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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 **SERGE MENKIN, M.D.** **LICENSE NO. 25MA08003800** TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	Administrative Action **COMPLAINT**

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

GENERAL ALLEGATIONS

I. Introduction

1. This case is about a physician who allowed his treatment and prescription decisions to be influenced by improper benefits he received from the infamous and now bankrupt pharmaceutical company, Insys Therapeutics, Inc. ("Insys"). In exchange for dinners posing as "lectures," an all-expense paid trip for "training," and payments thinly disguised as "speaker's

fees," which collectively totaled more than $111,000, Serge Menkin ("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 the 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 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, in addition to his indiscriminate prescribing of other high dose opioids, placed his patients at risk of addiction, overdose, and death.

6. It was not until Respondent received a subpoena form the Attorney General regarding his prescribing, on or about October 13, 2016, that he began curtailing his Subsys prescribing, writing only three Subsys prescriptions for the remainder of 2016, and none thereafter, by which time payments from Insys had also dried up.

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 is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA08003800. At all times relevant hereto Respondent has maintained medical practices specializing in pain management in Holmdel, Woodbridge, and Jersey 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 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. § 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. There are currently six approved TIRF medications, three of which, Subsys, Actiq, and Fentora, are at issue in this matter.

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, and 800mcg fentanyl solution.

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

16. Actiq is the trade name for a fentanyl oral transmucosal lozenge, a TIRF fentanyl formulation administered on a plastic stick designed to dissolve slowly in the mouth for absorption along the buccal mucosa. Actiq is manufactured and sold exclusively by Cephalon, Inc. ("Cephalon"), a Pennsylvania-based corporation, and is available in the following dosage strengths: 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg fentanyl solution.

17. 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, and is available in the following dosage strengths: 100mcg, 200mcg, 400mcg, 600mcg, and 800mcg fentanyl solution.

18. At all relevant times, the only FDA-approved use for all TIRF medicines, including Subsys, Actiq, 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.

19. 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, New Jersey: "'With the early onset

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

20. 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.

21. 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.

22. 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 Program 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."

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

24. 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

25. On or about October 20, 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, Actiq, and Fentora, and successfully completed the Knowledge Assessment.

26. 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.

[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 Access Program in late 2011.

. . .

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 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.

[(Emphasis in original.)]

27. 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** 100mcg.

[(Emphasis added.)]

28. By enrolling in the TIRF REMS Access Program, Respondent acknowledged having read the Full Prescribing Information for Actiq and Fentora, which provide warnings identical to those above regarding respiratory depression, medication errors, and abuse potential, and which provide that initial doses of these TIRF medicines is **always** 200mcg (for Actiq) and 100mcg (for Fentora).[2] (Emphasis added.)

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

> 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

[2] Unless converting a patient between Actiq (greater than or equal to 600mcg) to Fentora.

> 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

30. In both October 2014 and September 2016, Respondent renewed his enrollment in the TIRF REMS Access Program, and in so doing, each time he again completed and signed the above-mentioned Prescriber Enrollment Form and successfully completed the Knowledge Assessment.

31. 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."

32. Dr. Nelson opined 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."

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

VI. Respondent's Relationship with Insys

34. 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.[3]

35. Rather than serving as educational gatherings, ISP events "often did not involve any education or presentation about [Subsys]" and frequently had no attendees at all.[4] 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."[5]

36. In or about the spring of 2012, Respondent and Michelle Breitenbach ("Breitenbach"), a drug representative for Insys, formed a relationship meant to incentivize Respondent to prescribe Subsys to his patients, rather than competitor TIRF substances Fentora and/or Actiq.

37. On or about June 19, 2012, Respondent started prescribing Subsys. Shortly thereafter, on or about June 26, 2012, Respondent expressed to Breitenbach his interest in becoming a compensated speaker with the ISP.

38. On July 19, 2012, Respondent completed an ISP web-based training, for which he received a payment of $750 from Insys.

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[3] 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).

[4] Id.

[5] Id.

39. On October 23, 2012, after steadily prescribing Subsys, Insys offered Respondent his first ISP event. Notwithstanding that the event was attended by only one physician, Respondent received a payment of $1,000 from Insys.

40. As Respondent continued prescribing Subsys, Insys awarded him additional ISP events, as well as a promotion to "Regional" speaker status, in or about February 2013, which increased his ISP speaking fee from $1,000 to $1,600 per event. As of April 16, 2014, Respondent's ISP speaking fee was again increased to $2,200.

41. On multiple occasions, only one medical professional with prescribing privileges attended Respondent's ISP events. In some instances, no prescribers were present at Respondent's ISP events. In all cases, Insys paid Respondent his full honorarium, and, on at least one occasion, on or about June 19, 2015, Insys paid Respondent his full honorarium even though the ISP event was cancelled. The topic of these programs was breakthrough pain in cancer patients. Upon information and belief, the script for these events was prepared and provided to Respondent by Insys and remained substantially the same at each event.

