen 7.5-325 mg was listed twice.

[17] On or about March 8, 2016, Respondent was provided with a patient deactivation notice letting him know that a new PPAF was never provided by Respondent for W.R. and W.R. would not be able to fill TIRF medicine prescriptions. There was no record that Respondent and W.R. renewed the PPAF before or after this date of expiration. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

246. On or about March 11, 2014, W.R. filled his first prescription for Subsys, 600 mcg, 120 units as noted in pharmacy records.[18] FDA regulations stated that Subsys was for the management of breakthrough pain in patients with cancer; at no point did the patient records provided by Respondent for W.R. indicate that W.R. had been diagnosed with or treated for cancer.

247. On or about the same date, Express Scripts notified Respondent that it "reviewed the information [Respondent] provided in support of [W.R.'s] request to obtain Subsys Spray under his or her plan" and "this request [was] approved from 02/09/2014 until 03/11/2015." There was no documentation in the records provided by Respondent as to what "information" was sent to Express Scripts to support the Subsys approval. There was no record that W.R. had cancer or was suffering from any kind of associated breakthrough pain.

248. On or about March 18, 2014, patient records provided by Respondent stated that W.R. presented to Respondent's office with pain while urinating and blood in his urine. As to his issues with his urethra stricture, in which pain was documented as "severe," notes stated that W.R. was "given 3 days of samples of subsys." As to his issues with his urinary tract infection, notes stated that: "Pain control is adequate with oral medications, patient was given Subsys samples for pain 3 days." Further, records indicated that Respondent spent a "significant" amount of time (40 minutes) with W.R. during that visit regarding "counseling and/or coordination of care," but was vague as to what was spoken during those 40 minutes.

249. On or about March 21, 2014, W.R. filled a prescription written by Respondent for 30 units of Endocet 5-325 mg as reported by a pharmacy.

[18] Pharmacy records from a different pharmacy noted that W.R. attempted to fill this prescription for 120 units of Subsys, 600 mcg on or about March 18, 2014 at that pharmacy, but the medication "wasn't dispensed" to W.R. for reasons not documented.

250. On or about April 4, 2014, Respondent wrote a prescription for W.R for 120 units of Subsys, 600 mcg. On or about the same date, W.R. filled his second prescription for 120 units of Subsys, 600 mcg as reported by a pharmacy.

251. Between March and May 2014, patient records provided by Respondent documented that W.R. was treated for dysuria, microscopic hematuria, incontinence and prostatitis. Pain was typically deemed "moderate" and "intermittent," except for an emergent visit on or about May 5, 2014 when his dysuria was described as "a stabbing pain going down his rectum." Medication lists stated he was taking the following opioids: Tramadol Hydrochloride/Acetaminophen 37.5-325 mg, Percocet 5-325 mg, and Hydrocodone/Acetaminophen 7.5-325 mg, but there was no mention of Subsys. A cystoscopy performed during this time showed no tumors of the bladder.

252. On or about April 22, 2014, W.R. filled a prescription written by Respondent for 20 units of Hydrocodone/APAP 7.5-325 mg as reported by a pharmacy.

253. On or about June 2 and August 18, 2014, W.R. was seen for follow-up regarding his medication. Patient records provided by Respondent stated that W.R. finished his medication, there were no side effects, and pain was "absent." W.R. was recommended to continue his urinary retention medication. Patient records of W.R.'s current medication included: Subsys, 600 mcg. However, there was no explanation for why Subsys was prescribed or records of the prescription(s) during this time.

254. Between June and November 2014, after being referred by Respondent, W.R. was seen by Philip Hanno, M.D. for severe voiding dysfunction, hematuria, pelvic pain, and overactive bladder. Exams showed "an unobstructed normal outlet with no bladder mucosal lesions" and a

"benign" prostate biopsy. W.R. was reported to be doing better overtime with pelvic floor exercises and a bladder relaxant.

255. Between February and August 2015, W.R. was seen by Respondent's office for follow-up visits for overactive bladder, chronic prostatitis, benign enlarged prostate, dysuria, hematuria, impotence, urinary tract infection, and incontinence. W.R. continued to experience painful urination that was "moderate" in severity and was being controlled by urinary specific medications. Patient records of W.R.'s current medication included: Subsys, 600 mcg, but lacked any copies of any prescriptions written for W.R. for Subsys during this time and an explanation for why Subsys was prescribed.

256. On or about January 22, 2016, W.R. was seen for a follow-up of his microscopic hematuria. Tramadol HCL was the only opioid listed under the current medication notes provided by Respondent for W.R.; there was no mention of Subsys. W.R. was recommended for follow-up evaluations to evaluate his bladder visually and functionally. Patient records for W.R. continued to state that W.R. did not have cancer.

257. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT VIII

258. The Attorney General repeats and re-alleges the General Allegations and the allegations of the previous counts as if fully set forth herein.

259. B.R., a sixty-three-year-old disabled male, who had a history of GERD, arthritis, heart and lung issues, lupus, and overactive bladder, and an allergy to morphine, was referred to Respondent by his primary care physician Edward Maron, M.D. in or around February 2012. B.R. had underwent transurethral microwave therapy with another physician and reported that after the procedure, he had abdominal pain that was rated as "moderate in severity," bleeding when he urinated, erection problems, and a penis that was "black and swollen and in alot of pain." He reported taking medication for his heart. Patient records provided by Respondent diagnosed B.R with benign enlarged prostate, gross hematuria, and abdominal pain, and recommended that he undergo a series of tests for follow-up.

260. On or about February 17, 2012, an MRI of the abdomen revealed that B.R. suffered from a bile duct stone, pancreatitis, and anemia.

261. On or about a few days later, B.R. went to the emergency room at Kimball Medical Center for abdominal and joint pain. He was medicated with Dilaudid and diagnosed with pancreatitis. Patient records regarding that visit indicated that B.R. was not taking any opioids at the time. On or about March 24, 2012, B.R. returned to the hospital because he had difficulty urinating and had chest and abdominal pain.

262. On or about April 2, 2012, B.R. had a CT scan of the abdomen and pelvis that showed no "obstructing renal stone or hydronephrosis."

263. On or about April 13, 2012, Respondent performed a transurethral resection of bladder tumor on B.R., whereby testing of his bladder revealed: "fragments of prostatic tissue showing multiple foci of neurosis, clarifications, acute and chronic inflammation." The notes stated that the urothelial cells (bladder cells) were not malignant and radiotherapy was recommended for the dead prostatic tissue representing the prostatic tumor.

264. On or about May 9, 2012, B.R. had a follow-up visit, in which he continued to complain of abdominal pain that was rated "moderate in severity." Patient records provided by Respondent stated he was taking the following opioid: Oxycodone/Acetaminophen 5-325 mg, and a new opioid – Vicodin ES 7.5-750 mg – was added to his list. B.R. agreed to undergo transurethral microwave ablation of the prostate to treat his hypertrophy of prostate with urinary obstruction.

265. On or about the next date, B.R. underwent transurethral microwave thermotherapy and tolerated the procedure well. Patient records provided by Respondent documented that he was continuing to take Oxycodone/Acetaminophen 5-325 mg, but B.R. was told to discontinue taking Vicodin ES 7.5-750 mg.

266. On or about May 30 and June 6, 2012, B.R. was seen by Respondent's office for prostate gland enlargement, nocturia, abdominal pain, urinary retention, and testicular pain on the left side. Patient records provided by Respondent documented that B.R. had "mild to moderate pain starting the urine stream" and "moderate" pain relating to his enlarged prostate, which required "narcotic medication." The only "narcotic medication" listed in his current medication was: Oxycodone/Acetaminophen 5-325 mg. However, B.R. was "feeling mildly better since surgery" as it related to his abdominal pain. It was also noted that he had an umbilical hernia that required him to see a surgeon.

267. Patient records provided by Respondent included a Medication Reconciliation Form completed at Meridian Health for B.R. dated on or about October 18, 2012. The form stated that B.R. was advised to apply one Fentanyl Patch, 75 mcg every three days.

268. On or about January 24, 2013, B.R. attended a follow-up visit. He was supposed have come to the office at an earlier date, but was not able to complete his uroflow procedure at an earlier time. Patient records provided by Respondent stated that B.R.'s pain required "narcotic

medication," but the records failed to include any narcotics on the medication list for that visit. On or about February 14, 2013, B.R. completed his uroflow exam. B.R. was advised at his follow-up appointment on or about February 28, 2013 that he was recommended for transurethral microwave thermotherapy and other procedures. There continued to be no mention that B.R. was taking any opioids.

269. On or about March 13, 2013, B.R. had a CT scan of his abdomen and pelvis and the final impressions were that he had no obstructing stones, bowel obstructions, hydronephrosis, or abnormal renal mass, and there was minimal perinephric stranding and thickening of the wall of the urinary bladder.

270. On or about June 7, 2013, Respondent was notified by Jarod Kaufman, M.D. that B.R. underwent a surgery for his inguinal hernia, umbilical hernia, had no pain post-operatively, and was "doing very well." On or about September 13, 2013, Dr. Kaufman reported to Respondent that B.R. had "no pain, bulging, or discomfort in the left groin or umbilicus."

