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

By: David M. Puteska (000301995)
Deputy Attorney General
Tel. (973) 648-2972
David.Puteska@law.njoag.gov

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 **FELIX E. ROQUE, M.D.** **LICENSE NO. 25MA06482500** TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	Administrative Action **COMPLAINT**

GURBIR S. GREWAL, Attorney General of New Jersey, by David M. Puteska, 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 lavish dinners posing as "lectures," all-expense paid trips for "training," and more than $50,000 in cash payments thinly disguised as "speaker's fees," Felix Roque ("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 VII below, Respondent encouraged patients that did not have cancer or suffer from breakthrough cancer pain, and who were on stable pain management regimes, to switch to Subsys. In addition, after starting his patients on Subsys, Respondent steadily, but without regard for patient safety, increased the dosage strength resulting in more money for Insys because 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 switched to Subsys or their dosages were increased. In at least one case detailed below, for patient M.L., this practice had a devastating consequence resulting in her overdose. For other patients, Respondent's reckless use of Subsys placed them at risk of addiction, overdose, and death.

6. Ironically, it was Insys who broke off the financial relationship with Respondent in 2015 after he became involved in a well-publicized criminal matter and Respondent curtailed prescribing Subsys, writing only one or two prescriptions per month near the end of 2016 and none after 2017.

7. 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

8. 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").

9. 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.

10. Respondent, Felix E. Roque, M.D., is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA06482500. At all relevant times, Respondent maintained a medical practice specializing in pain management located in Union City, New Jersey.

III. Fentanyl

11. 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.

12. 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

13. 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.

14. 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.

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

16. 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.

17. 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

18. 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.

19. 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.

20. 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."

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

22. 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

23. In or about October 2013, Respondent enrolled in the TIRF REMS Access

Program.[1] 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.

24. 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.

[1] Upon information and belief, Respondent was enrolled in predecessor TIRF programs maintained by individual drug manufacturers prior to the creation of the TIRF/REMS program in late 2011.

> 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.

25. 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).]

26. 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

27. On multiple occasions, Respondent renewed his enrollment in the TIRF REMS Access Program, and, in so doing, each time again completed and signed the above-mentioned Prescriber Enrollment Form and successfully completed the Knowledge Assessment.

28. 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."

29. 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."

30. The overwhelming weight of the 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

31. In August 2012, Insys 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 ISP speaking fees, or "honoraria," paid to prescribers were in reality bribes used by the company to induce speaker-practitioners "to write more, medically unnecessary prescriptions" of Subsys.[2]

[2] 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).

32. Rather than serving as educational gatherings, ISP events "often did not involve any education or presentations about [Subsys]" and frequently had no attendees at all.[3] 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."[4]

33. In 2012, Respondent and Susan Beisler ("Beisler"), a drug representative for Insys, formed a relationship meant to incentivize Respondent to prescribe Subsys to his patients. In a May 2, 2012 email, Beisler informed her superiors that Respondent "would not write [Subsys prescriptions] until he attended a conference," specifically asking to "be put up at the Fairmount (sic) Princess."[5] Shortly thereafter, Respondent attended a conference in Arizona funded by Insys. The stated purpose of Respondent's attendance at this conference was so that he could receive training to become a compensated speaker with the ISP.

34. For all of 2012, Respondent issued only one Subsys prescription to one patient that was filled at a New Jersey pharmacy.

35. In or about October 2013, Insys awarded Respondent his first ISP event. These events were held at high-end restaurants chosen by Respondent. The ISP events featuring Respondent were sparsely attended, often attended multiple times by the same participants including those who did not have prescribing authority. The topic of these programs was

---

[3] Id.

[4] Id.

[5] Upon information and belief, the "Fairmount Princess" refers to the Fairmont Scottsdale Princess Resort located in Scottsdale, Arizona, a high-end luxury hotel less than 20 miles from Insys' Chandler, Arizona headquarters.

breakthrough pain in cancer patients. Upon information and belief, the script for these events was prepared and provided to Respondent by Insys and remained substantial the same at each event.