42. In addition to receiving speaking fees, Insys also compensated Respondent for ISP training events and his travel, as well as related expenses for him and his guests, such as meals. For instance, in 2013, Insys agreed to pay Respondent $2,500, plus travel expenses, for his attendance at a training event in Scottsdale, Arizona.

43. Open Payments is a federal program that collects and makes information public about financial relationships between the health care industry and physicians. The Centers for Medicare & Medicaid Services 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 as reported by drug manufactures and provided the opportunity to file a dispute.

44. As reflected in Open Payments and/or data provided by Insys, Insys made payments to Respondent virtually every month from October 2012 to September 2016. During this same time, Respondent became one of Insys's top prescribers of Subsys. Moreover, Respondent wrote few prescriptions for any other similar TIRF medications such as Actiq or Fentora.

45. 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 (or generics) and Fentora) he prescribed during those same years:

Year	**Subsys Prescriptions**	**Insys payments to Respondent**	**All other TIRF medications prescribed**
2012	18	$5,750	38
2013	121	$36,043.67	15
2014	182	$35,107.24	14
2015	239	$30,304.18	14
2016	92	$4,453.31	13
2017-date	0	$0	1
Total	652	$111,658.40	95

46. 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

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

48. On March 10, 2008, D.B., a 30-year-old female, first saw Respondent as a patient. At that time, D.B. presented with "[l]ow back" and "right lower extremity" pain following a motor vehicle accident three days earlier.[6]

49. Although Respondent thereafter purportedly treated D.B. for a wide variety of medical conditions, including, without limitation, chronic pain, headaches, tendonitis and joint dysfunction, at no time during Respondent's care and treatment of D.B. did he diagnose her with, or treat her for, cancer or breakthrough cancer pain, because she did not have cancer.

50. Notwithstanding that D.B. did not have cancer and, therefore, did not suffer from breakthrough cancer pain, Respondent prescribed her Fentora and Subsys, among other opioids.[7]

51. On July 31, 2008, following a physical examination, Respondent noted an "exacerbation" of D.B.'s pain and replaced her prescription of oxycodone (Roxicodone) 15mg with "Fentora 200mcg-400mcg," twice daily, contrary to the Full Prescribing Information for Fentora, which sets the initial dose at 100mcg.[8]

52. Beginning on August 28, 2008, Respondent, over the course of the next five years, persistently increased D.B.'s Fentora prescription, in addition to other opioids (not yet including

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[6] Pursuant to Board policy the names of all patients are redacted, but known to Respondent.

[7] In addition to prescribing Fentora and Subsys, Respondent also regularly prescribed D.B. hydromorphone (Dilaudid) 4mg, oxycodone (OxyContin) between 30mg to 40mg, and the muscle relaxant, Carisoprodol (Soma) 350mg.

[8] Although the first progress note that exists in Respondent's treatment record for D.B. is dated March 10, 2008, the record, as submitted by Respondent, does not include copies of D.B.'s prescriptions prior to August 28, 2008.

Subsys), for treatment of her non-cancer related pain, from 400mcg, twice daily, up to 600mcg, four times a day as of September 10, 2013.

53. On October 3, 2013, Respondent, without explanation, continued D.B. on Fentora 600mcg while adding a 30-dose "trial" prescription of Subsys 600mcg, six times greater than the indicated starting dose of Subsys, amongst other regularly prescribed drugs.

54. On or about that same date, Respondent executed the TIRF REMS Access Program PPAF. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys prescribed to D.B., was the lowest dose available; (b) he had reviewed with D.B. the "appropriate use" of Subsys; and (c) he had also reviewed with D.B. the Subsys Medication Guide.

55. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

56. In signing the PPAF on October 3, 2013, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REMS Access Program requirements.

57. On October 24, 2013, following D.B.'s "trial" dose of Subsys 600mcg, and in spite of TIRF REMS Access Program requirements and Subsys Medication Guide warnings, Respondent continued D.B. on Fentora 600mcg, four times daily, only to substitute Fentora for

Subsys, at that same dosage, on November 26, 2013, and then finally discontinue Subsys and return D.B. to Fentora 600mcg, four times daily, on December 26, 2013.

58. Ultimately, between October and December 2013, Respondent prescribed D.B. a combined 486 doses of Subsys and Fentora, both at 600mcg, for the management of her non-cancer related pain.

59. From January 23, 2014 onward, Respondent continued his attempts to treat D.B.'s non-cancer related chronic pain with Fentora 600mcg, along with other opioids including OxyContin, Dilaudid, and tramadol, and the muscle relaxant, Soma.

