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

By: Kathy Stroh Mendoza
Deputy Attorney General
Attorney ID No. 018561990
Tel. (973) 648-2779

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

KIERAN SLEVIN, M.D.
LICENSE NO. 25MA08620600

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

Administrative Action

COMPLAINT

GURBIR S. GREWAL, Attorney General of New Jersey, by Kathy Stroh Mendoza, 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 $83,000 in cash payments thinly disguised as "speaker's fees," Kieran Slevin ("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 IV 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. Respondent's reckless use of Subsys placed his patients 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, Kieran Slevin, M.D., is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA08620600. At all relevant times, Respondent maintained a medical practice specializing in pain management, North American Pain and Spine, located in Hainesport, 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. There are currently six approved TIRF medications, two of which, Subsys and Fentora, are at issue in this matter.

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. Fentora is the trade name for a fentanyl buccal tablet, an effervescent TIRF substance that is absorbed across the oral mucosa. Fentora is manufactured and sold exclusively by Cephalon, Inc., a Pennsylvania-based corporation, and is available in the following dosage strengths: 100mcg, 200mcg, 400mcg, 600mcg, and 800mcg fentanyl solution.

16. At all relevant times, the only FDA-approved use for all TIRF medicines, including Subsys and Fentora, is 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:

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

b. Preventing inappropriate conversion between TIRF medicines.

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

d. 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. When Respondent enrolled in the TIRF REMS Access Program,[1] 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.
>
> . . .

[1] Respondent failed to produce his enrollment documentation demanded by subpoena in discovery. Multiple Patient Prescriber Agreements signal that Respondent was enrolled in the TIRF REMS Program.

> I understand that the initial starting dose for TIRF medicines for all 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.

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
>
> <u>Respiratory Depression</u>
>
> 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.
>
> . . .
>
> <u>Medication Errors</u>
>
> 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 Full Prescribing Information for Fentora, which provide warnings identical to those above regrading respiratory depression, medication errors, and abuse potential, and which provide that initial doses of these TIRF medicines is **always** 100mcg (for Fentora). (Emphasis added).

27. 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

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]

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 2013, Respondent and Ben Ecker, a drug representative for Insys, formed a relationship meant to incentivize Respondent to prescribe Subsys to his patients. Respondent attended a conference in California funded by Insys. The ostensible purpose of Respondent's attendance at this conference was so that he could receive training to become a compensated speaker with the ISP.

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[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.), paragraphs 8-12. 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).

[3] Id.

[4] Id.

34. In or about October 11, 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 "Advancements in the Treatment of Breakthrough Pain in Cancer Patients" and "Managing Chronic Pain in Cancer Survivors: Benefits/Risks of Long Term Opioid Therapy." Upon information and belief, the scripts for these events were prepared and provided to Respondent by Insys and remained substantially the same at each event.

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

36. 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.

37. As reflected in Open Payments data, Insys made payments to Respondent virtually every month from May 2013 to December 2015. During this same time, Respondent wrote hundreds of prescriptions for Subsys generating millions of dollars in revenue for Insys. Moreover, Respondent wrote a few prescriptions for other similar TIRF medications such as Fentora.

38. 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 (including Fentora) he prescribed during the same years:

Year	**Subsys Prescriptions**	**Insys payments to Respondent**	**All other TIRF medications prescribed (Fentora)**
2012	0	$0	0
2013	14	$19,220.67	0
2014	70	$38,251.66	2
2015	70	$25,625.95	5
2016	0	$41.49	0
2017-date	0	$0	0
Total	154	$83,139.77	7

39. 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

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

41. On June 18, 2014, patient T.O.B. (DOB 12/17/1972) presented with abdominal pain and chronic pancreatitis. Following an earlier surgical procedure that left a syringe in her abdomen, she had suffered from sepsis, chronic neuropathic abdominal pain and chronic pancreatitis.

42. Respondent's diagnosis for T.O.B. was abdominal pain periumbilical, abdominal pain generalized, myalgia and myositis, neuropathic pain, myofascial pain syndrome, failed abdominal pain surgery syndrome and chronic pancreatitis.

43. Respondent managed T.O.B.'s pain with a combination of opioid and non-opioid pharmacotherapy and celiac sympathetic ganglion injections.