271. On or about July 10, 2013, B.R. went to Monmouth Medical Center for a steroid injection for his low back and leg pain, and lumbar spinal stenosis.

272. Between August and September 2013, Respondent treated B.R. for his enlarged prostate, urinary frequency, microscopic hematuria, and nocturia. B.R.'s cytology results reported that there was no "evidence of malignancy" and his cystoscopy results indicated he had "no significant bladder lesions." Patient notes provided by Respondent did not include any opioids, but stated he was recommended to continue his urinary retention medications, Flomax and Proscar. However, although not reflected in any of Respondent's office summaries of his visits with B.R., the records contained a medication list printout dated on or about August 19, 2013 from the Deborah Heart and Lung Center, where B.R. was being treated for heart and lung issues, that listed

B.R. was applying a Fentanyl 25 mcg/hr Transdermal Patch 72 Hour every three days, effective on or about November 21, 2012.

273. On or about September 13, 2013, B.R. saw Cary Pinelas, M.D. for a follow-up appointment. In her summary report to Respondent, in addition to clearing B.R. for his cystoscopy, she listed that B.R. was applying a Fentanyl 25 mcg/hr patch to his chest.

274. On or about February 19, 2014, B.R. visited Respondent to obtain his uroflow results, which stated that he had a "decrease in peak urinary velocity." B.R. was noted not to have any "new complaints at this time." However, B.R. did mention that he underwent an umbilical hernia repair ten months ago and his right testis retracted after that procedure, although pain was absent. Patient records provided by Respondent for B.R. did not indicate that B.R. was taking any opioids at this time.

275. On or about March 1, 2014, a scrotal ultrasound showed B.R. had bilaterally descended testes, a small left hydrocele, a small left varicocele, and a right epididymal cyst. B.R. advised that he was "not bothered" and no recommendations were made.

276. On or about May 7, 2014, Respondent registered B.R. for the TIRF REMS Access Program, in which Respondent and B.R.'s signatures appeared on documentation for the PPAF.[19]

277. On or about the same date, an Insys Reimbursement/Prior Authorization Request Form bearing Respondent's signature stated that B.R. should be prescribed Subsys because he was diagnosed with acute pain, lupus, and benign enlarged prostate, notwithstanding that Subsys was mandated by the FDA to only be used for breakthrough cancer pain. Respondent's specialty was

[19] On or about May 8, 2016, B.R.'s ability to fill TIRF prescriptions expired as patient records provided by Respondent for B.R. showed no evidence that Respondent took any steps to renew his PPAF before or after the date of expiration. By around the end of 2015, Respondent had stopped receiving payments from Insys as reflected in Insys's records.

incorrectly listed as "oncology" and the form stated that B.R. unsuccessfully used Oxycodone to manage his pain although there was no documentation of that in records provided by Respondent for B.R.[20]

278. On or about the same date, Respondent wrote a prescription for B.R for 120 units of Subsys, 600 mcg, which was six times the starting amount mandated by the FDA. Patient records provided by Respondent did not document why B.R. needed to be started on a Subsys dose that was substantially above the mandated amount. A letter dated on or about May 12, 2014 that was in Respondent's patient records for B.R. reflected that B.R. was approved for insurance coverage for Subsys, 600 mcg, 120 units at the request of Respondent until on or about December 31, 2014. However, on or about May 13, 2014, pharmacy records indicated that the prescription for 120 units of Subsys, 600 mcg was filled but "never dispensed" to B.R. because "product service not covered."

279. On or about May 9, 2014, B.R. went to Community Medical Center for green light laser transurethral resection of prostate to address his "moderate lower urinary tract symptoms secondary to prostatic hypertrophy." Records provided by Respondent stated that B.R. had been treated with medical therapy that included urinary retention medication, but did not document any opioids, including Subsys. On or about May 22, 2014, B.R. returned to the hospital for transurethral resection of the prostate for bladder outlet obstruction.

280. On or about June 11, 2014, B.R. visited Respondent's office for benign prostatic hypertrophy, urinary frequency, and nocturia. It was documented that B.R., who underwent transurethral resection of the prostate on or about May 23, 2014, reported at that visit that pain was

[20] Notably, pharmacy records showed that between 2011 and 2017, B.R. periodically filled prescriptions for Fentanyl 25 MCG/HR Patches and Oxycodone-Acetaminophen 5-325, which were not written by Respondent.