60. On September 29, 2015, Respondent again, without explanation, attempted to switch D.B. from Fentora 600mcg to Subsys 600mcg, only to resume prescribing Fentora 600mcg by October 20, 2015.[9]

61. To facilitate D.B.'s ability to obtain Subsys, in or about October 2015, Respondent completed a "Patient Authorization & Referral Form" issued by the Insys Reimbursement Center ("IRC").

62. On an IRC form dated October 1, 2015, Respondent certified that D.B.'s receipt of 120 doses of Subsys 100mcg was "medically necessary" for her treatment, even though she was not suffering from breakthrough cancer pain, and in spite of the fact that, at the time, Respondent had actually issued her a prescription for 120 doses of Subsys *600mcg*. Moreover, Respondent listed OxyContin, Dilaudid, tramadol, and Fentora as "Tried/Failed" analgesic medications on the IRC form, notwithstanding that Respondent continued to regularly prescribe these drugs to D.B. on a near monthly basis thereafter.

[9] D.B.'s treatment records, as submitted by Respondent, fail to include any progress notes for the timeframe when this purported medication switch occurred.

63. After discontinuing her prescription of Subsys, as of October 20, 2015, Respondent would continue treating D.B.'s non-cancer related chronic pain complaints with Fentora at 600mcg, among other opioid medications.

64. Additionally, D.B.'s treatment record further provides evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of D.B.'s use of opioid medications, including Fentora and Subsys. This includes, as the following:

a. On November 22, 2014, Respondent received a report from Keystone Lab indicating that D.B., although receiving regular prescriptions of Fentora 600mcg from him, had not tested positive for either fentanyl or its metabolite, norfentanyl. Other regularly prescribed medications, Dilaudid and Soma, were also undetected in the report.

b. D.B. would continue testing negative for fentanyl and norfentanyl, as well as Dilaudid, on five subsequent urine drug screens reported to Respondent between December 8, 2014 and March 25, 2015, even though D.B. received regular monthly prescriptions of Dilaudid, and Fentora at 600mcg from him.

c. Only one urine drug screen, reported on May 17, 2016, exists in Respondent's treatment record for D.B., indicating a positive result for norfentanyl.

d. Notwithstanding these successive discrepancies in the urine drug screen results, Respondent continued to regularly prescribe D.B. highly potent opioid medications, including Fentora, Subsys, OxyContin, Dilaudid, and tramadol, along with other drugs, with no documented discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion. Nor did Respondent review D.B.'s prescription history through the New Jersey Prescription Monitoring Program ("NJPMP").

65. As detailed above, and more fully in Respondent's records for D.B., Respondent improperly treated D.B. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to D.B. 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 REMS agreement and grossly outside the standard of care.

66. 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, safety, and welfare 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. the issuing 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

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

68. On March 15, 2011, J.N., a 50-year-old female, first saw Respondent as a patient. At that time, J.N. presented with pain complaints stemming from a January 2006 work-related injury.

69. Although Respondent thereafter purportedly treated J.N. for a wide variety of medical conditions, including, without limitation, cervical, shoulder and knee pain, lumbar radiculitis, and disc herniation, at no time during Respondent's care and treatment of J.N. did he diagnose her with, or treat her for, cancer or breakthrough cancer pain, because she did not have cancer.

70. Notwithstanding that J.N. did not have cancer, and therefore, did not suffer from breakthrough cancer pain, Respondent prescribed her Subsys, among other opioids.[10]

71. Beginning on April 4, 2013, Respondent first prescribed J.N. a ten-day "trial" of Subsys at 200mcg as a replacement for her 50mcg fentanyl transdermal patch due to an alleged side effect caused by the patch's adhesive, in spite of product instructions and warnings. The full prescribing information for Subsys instructs that the initial dose of the drug is always 100mcg since Subsys "**is not bioequivalent to other fentanyl products,**" and there are "**no conversion directions available for patients on any other fentanyl products. . . . [including] oral, transdermal, or parenteral formulations of fentanyl.**" (Emphasis in original.) Moreover, notably absent from J.N.'s patient record at this time is the required PPAF relating to Subsys.

72. It was not until June 25, 2013, when Respondent increased J.N.'s Subsys prescription to 120 doses at 200mcg, four times a day, that he and J.N. executed the TIRF REMS Access Program's PPAF. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys prescribed to J.N., was the lowest dose available; (b) he had reviewed with J.N. the "appropriate use" of Subsys; and (c) he had also reviewed with J.N. the Subsys Medication Guide.

73. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your

[10] In addition to prescribing Subsys, Respondent also regularly prescribed J.N., throughout her treatment, various strengths and combinations of opioids including hydrocodone/acetaminophen (Vicodin and Norco); fentanyl patches; tapentadol (Nucynta); oxymorphone (Opana Extended Release); and hydromorphone (Exalgo).

healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

74. In signing the PPAF on June 25, 2013, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REMS Access Program requirements.