44. He administered injections in June, October and November 2014 and in February, September and December 2015.

45. He prescribed Horizant ER 600 mg bid; Dilaudid 8 mg tid, Oxycontin 30 mg and Valium 5mg.

46. When T.O.B. reported lack of efficacy from Dilaudid and Oxycontin, Respondent wrote a prescription on November 20, 2014 for Subsys 200 mcg qid #30. He wrote a second script for Subsys 200 mcg #20.

47. According to FDA guidelines, in outpatient settings, all healthcare providers must complete and sign a TIRF-REMS Access Patient-Prescriber Agreement Form with each new patient BEFORE writing the patient's first TIRF prescription.

48. Respondent completed the TIRF-REMS Access Patient-Prescriber Agreement with T.O.B. on January 6, 2015.

49. The Patient-Prescriber Agreement Form acknowledges 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."

50. T.O.B. did not have cancer.

51. The TIRF-REMS protocol requires that the initial dose of Subsys always be 100 mcg.

52. Respondent started T.O.B. on a dose of Subsys 200 mcg.

53. Respondent's practice of prescribing concomitantly two short acting opioids (e.g. Dillaudid and Subsys) for a prolonged period of time at substantial doses created a dangerous pharmacological plan of care as these are two of the most abuseable opioids.

54. Respondent continued prescribing Horizant 600 mcg, Dilaudid 8mg and Oxycontin 30 mg and Subsys 200 mcg.

55. On February 24, 2015, Respondent wrote "Subsys 200 mcg is controlling the breakthrough pain on background of Oxycontin 30 mg tid…She is using the medication appropriately…"

56. On April 22, 2015, Respondent refilled T.O.B.'s medication for two months for respiratory depression "as she has been a long standing and compliant patient who uses her medications judiciously and has an appropriate UDS at all times."

57. On June 3, 2015, when T.O.B reported "lack of efficacy of Subsys 200 mcg," Respondent increased the dose "to 400 mcg up to qid for severe BTP (break through pain) on background of OxyContin (sic) 30 mg tid. Dilaudid 8 mg qid is prescribed as an alternative to SAO (short acting opioid) and not to be used concurrently with the SL fentanyl." On this same day "as a prophylactic measure," Respondent also prescribed Narcan.

58. On July 1, 2015 Respondent continued T.O.B.'s regimen of Subsys 400 mcg qid.

59. On August 2, 2015, T.O.B. reported that she uses Subsys "on occasions when her Dilaudid is unable to control her severe pain exacerbations." Respondent refilled Oxycontin and Dilaudid as well as Subsys, instructing her not to use both Oxycontin and Dilaudid concurrently.

60. On September 14, 2015 Respondent again prescribed Subsys 400 mcg.

61. On October 7, 2015 and on December 8, 2015, Respondent increased the dose of Subsys to 600 mcg after patient told him her pain was not controlled with Dilaudid.

62. As documented in his progress note, on or around January 13, 2016, Respondent discontinued prescribing Subsys to T.O.B. Respondent refilled Oxycodone and Hydromorphone and added fentanyl patch "since the Subsys has been discontinued and she had FLP (fentanyl patch) in addition to her current regimen while recently inpatient in November for management of pain exacerbation . . . The FLP will be used as a transition from inpatient to out-patient pain management as well as to aid in weaning off SLFentanyl spray. Transdermal FLP to be used for one month only."

63. Respondent's progress notes fail to document T.O.B.'s inpatient stay. It is not mentioned in notes on T.O.B.'s December office visit.

64. Respondent continued T.O.B. on Oxycodone. He started her on methadone in June 2016. He cancelled methadone in November 2016. His last prescriptions for T.O.B. were Horizant ER 600 mg, Dilaudid, Oxycontin 30 mg and Valium, the same medications with which he had begun her treatment.

65. In his final progress note dated October 12, 2017, Respondent diagnosed T.O.B. as "opioid dependent with other opioid induced disorder; chronic pain syndrome, post laminectomy syndrome, and generalized abdominal pain." He prescribed short acting opioids on a prn (as needed) basis, although he wrote these in sufficient quantifies to be taken continually without interruption around the clock.

66. He had prescribed Subsys from November 20, 2014 to December 8, 2015 for T.O.B.'s non-cancer abdominal pain. His inappropriate prescribing of Subsys was bound to worsen her underlying condition, as Subsys is associated with rapid onset and offset fentanyl concentrations that would likely exacerbate T.O.B.'s opioid tolerance, dependence, gastrointestinal and neurological conditions.