36. In addition to his Speaker's Fee, Respondent and his guests received free meals with the total cost of meals for the event often exceeding $1,000.

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, Insys made payments to Respondent virtually every month from August 2013 to June 2015. During this same time, Respondent wrote hundreds of prescriptions for Subsys generating millions of dollars in revenue for Insys. Moreover, Respondent wrote few prescriptions for any other similar TIRF medications such as Actiq or Fentora.

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	Insys payments to Respondent	All other TIRF medications prescribed.
2012	1	0	41
2013	53	$10,535	31
2014	106	$30,752	9
2015	79	$12,256	1
2016	49	0	10
2017-date	0	0	10
Total	281	$53,543	102

41. In June 2015, Respondent was charged with criminal offenses unrelated to his medical practice. Insys then stopped making payments to him.

42. On October 7, 2015, Beisler sent an email to John Kapoor, the CEO of Insys. She noted that Respondent, who she described as her "top HCP" [health care provider], "was cut off." She noted that it was "[i]n our best interest to keep him at arms length," based on legal problems Respondent was having at the time.

43. 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

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

45. M.L. was a forty-six year-old female patient of Respondent.[6] During her initial visit on December 19, 2012, she gave a history of chronic spinal pain that had worsened since first

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

presenting in 2008.

46. Eight months prior to her initial visit with Respondent, M.L. had been placed on opioid protocols by her then-treating physician. Following her initial visit with Respondent in December 2012, Respondent prescribed M.L. Percocet 5-325mg, fentanyl 50mcg, Duragesic 50mcg, and clonazepam .5mg.

47. The fentanyl and Duragesic prescriptions appear to both be for a fentanyl topical patch (brand name Duragesic), but it is unclear from the patient record why two prescriptions for the same medication were recorded.

48. In April 2013, along with her first Subsys prescription, Respondent and M.L. entered into the TIRF/REMS Patient-Prescriber Agreement. That agreement included an acknowledgement by Respondent that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . . ." Nevertheless, at no point while being treated by Respondent was M.L. diagnosed with cancer; nor did she suffer from breakthrough cancer pain.

49. On April 22, 2013, Respondent first issued M.L. a prescription for Subsys. Although M.L. claimed to be suffering from chronic pain, as recently as her previous visit on April 2, 2013, M.L. had told Respondent she had "satisfactory relief" from her existing opioid protocols.

50. On May 9, 2013, M.L. had a poor clinical response to Subsys, and did not want to continue with the prescription. However, on May 22, 2013, Respondent continued to prescribe Subsys to M.L. despite her poor response. Respondent, without a legitimate medical basis and despite M.L.'s complaints, doubled her dosage of Subsys to 200mcg at this visit.

51. Respondent continued prescribing Subsys to M.L. until July 3, 2013. On July 3, 2013, M.L. reported, "Subsys is not properly helping her and also she feels silly under the effect of it." As a result, Respondent indicated that he would stop her Subsys prescription. Respondent

issued M.L. prescriptions for Percocet 10/325mg, Naprelan 750mg, Klonipin .5mg, and Duragesic 75mcg at this visit.

52. Respondent's patient record for M.L. did not reflect any attempt to taper M.L.'s dosage or wean her from this prescription despite her concerns with the side effects of Subsys.

53. Despite Respondent's decision to stop prescribing Subsys to M.L., her progress notes thereafter continue to include Subsys 200mcg among her medications. At M.L.'s November 12, 2013 visit, Respondent noted that M.L. "is on Subsys reporting good response with this medication." There is no explanation for the inconsistency between this continued prescribing and Respondent's prior decision to stop prescribing Subsys to M.L. Respondent further stated that he was going to "continue with Subsys 200mcg Q 6hrs and will titrate [increase] slowly at my office under a supervised setting."