"absent" as it related to his benign prostatic hypertrophy, pain was "occasional" for his urinary frequency, and he had no "urination complaints" and was "doing well" as it related to his nocturia. Patient records provided by Respondent at this time lacked documentation that B.R. was taking any opioids, including Subsys, and failed to record that Respondent wrote B.R. a prescription for Subsys.

281. Between July and November 2014, patient notes provided by Respondent documented that he was treated at Respondent's office for dysuria, urinary frequency, nocturia, acute prostatitis, and urinary tract infection. B.R. stated that his pain for his dysuria and prostatitis was "intermittent." Records prepared summarizing B.R.'s care further documented that B.R. was not taking any opioids at the time, and Respondent was starting B.R. on Bactrim (antibiotics) and Naproxen. However, undated and handwritten notes in the patient records reflected that B.R. was also applying a Fentanyl Transdermal System Patch, 25mg every 72 hours as part of his medication regimen.

282. On or about April 2, 2015, B.R. visited Respondent's office for a follow-up on his urinary frequency and nocturia. B.R.'s bladder ultrasound showed a "normal post void residual" although B.R. still complained of incomplete voiding. Patient records provided by Respondent did not state that B.R. reported any pain or that he was taking any opioids.

283. On or about April 16, 2015, B.R. returned for another assessment of his urinary tract symptoms. B.R. reported that he was "pleased with his quality of life" as he had no complaints of urinary frequency, intermittency, gross hematuria, and weak stream, and was only up once per night to urinate. Patient records provided by Respondent stated that B.R. should continue to take his urinary retention medication and Tylenol 8 Hour 650 mg, "1 PO every 8 hours." Although not listed in his records for B.R. prior to April 2015, patient records provided

by Respondent now listed Fentanyl 12 mcg/HR and Percocet 10-325 mg on B.R.'s current medications, but no explanation was provided for why B.R. was taking the opioids, for how long, and who prescribed these drugs.

284. On or about November 5, 2015, B.R. visited Respondent's office for a follow-up appointment and his urinary tract problems remained consistent and stable from his visit on or about April 16, 2015.

285. On or about May 3, June 23, and July 26, 2016, B.R. had follow-up visits at Respondent's office for his enlarged benign prostate. B.R. reported "feeling significantly better compared to last visit" and his condition being "well controlled since last visit." He was also taking his medication without any side effects. The medication listed for B.R. on his patient notes for this date included Fentanyl 12 mcg/HR and Percocet 10-325 mg.

286. At no point for the time period between February 2012 and July 2016 do the patient records provided by Respondent for B.R. indicate that B.R. had been diagnosed with or treated for cancer. Further, records failed to explain why one prescription for B.R. was written for Subsys in or around May 2014. By around the end of May 2014, Respondent had received over $10,000 from Insys as reflected in Insys's records.

287. Respondent's actions described herein constitute:

a. the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b);

b. gross negligence which endangered the life, health, welfare, safety or property of a person in violation of N.J.S.A. 45:1-21(c);

c. repeated acts of negligence in violation of N.J.S.A. 45:1-21(d);

d. professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e);

e. failure to comply with the provisions of an act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), specifically:

i. directly or indirectly receiving a fee for the use or promotion of a specific product which a reasonable person would recognize as having been received in appreciation for conduct by a licensee, specifically the prescribing of Subsys, in violation of N.J.A.C. 13:35-6.17(c);

ii. preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5;

iii. failure to perform an appropriate history, perform a physical examination, make a diagnosis, and formulate a treatment plan prior to issuing a prescription in violation of N.J.A.C. 13:35-7.1A;

iv. failure to comply with certain limitations on prescribing controlled substances in violation of N.J.A.C. 13:35-7.6 (including, but not limited to, periodically making reasonable efforts to stop or reduce prescribing of controlled substances);

f. issuance of prescriptions for controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or

g. failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

WHEREFORE, Complainant, the Attorney General of New Jersey, demands the entry of an Order:

1. Suspending or revoking the Respondent's license to practice medicine and surgery in the State of New Jersey following a plenary hearing;

2. Assessing civil penalties against Respondent for each and every separate unlawful act as set forth above, pursuant to N.J.S.A. 45:1-21;

3. Requiring Respondent to pay costs, including investigative costs, attorney's fees and costs, expert and fact witness fees and costs, costs of trial, and transcript costs, pursuant to N.J.S.A. 45:1-25; and

4. Ordering such other and further relief as the Board of Medical Examiners shall deem just and appropriate under the circumstances.

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY

By: _____
Kelly Elizabeth Levy
Deputy Attorney General

Dated: November 23, 2020