75. Following the execution of the PPAF, Respondent continued prescribing J.N. 120 doses of Subsys at 200mcg, four times a day, for the management of non-cancer related pain.

76. Notably, between December 12, 2013 and July 3, 2014, Respondent prescribed J.N., on regular monthly basis, Subsys 200mcg, four times daily, for treatment of her non-cancer pain without prescribing her another "around-the-clock" opioid pain medicine. As noted, product warnings provide that Subsys is indicated only for the treatment of breakthrough cancer pain in patients who "are tolerant to opioid therapy for their underlying persistent cancer pain" and that such patients "must remain on around-the-clock opioids" when taking Subsys due to the risk of fatal respiratory depression in opioid non-tolerant patients.

77. Beginning on or about July 31, 2014, Respondent began prescribing J.N. hydrocodone/acetaminophen (Norco) 10/325mg, to be taken up to twice daily, in addition to Subsys 200mcg, four times daily, until on or about September 3, 2015, when, without explanation, he ceased prescribing J.N. Subsys.[11]

78. After discontinuing J.N.'s Subsys prescription, Respondent continued treating J.N.'s pain symptoms with opioids, alternating between hydrocodone (Hysingla Extended Release) 20mg, oxymorphone (Opana Extended Release) 10mg, and Norco 10/325mg.

[11] J.N.'s treatment records, as provided by Respondent, fail to include corresponding progress notes for several prescriptions issued by him for Subsys, among other opioids, between November 2014 and July 2015, and between October 2015 and January 2016.

79. Additionally, J.N.'s treatment records further provide evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of J.N.'s use of opioid medications, including Subsys. This includes, as the following:

a. On December 8, 2014, Respondent received a report from Keystone Lab indicating that, although J.N. had been receiving regular prescriptions of Subsys at 200mcg at the time, neither fentanyl nor its metabolite, norfentanyl, were detected in her November 25, 2014 urine sample. Moreover, the report further noted that the sample had tested positive for an unprescribed benzodiazepine, alprazolam (Xanax), as well as marijuana.

b. The December 8, 2014 report further notes that both fentanyl and norfentanyl were not detected in J.N.'s urine samples collected in September and October 2014, despite her receipt of prescription of Subsys in those months, and that marijuana had also been detected in September 2014.

c. On January 27, 2015, a subsequent Keystone Lab report similarly showed that J.N. had tested negative for fentanyl and norfentanyl in a urine sample collected that month, despite her ongoing prescription of Subsys 200mcg.

d. Notwithstanding these successive discrepancies in the urine drug screen results, Respondent continued regularly prescribe J.N. highly potent opioid medications, including Subsys, among other drugs, with no documented discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion. Nor did Respondent review J.N.'s prescription history through the NJPMP.[12]

[12] J.N.'s treatment record has only two NJPMP reports, one of which was obtained shortly after Respondent received the Attorney General's subpoena for his patient records, and both of which document J.N. receiving CDS from multiple prescribers.

80. As detailed above, and more fully in Respondent's records for J.N., Respondent improperly treated J.N. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to J.N. 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 REMS agreement and grossly outside the standard of care.

81. 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, safety, and welfare 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. the issuing 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

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

83. On January 3, 2012, D.K., a 51-year-old male, first saw Respondent as a patient. At that time, D.K. presented with complaints of back, neck and lower extremity pain.

84. Although Respondent thereafter purportedly treated D.K. for a wide variety of medical conditions, including, without limitation, chronic pain, degenerative joint disease, and neuropathy, at no time during Respondent's care and treatment of D.K. did he diagnose him with, or treat him for, cancer or breakthrough cancer pain, because he did not have cancer.

85. Notwithstanding that D.K. did not have cancer, and, therefore, did not suffer from breakthrough cancer pain, Respondent prescribed him Actiq and Subsys, among other opioids.[13]

86. On January 3, 2012, Respondent prescribed D.K. 30 doses of Actiq at 400mcg, which is twice the indicated starting dose, and he continued prescribing D.K. Actiq at that dosage for the next eight months.

87. On October 4, 2012, Respondent discontinued Actiq and prescribed D.K. a 30-dose "trial" of Subsys at 400mcg, which is four times the indicated starting dosage and contrary to product warnings against converting between TIRF medications on a mcg per mcg basis.[14] Moreover, absent from D.K.'s patient record at this time is a PPAF corresponding with this Subsys prescription.

88. Nonetheless, Respondent continued steadily increasing D.K.'s 400mcg Subsys prescription for the management of his non-cancer pain from once daily, to twice daily on November 8, 2012, then to three times daily as of October 17, 2013, and finally to four times daily as of March 6, 2014.