67. Respondent created a dangerous pharmacological plan of care by prescribing two short acting opioids (Dilaudid and Subsys) at substantial doses for a prolonged period of time.

68. Respondent's opioid prescribing mismanagement led to excessive daily dosing. He prescribed short acting opioids on a prn basis although he wrote these in sufficient quantities to be taken around the clock.

69. Respondent's prescribing for T.O.B. grossly elevated her risk of misuse, addiction, diversion, overdose and death.

70. As detailed above, and more fully in Respondent's records for T.O.B., Respondent improperly treated T.O.B. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to T.O.B. 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.

71. 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

72. The Attorney General repeats and re-alleges the General Allegation and allegations of Count I as if fully set forth herein.

73. The first progress note in the file of patient B.C. (DOB 12/22/1961) is a reevaluation dated July 2, 2014. The file includes a prescription dated May 30, 2014 indicating

that B.C. was an established patient before July 2014. Respondent's prescription dated May 30, 2014 for B.C. is for Subsys 600 mcg q4-6h #120.

74. B.C. presented with a history of back pain and left leg pain. He had undergone surgery, nerve block injections, and physical therapy without significant sustained pain relief. He had a history of severe failed neck surgery syndrome, chronic myofascial pain, cervical pain, cervical DDD, cervical HNP, lumbar DDD, lumbar HNP, HIV neuropathy that required multi-medication management. His past medications included Avinza (morphine sulfate), Oxycodone and fentanyl spray.

75. Respondent diagnosed B.C. with chronic back pain, postlaminectomy syndrome, cervical region, myalgia and myositis.

76. The first progress note in patient's file is a reevaluation dated July 2, 2014. "I will continue to prescribe Avinza 120 mg per day as well as Subsys 600 mcg up to 4 per day. He has in the past failed to respond to all other short acting opioids which were used to treat pain and he is compliant with TIRF-REMS Patient Provider Agreement. This medication regimen is controlling his pain. He denies opioid related side effects and is using these medications exactly as prescribed."

77. There is no TIRF REMS agreement in this file on or before July 2, 2014.

78. Notwithstanding the TIRF-REMS protocol requirements that prescribers initiate Subsys at the lowest dose of 100 mcg, Respondent's initial dose began at 600 mcg.

79. The Prescription Monitoring Program (PMP) documents Subsys prescriptions on March 11, 2014 400 mcg, on April 10, 2014 600 mcg, on May 9 and May 30, also 600 mcg, all far above the initial dose mandated at 100 mcg.

80. Respondent managed B.C. with a combination of opioid and non-opioid pharmacotherapy and a series of epidural injections and trigger point injections.

81. Throughout 2014 and 2015, Respondent administered multiple series of injections, including the high risk cervical transforaminal epidural steroid injections that exposed B.C. to neurological injury.

82. Notwithstanding that B.C. did not have cancer, Respondent prescribed Subsys 600 mcg on an ongoing basis. The file contains scripts dating from May 2014 through December 2015. (The earliest record in the PMP is March 2014.) Doses at up to #120 per month allowed full round the clock ingestion.

83. It was not until July 23, 2015 that Respondent and B.C. signed a TIRF REMS Patient Provider Agreement.

84. Prior to July 23, 2015, Respondent and B.C. operated under a pain contract countersigned by APN Patricia Mazza. On numerous occasions B.C.'s urine drug tests came back positive for Oxycodone in violation of the terms of the pain contract. These violations of the agreement should have resulted in cessation of treatment, as set forth in paragraphs 5, 10 and 11 of the pain contract, but Respondent continued to prescribe to B.C.

85. Respondent's prescribing grossly deviated from the standard of care in his off label use of Subsys for a patient who did not suffer from severe cancer breakthrough pain, in his dosing, and in his combining Subsys with dangerous epidural injections.

86. As detailed above, and more fully in Respondent's records for B.C., Respondent improperly treated B.C. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to B.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.

87. 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

88. The Attorney General repeats and re-alleges the General Allegations and allegations of Counts I and II as if fully set forth verbatim herein.

89. On May 29, 2014, patient N.P. (DOB 2/5/1975) presented with a history of back pain and lower back pain radiating down bilateral legs that began in 2011. He had undergone surgery, nerve block injections and physical therapy without significant sustained pain relief. Past medications included morphine and MSContin.

90. Respondent diagnosed N.P. with lumbar stenosis, lumbar radiculopathy, lumbar herniated nucleus pulposis, lumbar facet arthropathy and lumbar degenerative disc disease.