54. By M.L.'s next office visit on December 10, 2013, Respondent had doubled her Subsys dosage to 400mcg. Despite this, Respondent's patient record continues to reflect M.L.'s Subsys dose as 200mcg and that she "has noticed that is not last to help her. [sic]"

55. On February 13, 2014, M.L. was found unresponsive by her sister. She was administered Narcan by paramedics, and informed them that she was on fentanyl spray for chronic pain, and "took 'too much.'"

56. On February 25, 2014, M.L. was seen by Respondent. At this point, Respondent noted that M.L. had been admitted to University Medical Center due to respiratory problems and syncope. Although M.L. told Respondent that she was suffering from pneumonia, after speaking with the hospital and being provided a copy of the hospital record, Respondent knew that she did not have pneumonia, but rather had overdosed on the Subsys prescription he had prescribed. Respondent decided that he would not prescribe her any more medication. Respondent's treatment

records for M.L. end after this visit.

57. As detailed above, and more fully in Respondent's records for M.L., Respondent improperly treated M.L. with a high-risk pharmacological plan of care that included the use of Subsys and a combination of high-dose opioids and benzodiazepines. Respondent's prescribing regime created a risk of harm to M.L. and, given her overdose related to Subsys, caused actual harm to M.L. The complexity of Respondent's controlled substance prescribing, the doses and the way he prescribed Subsys to this non-cancer patient are outside of the Program guidelines, the terms of the Prescriber Enrollment Form, and the appropriate standard of care.

58. 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

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

60. On June 11, 2013, C.R., a twenty-nine year-old female patient, had her initial visit with Respondent. C.R. sought treatment for pain related to neck and back issues stemming from a car accident that occurred four years prior. Respondent noted that C.R had been on an opioid and muscle relaxant protocol since the accident with some temporary relief of her pain. At the time of this visit, C.R. was prescribed a host of medications including methadone, Percocet, Xanax, Ambien and Soma.

61. Respondent's treatment plan for C.R. at this initial visit was for her to begin

physical therapy and continue with her opioid protocol. Although Percocet and methadone are listed as existing medications, Respondent's patient record also states that his plan is to place C.R. on methadone and suspend Percocet. Respondent's treatment plan fails to provide a basis for this change in prescribing.

62. On January 14, 2014, Respondent received a faxed letter from the New Jersey State Division of Child Protection and Permanency ("DCPP") regarding C.R. The letter stated that C.R. "keeps her medications in zip lock plastic bags as she does not take them as prescribed and typically has more than the typical dispensed amount in each plastic bag of medication she provided." DCPP also reported that C.R. had recently *relapsed* on illegal substances and provides details of failed urine screens that began in November 2013. DCPP further reported that C.R. has been referred for intensive outpatient substance abuse treatment and urges Respondent to "take the above information into consideration when treating [C.R.] and planning for her pain management needs." The DCPP caseworker provided Respondent with his name and contact information should he have any questions or concerns.

63. Respondent saw C.R. on February 2, 2014. At no point did Respondent discuss the DCPP letter, its findings, her substance abuse issues, attendance or non-attendance at intensive outpatient substance abuse treatment, or any other issues related to the DCPP letter. Respondent prescribed C.R. the same CDS regimen she had been receiving: methadone 10mg and Soma 350mg.

64. Respondent's prescribing to C.R. consisted primarily of methadone until August 8, 2014 where he adds, without a legitimate medical basis, Dilaudid 4mg every 6 hours.

65. On January 6, 2015, Respondent replaced the Dilaudid prescription with Percocet 10-325, 1 tablet every six hours. There is no legitimate medical basis for this change.

66. On March 3, 2015, Respondent's treatment plan reflected that he had discontinued Tylenol (an ingredient in Percocet) as C.R.'s lab tests reflect high hepatic enzyme levels. Respondent altered C.R.'s prescribing by replacing Percocet with Oxycodone 10mg, 1 tablet every six hours.

67. C.R.'s last visit with Respondent was on November 10, 2015. At this visit, Respondent noted that C.R.'s pain management insurance benefits had run out. Respondent prescribed C.R. Oxycodone, Soma, Methadone and Neurontin, but his treatment plan did not address how he would transition C.R. or her prescribing to another physician.