89. On April 8, 2014, upon prescribing D.K. 120 doses of 400mcg Subsys, Respondent and D.K. executed the TIRF REMS Access Program's PPAF. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys, which he had already prescribed to D.K. in steadily increasing doses between November 2012 and March 2014, was the lowest dose available; (b) he had reviewed with D.K. the "appropriate use" of Subsys; and (c) he had also reviewed with D.K. the Subsys Medication Guide.

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[13] In addition to prescribing Actiq and Subsys, Respondent also regularly prescribed D.K., oxymorphone, and later oxycodone, in extended and immediate release formulations, at 40mg and 10mg to 15mg, respectively, throughout his treatment.

[14] Subsys prescribing information indicates that the starting dose is always 100mcg, unless the patient is being converted from Actiq at a level greater than, or equal to, 600mcg.

90. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

91. In signing the PPAF on April 8, 2014, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REM Access Program requirements. Respondent continued prescribing D.K. 120 doses of Subsys, 400mcg, with instructions that D.K. consume four doses daily for treatment of non-cancer related pain.

92. Subsequently, for the next two years, Respondent continued regularly prescribing D.K. Subsys at 400mcg, amongst other opioid medications. Moreover, notwithstanding the assortment of opioid medications prescribed, D.K.'s treatment record lacks both detailed drug testing results and/or NJPMP prescription history reports. Nonetheless, D.K. continued receiving Subsys for the treatment of his non-cancer related pain until Respondent discontinued the medication on or about October 18, 2016, following the issuance of the Attorney General's subpoena on October 13, 2016.

93. As detailed above, and more fully in Respondent's records for D.K., Respondent improperly treated D.K. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to D.K. 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 REMS agreement and grossly outside the standard of care.

94. 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, safety, and welfare 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. the issuing 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

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

96. On October 10, 2012, J.D., a 38-year-old male, who had already been treated for pain symptoms by Respondent, was evaluated by Respondent's associate, Dr. Seth Schran, for lower back pain.[15]

97. Although Respondent thereafter purportedly treated J.D. for a wide variety of medical conditions, including, without limitation, disc herniation, spondylosis, and radiculopathy, at no time during Respondent's care and treatment of J.D. did he diagnose him with, or treat him for, cancer or breakthrough cancer pain, because he did not have cancer.

98. Notwithstanding that J.D. did not have cancer and therefore did not suffer from breakthrough cancer pain, and in spite of his documented history of alcoholism and depression, Respondent prescribed J.D. Subsys, among other opioids.[16]

[15] Despite an indication in the treatment record that a doctor-patient relationship existed between Respondent and J.D. previously, Respondent's treatment record for J.D. does not include any progress notes prior to October 10, 2012.

[16] In addition to prescribing Subsys, Respondent also regularly prescribed J.D., throughout his treatment, various strengths and combinations of opioids including hydromorphone (Dilaudid),

99. Beginning on November 19, 2013, and prior to completing a PPAF, Respondent prescribed J.D. ten doses of Subsys, 100mcg, to be consumed twice daily.

100. On November 21, 2013, Respondent and J.D. executed and submitted a PPAF. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys, the TIRF medication that he had in fact already prescribed to J.D., was the lowest dose available; that (b) he had reviewed with J.D. the "appropriate use" of Subsys; and (c) he had also reviewed with J.D. the Subsys Medication Guide.

101. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

102. In signing the PPAF on November 21, 2013, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, including risks associated with prescribing Subsys to patients who have a history of substance abuse and mental health issues, and also represented, and agreed that, he would comply with all TIRF REM Access Program requirements.

103. Soon thereafter, on December 5, 2013, J.D.'s insurance carrier notified Respondent that it had denied coverage of Subsys because Respondent had prescribed Subsys for a reason that is not medically accepted.

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oxymorphone (Opana Extended and Immediate Release), morphine (MS Contin), fentanyl patches, and oxycodone.

104. On January 8, 2014, Respondent submitted a letter to J.D.'s insurance carrier challenging that denial. In that letter, Respondent acknowledged that he had prescribed J.D. Subsys for an unindicated use, namely to treat J.D.'s non-cancer pain relating to "lumbago, lumbosacral spondylosis and cirrhosis of liver [sic]." He further claims J.D.'s "severe dysphagia" makes swallowing difficult, and that other "modalities have been exhausted."

105. Nevertheless, on January 23, 2014, despite insurance company's red flag, Respondent continued prescribing J.D. Subsys, for treatment of non-cancer related pain, and further increased J.D.'s prescription to 60 doses at 200mcg, with instruction that he take the drug twice a day.

106. On January 31, 2014 and January 7, 2015, J.D.'s insurance carrier twice notified Respondent that it had again denied coverage of Subsys finding, "upon clinical review," that Respondent had prescribed the drug without a "medically accepted indication."