91. On May 29, 2014, the initial progress note in N.P.'s file documents that Subsys 400 mcg was refilled, indicating that N.P. was an established patient by that date. The file does not include a TIRF-REMS Patient-Provider Agreement.

92. According to the PMP, beginning in April 2013, Respondent treated N.P.'s failed back pain syndrome with Subsys, soma, gabapentin, Oxycodone and Oxycontin. This combination therapy is dangerous and generally would be expected to worsen N.P.'s pain and function.

93. Failed back surgery syndrome produces mechanical pain of musculoskeletal and neuropathic character. This should be managed in a manner that is minimally psychoactive in order

to minimize or eliminate dependence and addiction risks. But short acting medicines such as Subsys can induct worsening neuropathic and musculoskeletal pain, while promoting building of tolerance and dependence.

94. Notwithstanding the TIRF-REMS protocol requirement that prescribers initiate Subsys at the lowest dose of 100 mcg, Respondent's initial scripts began at 400 mcg, crept up to 600 mcg on August 4, 2014, up again to 800 mcg on March 16, 2015, where it is alternated with doses of 600 mcg.

95. "Dose creep" is inevitable when Subsys doses and frequency are escalated due to development of tolerance, dependence, higher grade end of dose failure, withdrawal pain and hyperalgesia (abnormally heightened sensitivity to pain) resulting from an analgesic strategy that repeatedly fails.

96. Irregularities in Respondent's prescribing for N.P. include: unexplained back to back Subsys prescriptions (e.g. January 6, 2015 #120 and January 7, 2015 #150); refills absent justification (the April 27, 2015 and on May 12, 2015 prescriptions for Subsys 600 mcg #150); and prescriptions written without an office visit (such as December 9 and 30, 2014, January 6 and 7, 2015, April 1, 15 and 27, 2015, May 28, 2015 and June 5, 2015.)

97. Respondent discontinued Subsys for N.P. on July 7, 2015 "as he is no longer receiving adequate analgesia." Respondent added morphine sulfate instant release (MSIR), Oxycontin and antidepressant Elavil (amitriptyline). When N.P.'s spinal cord stimulator was reprogrammed on September 2, 2015, Respondent switched N.P. from Oxycontin to methadone to better control N.P.'s pain.

98. On August 6, 2015, Respondent and N.P. executed a TIRF-REMS Patient Prescriber Agreement, months after Respondent had stopped writing Subsys prescriptions for N.P.

99. Respondent's prescribing of Subsys for N.P. grossly deviated from the standard of care in his off label use of Subsys for this patient who did not suffer from cancer, in his upping the doses in dose creep from an initial heavy dose, in his writing early prescriptions, and in writing prescriptions absent office visits.

100. As detailed above, and more fully in Respondent's records for N.P., Respondent improperly treated N.P. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to N.P. 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.

101. 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

102. The Attorney General repeats and re-alleges the General Allegations and allegations of Counts I through III as if fully set forth herein.

103. Patient J.W. (DOB 12/15/1977) presented on June 13, 2014 with a history of headaches related to a cavernous hematoma that could not be surgically treated. Multiple intracranial bleeds had caused deficits with right peripheral vision and weakness of the right side. In September 2014 she reported that the head pain was causing her the most significant amount of pain.

104. Respondent diagnosed J.W. with cervicalgia, cervical spondylosis without myelopathy, variant of migraine without mention of intractable migraine or status migrainosus, cervicalgia myalgia and myositis unspecified. Later in Respondent's record, he diagnoses J.W. with ADHD disorder and anxiety.

105. The initial progress note is dated June 13, 2014. However, the file contains a prescription dated February 5, 2014 for Subsys 600 mcg Q4 prn #150 for "intractable pain." The June progress note indicates "Subsys trials, is helpful for flare-ups but her insurance has denied."

106. Respondent continued the medications J.W. had been receiving previously including Oxycodone, gabapentin and methadone.

107. According to FDA guidelines, in outpatient settings, all healthcare providers must complete and sign a TIRF REMS Access Patient Prescriber Agreement Form with each new patient BEFORE writing the patient's first TIRF prescription.

108. On June 3, 2014 J.W. entered into a pain management contract. Not until August 6, 2015 did Respondent and J.W. enter into a TIRF REMS Access Patient Prescriber Agreement Form, Respondent having prescribed Subsys to J.W. since at least February 2014.