68. Prescribing records for C.R. reflect that on June 18, 2014, C.R. filled one prescription for 30 dosage units of Subsys 200mcg written by Respondent on that same date. This prescription was paid for via "coupon."

69. As detailed above, and more fully in Respondent's records for C.R., Respondent improperly treated C.R. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to C.R. The complexity of Respondent's controlled substance prescribing, the doses that he reached, including but not limited to the way he prescribed Subsys to this non-cancer patient, and his failure to address her known substance abuse issues, are outside of the TIRF agreement and grossly outside the standard of care.

70. 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.

h.

COUNT III

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

72. T.R. was a fifty-one year-old male patient of Respondent with a history of substance abuse, opioid overdose, and attempted suicide by opioid overdose. By June 2010, T.R. was an established patient of Respondent and being treated for continuous mid back and chest pain.[7]

73. On June 23, 2015, Respondent and T.R. entered into the TIRF/REMS Patient-Prescriber Agreement.[8] That agreement included an acknowledgement by Respondent that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . . ." At no point was T.R. diagnosed with cancer or suffering from breakthrough cancer pain.

74. On April 29, 2013, Respondent prescribed T.R. OxyContin and Dilaudid for his pain that, according to Respondent's notes, provided "acceptable relief of the spinal symptoms." Respondent noted without further explanation that he "will consider placing the patient on Subsys for his short acting pain."

75. On May 21, 2013, Respondent prescribed 100mcg Subsys to T.R. with plans to titrate slowly.

76. On June 4, 2013, Respondent noted that T.R. "is on opioid protocols with acceptable control [of] the symptoms and recently . . . was placed on long-acting opioid medications to include Subsys 100 mcg instead of Dilaudid 4mg. but he notes that it is not enough

[7] Respondent appears to have treated T.R. prior to June 2010; however, the first record reflecting ongoing patient care provided to the Attorney General is for June 22, 2010.

[8] Upon information and believe, Respondent and T.R. entered into earlier TIRF/REMS agreements at or near the time Respondent first prescribed Subsys.

to control the pain's intensity . . . ." While Dilaudid is a long-acting pain medication, Subsys and other TIRF medications are considered among the shortest acting of all pain relief medications.

77. Respondent then doubled T.R.'s Subsys dosage to 200mcg, with directions to use "1 unit every 6 hours PRN [as needed] for 30 days," for a total of 120 units.

78. At his next appointment, on July 2, 2013, T.R.'s Subsys dosage was doubled again to 400mcg.

79. At T.R.'s next appointment, on July 30, 2013, the Subsys prescription was increased again to 600mcg.

80. Respondent continued to prescribe Subsys 600mcg to T.R. until June 2016. At that time he noted that T.R.'s insurance company would will no longer cover Subsys for T.R.

81. As detailed above, and more fully in Respondent's records for T.R., Respondent improperly treated T.R. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to T.R. The complexity of Respondent's controlled substance prescribing, the doses Respondent reached, and the way he prescribed Subsys to this non-cancer patient are outside of the TIRF agreement and grossly outside the standard of care.

82. 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

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

84. A.W. was a fifty-four year-old female patient of Respondent. During her initial visit on January 18, 2014, she suffered from pain related to a September 2006 slip-and-fall accident. A.W. suffered from right neck pain, right shoulder pain, and right arm pain. The most recent imaging studies for A.W. were from 2008 and 2009. At the time of her first visit, A.W. was being prescribed OxyContin and Roxicodone by her previous physician.

85. In March 2016, Respondent and A.W. entered into the TIRF/REMS Patient-Prescriber Agreement. That agreement included an acknowledgement by Respondent that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . . ."[9] At no point in her treatment with Respondent was A.W. diagnosed with cancer or suffering from breakthrough cancer pain.