107. Notwithstanding his receipt of a second and third denial of coverage notice for J.D.'s Subsys prescription, on January 12, 2015, Respondent and J.D. completed another PPAF. Respondent continued prescribing J.D. Subsys, for treatment of non-cancer related pain, in increasing doses, for another year, until January 5, 2016.

108. Moreover, contrary to Respondent's claim that J.D. required Subsys because he suffered from severe dysphagia that made swallowing pills difficult, throughout his treatment Respondent prescribed J.D. oral medications in addition to Subsys, including morphine and hydromorphone (Dilaudid), without any documented difficulty swallowing these pills.

109. Nor did Respondent document any investigation into J.D.'s liver functioning on account of his history of alcoholic cirrhosis/hepatitis with encephalopathy, while continuing to prescribe him exceptionally high doses of opioids. Opioid medications are metabolized by the

liver putting patients with underlying liver dysfunction at a higher risk of opioid-related complications.

110. Additionally, J.D.'s treatment record further provides evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of J.D.'s use of opioid medications, including Subsys. This includes, as the following:

a. On November 7, 2012, Respondent and J.D. entered a "Patient – Doctor Opioid Agreement," which included, among other terms, J.D.'s agreement to participate in urine drug screens "and/or see a specialist in Addiction Medicine, if there is a concern about addiction," at Respondent's instruction.

b. On November 14, 2014, Phoenix Toxicology & Lab Services reported to Respondent that J.D., although receiving regular prescriptions of Subsys at 200mcg since January of that year, had not tested positive for fentanyl, or its metabolite, norfentanyl, from a urine sample collected on May 22, 2014. The lab reported, however, that J.D. had tested positive for an unprescribed opioid, tapentadol.

c. Similarly, on January 3, 2015, a service called Pathnostics, reported to Respondent that J.D. tested negative for fentanyl and norfentanyl, despite his continuing prescription of Subsys at 200mcg. Pathnostics also reported that regularly prescribed opioids, including morphine (MS Contin) and hydromorphone (Dilaudid), were not found in J.D.'s system, but that an unprescribed benzodiazepine and buprenorphine were detected.

d. On February 24, 2015, Pathnostics again reported to Respondent that J.D. had failed to test positive for any prescribed medications, but had tested positive for an unprescribed benzodiazepine, as well as buprenorphine and methadone.

e. On December 7, 2015, a service called Element7 reported to Respondent that neither fentanyl nor Subsys were detected in J.D.'s urine sample, collected on December 1, 2015, despite his prescriptions for both a fentanyl patch, and Subsys, 200mcg.

f. On June 13, 2016, Advanced Clinical Laboratory Solutions, Inc. reported to Respondent that, although prescribed fentanyl and morphine were detected in a urine sample collected from J.D. on June 7, 2016, J.D. also tested positive for unprescribed methylphenidate (Ritalin), oxymorphone and oxycodone.

g. Notwithstanding these successive discrepancies in the urine drug screen results, and in spite of J.D.'s history of substance abuse and the terms of the prescribing agreement, Respondent continued to regularly prescribe J.D. highly potent opioid medications, including Subsys, among other drugs, with no documented discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion. Nor did Respondent review J.D.'s prescription history through the NJPMP.

111. As detailed above, and more fully in Respondent's records for J.D., Respondent improperly treated J.D. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to J.D. 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 REMS agreement and grossly outside the standard of care.

112. 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, safety, and welfare 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. the issuing 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

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

114. On January 22, 2013, T.M., a 44-year-old female, first saw Respondent as a patient. At that time, D.B. presented with complaints of rheumatoid arthritis and ongoing back, neck, and extremity pain.[17]

115. Although Respondent thereafter purportedly treated T.M. for a wide variety of medical conditions, including, without limitation, rheumatoid arthritis, fibromyalgia, and radiculopathy, at no time during Respondent's care and treatment of T.M. did he diagnose her with, or treat her for, cancer or breakthrough cancer pain, because she did not have cancer.

116. Notwithstanding that T.M. did not have cancer, and, therefore, did not suffer from breakthrough cancer pain, Respondent prescribed her Subsys, among other opioids.[18]

117. On or about February 7, 2013, following her initial consultation with Respondent in January, Respondent increased T.M.'s Subsys prescription, for treatment of her non-cancer related pain, from 800mcg to the highest dose available, 1600mcg, and instruction to consume the drug four times daily, contrary to the indicated titration process, which recommends a titration step of 1200mcg between doses of 800mcg and 1600mcg.

[17] T.M. had been referred to Respondent by Dr. Richard Haddad, who had been treating T.M.'s pain symptoms for over five years and had prescribed her 800mcg Subsys in December 2012.

[18] In addition to prescribing Subsys, Respondent also regularly prescribed T.M., throughout her treatment, extended release morphine (Kadian), between 60mg to 100mg daily.