109. Dose creep is evident in Respondent's prescribing. He starts J.W. at 600 mcg, well above the required initial dose of 100 mcg, and on March 6, 2015 ups the dose to 800 mcg. He continues dosing either 600 mcg or 800 mcg through December 11, 2015.

110. J.W.'s file includes a Letter of Medical Necessity dated November 6, 2015 to J.W.'s insurance company explaining that J.W. "has a medical necessity for Subsys at the prescribed dose in order to treat breakthrough pain," as "currently there is no FDA approved agent available for breakthrough pain in patients who do not have cancer." "Vicodin, Percocet, Nucynta, Opana, Norco and other similar medications did not receive FDA approval for any type of breakthrough

pain. This does not mean that breakthrough pain should not be treated." Respondent concludes in the letter: "It is my medical opinion, Subsys is medically necessary in alleviating my patient's breakthrough pain." He makes no mention of the TIRF REMS protocol. There is no reply from the insurance company in J.W.'s file.

111. On January 7, 2016, Respondent discontinued prescribing Subsys for J.W. He refilled J.W.'s Oxycodone and methadone prescriptions.

112. Respondent's choice of chronic opioid therapy for J.W., especially high risk opioids with quick onset and offset pharmacokinetic properties such as Subsys, contradicts J.W.'s diagnosis of headaches, ADHD and anxiety. The pharmacodynamics properties of opioids and Subsys specifically are associated with chronic daily headache.

113. Notwithstanding the TIRF-REMS protocol requirement that prescribers initiate Subsys at the lowest dose of 100 mcg, Respondent's initial script began dosing at 600 mcg.

114. As detailed above, and more fully in Respondent's records for J.W., Respondent improperly treated J.W. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to J.W. 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.

115. 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

116. The Attorney General repeats and re-alleges the General Allegations and allegations of Counts I through IV as if fully set forth herein.

117. Complainant issued a subpoena for patient records (to include TIRF REMS enrollment documentation) for the period May 2014 through October 2017 for patients T.O.B., B.C., N.P., and J.W. ("Set 1"). On July 18, 2017, Respondent certified that these were true, accurate and complete.

118. Following the State's request for supplemental material, Respondent again submitted copies of electronic records for these same patients ("Set 2"), certifying on February 11, 2018 that these were true, accurate and complete.

119. The two sets ("Set 1 and Set 2") differ in their completeness and in internal editing. Neither includes all the prescriptions that are identified in the PMP. For example,

- For patient T.O.B. nine dates of service are missing from Set 1 that are included in Set 2;

- For patient B.C. information found in Set 1 is missing from Set 2 and the history of recent illness differs from Set 1 to Set 2;

- For patient N.P. information found in Set 1 is missing from Set 2 (e.g. Caudal Epidural injections noted in Set 1 are missing from Set 2). N.P.'s age differs in the two sets;

- For patient J.W. Set 1 includes past medication that does not appear in Set 2. The History of present illness missing in Set 1 is included in Set 2. The physical examination included in Set 1 is missing from Set 2 (see January 7, 2015; March 6, 2015). J.W.'s age differs in the two sets.

120. Respondent's progress notes are not original to each visit and are largely copy and paste forwards (e.g. J.W.'s progress note for April 11, 2016 includes care from 2015 without segregating it from the 2016 note and Respondent's note for J.W. that he had a lengthy discussion

with her and her husband regarding the risks of polypharmacy). This identical note appears in Set 1 on June 11, 2015, July 12, 2015, August 6, 2015, September 2, 2015 and September 30, 2015).

121. Respondent's records do not meet the "contemporaneous permanent professional treatment records" standard set forth in Board regulation N.J.A.C. 13:35-6.5. Respondent has altered his records, as evidenced by the differences in the two sets of records to which he certified to (July 18, 2017 and February 11, 2018). He certified that each of these sets was true, accurate and complete, clearly an impossibility.

122. Respondent's records indicate that he has engaged in professional or occupational misconduct as may be determined by the Board, contrary to N.J.S.A. 45:1-21(e) and has violated or failed to comply with the provisions of any act or regulation administered by the Board, contrary to N.J.S.A. 45:1-21(h)(specifically N.J.A.C. 13:35-6.5).

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: *Kathy Stroh Mendoza, a.m.n.*
Kathy Stroh Mendoza
Deputy Attorney General

Dated: November 23, 2020