86. Respondent initially prescribed Subsys to A.W. on February 12, 2014, her second visit. Respondent's treatment plan failed to provide a basis for the introduction of Subsys into A.W.'s prescription regime. Rather, Respondent noted that A.W. "is on pain medication, which helps [her] to cope [with] her pain . . . ."

87. Respondent started A.W. on 200mcg of Subsys, double the mandatory 100mcg starting dosage stated in the prescribing information.

88. On April 7, 2014, Respondent doubled A.W.'s Subsys dose to 400mcg.

89. On May 5, 2014, Respondent again increased A.W.'s Subsys dose to 600mcg.

90. On or about July 21, 2014, Respondent again increased A.W.'s Subsys dose to 800mcg.

[9] Upon information and belief, although not contained within Respondent's patient file for A.W., Respondent entered into previous TIRF/REMS agreements when he commenced prescribing Subsys to A.W.

91. Respondent's July 21, 2014 progress note for A.W. documented only that her husband "states that she snores loudly and has noticed she stops breathing suddenly through the night." There is no further discussion regarding this issue documented and there is no change made to her medications except the increase in the dosage of Subsys.

92. On October 13, 2014, Respondent again increased A.W.'s Subsys dose to 1200mcg.

93. On November 3, 2014, Respondent again increased A.W.'s Subsys dose to 1600mcg, the highest available strength. Respondent noted that A.W. was not dispensed Subsys 1200mcg by her pharmacist and that she had run out of her medication. Respondent failed to ascertain why the pharmacist did not dispense the prior dose or why A.W. ran out of the prior 800mcg dose. Rather, Respondent's patient record incorrectly noted that A.W. will continue on the existing 1200mcg dosage.

94. On January 26, 2015, Respondent altered A.W.'s Subsys dosage from the 1600mcg strength to double dosage units of 800mcg strength and increased her Roxicodone, noting, without further explanation, that she had been having trouble receiving her Subsys prescription.

95. Respondent continued A.W. on this Subsys dosage through at least October 2016.

96. Respondent's pharmacological plan for A.W. was extremely high-risk because of her morbid obesity and risk of obstructive sleep apnea. The Subsys dosing was adjusted to as high as 1600mcg, the maximum dose, without detailed explanation and despite reports of obstructive sleep apnea by A.W.'s husband that further increased the risk of harm, including death, to A.W.

97. As detailed above, and more fully in Respondent's records for A.W., Respondent improperly treated A.W. with a high-risk pharmacological plan of care. The complexity of Respondent's controlled substance prescribing and the doses that he reached, including but not limited to the way he prescribed Subsys to this non-cancer patient, are outside of the TIRF

agreement and grossly outside the standard of care.

98. 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

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

100. A.O. was a female patient of Respondent. Her initial visit occurred on July 6, 2015, during which she gave a history of chronic neck pain that had been progressively worsening over the past year. A.O. also presented with back pain and radiating pain in her left shoulder and arm. A.O. was already on opioid protocols and Respondent reported that they provided her "significant clinical relief."

101. In March 2016, Respondent and A.O. entered into the TIRF/REMS Patient-Prescriber Agreement. That agreement included an acknowledgement by Respondent that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . . ."[10] At no point during her treatment with Respondent was A.O. diagnosed with cancer nor suffering from breakthrough cancer pain.

102. At her first visit, Respondent prescribed A.O. Percocet 7.5-325mg, Duragesic

[10] Upon information and belief, although not contained within Respondent's patient file for A.O., Respondent entered into previous TIRF/REMS agreements upon commencing his prescribing of Subsys to A.O.

75mcg, and Subsys 200mcg. Respondent's treatment plan failed to provide a basis for the addition of the Subsys prescription.

103. Respondent continued to prescribe A.O. Subsys 200mcg on a monthly basis until August 30, 2016.

104. Respondent stopped prescribing Subsys to A.O. in August 2016. Respondent does not describe how Subsys was removed from A.O's prescribing routine or a treatment plan for A.O in light of the cessation of Subsys. There is no indication that Respondent made any effort to taper the Subsys dose or otherwise address the significant risk of harm which accompanies the cessation of a TIRF drug.