118. Ultimately, in a twenty-four day period between January and February 2013, through Respondent, T.M. obtained prescriptions for 480 doses of Subsys at 800mcg, which amounted to a sixty-day supply of the drug, without evidence of entering into a PPAF.

119. Finally, on April 28, 2016, after over three years of continued Subsys prescriptions at 1600mcg, for the treatment of T.M.'s non-cancer related pain symptoms, Respondent's treatment record evidences his execution of a PPAF with T.M. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys, the TIRF medication that he had in fact already prescribed to T.M., was the lowest dose available; (b) he had reviewed with T.M. the "appropriate use" of Subsys; and (c) he had also reviewed with T.M. the Subsys Medication Guide.

120. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

121. In signing the PPAF on April 28, 2016, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REMS Access Program requirements.

122. In spite of the agreements, directives and warnings in those forms, Respondent continued prescribing T.M. Subsys at 1600mcg to treat her non-cancer related pain.

123. Additionally, T.M.'s treatment record further provides evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of T.M.'s use of opioid medications, including Subsys. This includes, as the following:

a. Only two urine drug testing laboratory reports exist in T.M.'s treatment record, from December 9, 2014 and January 24, 2015, despite her being under Respondent's care for nearly three-years.

b. Although the December 9, 2014 laboratory report indicated that T.M. tested positive for an unprescribed opioid, codeine, Respondent documents no discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion on subsequent progress notes dated December 19, 2014 and December 24, 2014.

c. On approximately seven other occasions, Respondent's progress notes simply reflect "Urine tox (+)" for "opiates" or "opioids" or that T.M. returned a result consistent with prescribed medications.

d. The only NJPMP report that exists in T.M.'s record was generated October 25, 2016, approximately two weeks following the issuance of the Attorney General's subpoena.

124. As detailed above, and more fully in Respondent's records for T.M., Respondent improperly treated T.M. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to T.M. 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 REMS agreement and grossly outside the standard of care.

125. 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, safety, and welfare 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. the issuing 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

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

127. On September 17, 2013, G.F., a 53-year-old male, first saw Respondent as a patient. At that time, G.F. presented with complaints of neck pain, joint stiffness and swelling, numbness, and headaches, among other symptoms.

128. Although Respondent thereafter purportedly treated G.F. for a wide variety of medical conditions, including, without limitation, chronic pain, cervicalgia, and rheumatoid arthritis, at no time during Respondent's care and treatment of G.F. did he diagnose him with, or treat him for, cancer or breakthrough cancer pain, because he did not have cancer.

129. Notwithstanding that G.F. did not have cancer, and, therefore, did not suffer from breakthrough cancer pain, Respondent prescribed G.F. Subsys, among other opioids.[19]

130. Following G.F.'s first office visit on September 17, 2013, Respondent initiated a treatment plan to address G.F.'s non-cancer related pain symptoms that included 15mg oxycodone, four times daily, for "pain relief for acute breakthrough pain[,]" as well as a 10-dose "trial" of Subsys at 100mcg. In a progress note of that same date, Respondent documented that G.F.

[19] In addition to prescribing Subsys, Respondent also regularly prescribed G.F., throughout his treatment, oxycodone in dosages as high as 20mg, six times a day.

reportedly had not responded to treatment with a Butran patch, and that the fentanyl patch and oxycodone at 30mg were both "too strong" for him.

131. On that same date, Respondent and G.F. executed a PPAF. In signing, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys prescribed to G.F., was the lowest dose available; (b) he had reviewed with G.F. the "appropriate use" of Subsys; and that (c) he had also reviewed with G.F. the Subsys Medication Guide.

132. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

133. By submitting the PPAF on September 17, 2013, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REMS Access Program requirements.

134. In spite of the terms of the PPAF and the warnings of the Subsys Medication Guide, Respondent continued prescribing G.F. Subsys, at 100mcg, in increasing doses, between October 15, 2013 to December 10, 2013.

135. Through the remainder of 2013 and into 2014, Respondent continued prescribing G.F. Subsys, 100mcg for the management of non-cancer related pain. On or about September 19, 2014, G.F.'s insurance carrier notified him that his Subsys claim had been denied because he did not meet medical necessity requirement for a TIRF medication. Regardless, Respondent persisted in prescribing G.F. Subsys, and increased his dosage to Subsys 200mcg as of April 2, 2015.

136. Incidentally, following G.F.'s insurance carrier's denial of coverage for Subsys, as of March 3, 2015, Respondent began documenting that G.F. saw "most oral medications unchanged when emptying colostomy[,]" notwithstanding that Respondent had already been prescribing G.F. oxycodone pills, as well as Subsys (both oral medications), for nearly 18 months at that point.