105. As detailed above, and more fully in Respondent's records for A.O., Respondent improperly treated A.O. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to A.O. The complexity of Respondent's controlled substance prescribing and the doses that he reached, including but not limited to the way he prescribed Subsys to this non-cancer patient, are outside of the TIRF agreement and grossly outside the standard of care.

106. 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

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

108. E.C. was a thirty-seven year-old male patient of Respondent. He first came under Respondent's care on January 2, 2014, following a car accident on October 30, 2013. He complained of whiplash, mid and lower back pain, as well as left shoulder trauma. Respondent placed E.C. on Nexium 40mg and Motrin 400mg. Motrin is an over the counter non-steroidal anti-inflammatory drug ("NSAID") commonly utilized for pain management. Nexium is commonly utilized for acid reflux.

109. The patient record does not contain a copy of any TIRF/REMS Patient-Prescriber Agreement between Respondent and E.C. E.C. was not diagnosed with cancer at any time during his treatment with Respondent; nor was he suffering from breakthrough cancer pain.

110. Respondent's January 15, 2014 notes for E.C.'s next visit reflect no change in his prescribing and that E.C. wanted "to continue his current treatment."

111. On February 12, 2014, Respondent noted that E.C. was on an NSAID and a muscle relaxant with some relief. Respondent's treatment plan included interventional procedures such as a median nerve block. Despite this plan, Respondent began E.C. on opioids by prescribing Percocet 5/325mg.

112. Following E.C.'s March 10, 2014 visit, Respondent noted that E.C. had been taking more pain medication than Respondent had prescribed in order to manage E.C.'s pain. Respondent recommended additional interventional procedures and maintained E.C. on the same opioid protocol. Respondent did not discuss with E.C. his excessive use of pain medication beyond what had been prescribed.

113. Respondent first prescribed Subsys 200mcg to E.C. on or about April 21, 2014. At this time, E.C. was on two opioids: Percocet 5-325mg and Duragesic 25mcg. Respondent's treatment plan provided no explanation for the introduction of Subsys into E.C.'s prescription

regime. Nor did Respondent explain why E.C.'s starting dosage of Subsys was twice the mandatory starting dose of 100mcg.

114. E.C. remained on Subsys 200mcg through Respondent's last submitted patient progress note, May 19, 2014.

115. As detailed above, and more fully in Respondent's records for E.C., Respondent improperly treated E.C. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to E.C. The complexity of Respondent's controlled substance prescribing, the doses that he reached including but not limited to the way he prescribed Subsys to this non-cancer patient, are outside of the TIRF agreement and grossly outside the standard of care.

116. 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

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

118. In 2012, J.S. was a sixty-one year-old female patient of Respondent. Upon information and belief, Respondent had treated J.S. with both interventional pain management and opioid treatments for a variety of issues dating back to at least 2010.

119. In March 2016, Respondent and J.S. entered into the TIRF/REMS Patient-Prescriber Agreement. That agreement included an acknowledgement by Respondent that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . .

."[11] J.S. was not diagnosed with cancer during her treatment with Respondent; nor was she suffering from breakthrough cancer pain.

120. As of her November 6, 2012 visit, Respondent was treating J.S. for neck and back pain with interventional pain management and prescription medication including Dilaudid 8mg, Gabapentin 300mg and Methadone 10mg (which had been recently prescribed following an emergency room visit). Respondent's treatment plan at this visit included that J.S. would "continue on the same opioid protocols," initiate physical therapy and consider additional interventional pain management procedures.

121. Respondent's December 5, 2012 progress note states that J.S. "is on opioid protocol with good response." J.S.'s medication protocol as of this visit continued to include Dilaudid, Gabapentin and Methadone.

122. On January 8, 2013, Respondent prescribed J.S. Subsys 100mcg. Respondent provides no explanation as to the addition of Subsys to J.S. prescribing routine.

123. On February 6, 2013, J.S. was "currently on pain medication, which is helping her cope with her pain." Respondent's treatment plan included that the patient will "continue the same pharmacological protocol." Despite this notation, Respondent quadrupled the dosage for Subsys to 400mcg.

124. On March 6, 2013, Respondent notes that J.S. "is taking Subsys 400mcg from December 2012 feeling better and getting relief from it." Respondent's treatment plan included that J.S. "will continue under the same opioid protocols since she feels better to daily function."

[11] Upon information and belief, although not contained within Respondent's patient file for J.S., Respondent entered into previous TIRF/REMS agreements commencing with his prescribing of Subsys to J.S.

Despite this notation, Respondent increased the Subsys dose to 600mcg.

125. On April 2, 2013, Respondent noted that J.S.'s "neck and lumbar pain remain stable since she is on opioid protocols; The patient is taking Subsys 600mcg from December 2012 feeling better and getting more relief from it but is still noticing multiple break though pain episodes." Respondent's treatment plan included that she "will continue the same pharmacological protocol." Despite this notation, Respondent increased the Subsys dose to 800mcg.

126. On May 29, 2013, Respondent's treatment plan stated that J.S. will continue the same opioid protocol but again he increased the Subsys dosage to 1200mcg.

127. On June 11, 2013, Respondent noted that J.S. "had problems with her insurance in relation with the medication Subsys. She is using 1200mcg divided on 600mcg. The patient refrs (sic) that this medication is helping to cope [with] her pain . . . ." Presumably, to address the insurance coverage issues, Respondent altered J.S.'s Subsys dosing to reflect 600mcg, 2 units every six hours.

128. On December 11, 2013, Respondent noted that J.S. is no longer taking Subsys as coverage for it was suspended by her insurance company. Respondent does not describe how Subsys was removed from J.S.'s prescribing routine or a treatment plan for J.S. in light of the cessation of Subsys. Respondent also does not address a plan to taper J.S.'s Subsys dosage or otherwise manage the harm which can accompany reduction from high dose TIRF substance usage.

129. At J.S.'s next visit, January 13, 2014, J.S.'s pain was unchanged and her pain medication was no longer helping her cope with her pain. Respondent's treatment plan at this visit included that J.S. continue the same pharmacological protocol. Without further explanation, Respondent added Subsys 600mcg, 2 units every six hours as needed for "severe pain." There is

no explanation as to the discrepancy between this patient note and the previous visit that stated that she was no longer taking Subsys.

130. Respondent continued to prescribe J.S. Subsys 1200mcg every six hours until October 14, 2014, when he noted that a pharmacy would not fill J.S.'s methadone prescription and that she was exclusively using Subsys for pain management and using it more frequently than prescribed. Respondent did not prescribe Subsys at this visit, but instead gave J.S. a new prescription for Methadone and added Dilaudid 8mg because J.S. had been "lacking of her opioid prescriptions during the prior 2 weeks." Respondent failed to discuss with J.S. her misuse of her prescribed CDS.

131. On October 29, 2014, Respondent prescribed J.S. Subsys 600mcg, 2 units every six hours.

132. At J.S.'s February 18, 2015 visit, Respondent noted that she "is on pain medication which helps her cope with her symptoms." Respondent's treatment plan for this visit included that J.S. will "continue under conservative management to include opioid medications." Despite this notation, and without further explanation, Respondent issued J.S. two Subsys prescriptions: 120 dosage units, 1200mcg, 1 unit every 6 hours as needed and 240 dosage units, 600mcg, 2 units every 6 hours as needed.

133. Respondent continued prescribing Subsys to J.S. until at least September 2016.

134. As detailed above, and more fully in Respondent's records for J.S., Respondent improperly treated J.S. with a high-risk pharmacological plan of care. The complexity of Respondent's controlled substance prescribing and the doses that he reached, including but not limited to the way he prescribed Subsys to this non-cancer patient, are outside of the TIRF agreement and grossly outside the standard of care.

135. 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: _____
David M. Puteska
Deputy Attorney General

Dated: November 23, 2020