137. In addition, as of September 22, 2015, and in the midst of G.F.'s appeal of his insurer's denial of coverage, Respondent began documenting that G.F. had been prescribed Subsys due to his "poor GI absorption s/p colectomy." However, Respondent cited neither of these reasons as grounds for G.F.'s Subsys prescription on an IRC program form, dated September 24, 2015, that he had submitted on G.F.'s behalf.[20] Moreover, Respondent continued prescribing G.F. oxycodone 20mg, to be taken up to six times daily, on a regular monthly basis, even after raising the "GI absorption" issue with G.F.'s insurer.

138. On September 30, 2015, G.F.'s insurance carrier again denied his claim for Subsys, resulting in Respondent submitting another letter of appeal on October 2, 2015. In that letter, Respondent acknowledges prescribing G.F. Subsys for an unindicated use, namely to treat his non-cancer pain due to "cervical radiculopathy, cervicalgia, lower back pain, chronic pain, rheumatoid arthritis and a colectomy," and that G.F. cannot "swallow and digest oral medications due to having a colectomy."

139. On October 20, 2015, Respondent and G.F. executed another PPAF, and in doing so, Respondent again represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all TIRF REMS

[20] Notably, the IRC form, under a section titled "RATIONALE FOR PRIOR AUTHORIZATION", provides as specific a basis for Insys's reimbursement assistance, a patient's "difficulty swallowing/cannot tolerate medications by mouth (PO)."

Access Program requirements. Nevertheless, on October 29, 2015, Respondent prescribed G.F. Subsys, 200mcg, with instructions that he consume the drug at this strength three times daily.

140. On November 15, 2015, G.F.'s insurance carrier notified Respondent that it had denied G.F.'s appeal, explaining that Respondent's prescription did not meet the insurance company's "Medical Necessity Criteria" because G.F. did not "require [Subsys] for treatment of chronic cancer pain caused by an active malignancy."

141. Nevertheless, Respondent continued treating G.F. with monthly prescriptions of Subsys, in increasing doses, for the treatment of his non-cancer pain, along with monthly prescriptions of oxycodone 20mg, 180 pills, four times daily, in spite of G.F.'s alleged "GI absorption" issues.

142. Additionally, G.F.'s treatment record further provides evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of G.F.'s use of opioid medications, including Subsys. This includes, as the following:

a. Only two laboratory reports exist in G.F.'s record that confirm the presence of Subsys in his system (from April 2014 and January 2016).[21]

b. From July 22, 2014 onward, several progress notes simply make a unexplained reference to "u tox" or "Urine tox (+) Oxycodone."

c. Moreover, Respondent reports "u tox pos for oxycodone and benzos" on a September 11, 2014 progress note even though Respondent had neither prescribed G.F. a benzodiazepine, nor had he documented such a prescription in a "Current medications" section of that note.

[21] Five laboratory urine drug test reports included in G.F.'s records are for other patients, presumably submitted by Respondent in error.

d. Between January 19, 2016 and July 12, 2016, Respondent documented on progress notes within those dates his impression that G.F. suffered from "Chronic opioid use."

e. Notwithstanding the foregoing monitoring reports associating G.F. with potential misuse of Subsys and the use of an unauthorized benzodiazepine, as well as Respondent's concern over G.F. suffering from "Chronic opioid use," Respondent continued prescribing G.F. Subsys, among other drugs, with no documented discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion. Nor did Respondent regularly review G.F.'s prescription history through the NJPMP.

143. As detailed above, and more fully in Respondent's records for G.F., Respondent improperly treated G.F. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to G.F. 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 REMS agreement and grossly outside the standard of care.

144. 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, safety, and welfare 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. the issuing 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

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

146. On September 15, 2011, M.B., a 49-year-old female, first saw Respondent as a patient. At that time, M.B. presented with complaints of joint stiffness, headaches, and depression, among other conditions.

147. Although Respondent thereafter purportedly treated M.B. for a wide variety of medical conditions, including, without limitation, neck and cervical facet pain, tendonitis, and radiculopathy, at no time during Respondent's care and treatment of M.B. did he diagnose her with, or treat her for, cancer or breakthrough cancer pain, because she did not have cancer.

148. Notwithstanding that M.B. did not have cancer, and, therefore, did not suffer from breakthrough cancer pain, Respondent prescribed M.B. Subsys, among other opioids.[22]

149. Beginning on December 6, 2012, Respondent prescribed M.B. 30 doses of Subsys at 200mcg, which is twice the indicated starting dose. Absent from M.B.'s patient record at this time, however, is a PPAF corresponding with this Subsys prescription. Regardless, Respondent continued prescribing M.B. Subsys through January and February 2013.

150. On February 21, 2013, M.B.'s insurance carrier informed Respondent that, following a review of information he provided in support of M.B.'s Subsys prescription, it had denied coverage of the drug, determining that coverage for Subsys is warranted only based on "FDA-approved prescribing and safety information," where the "drug is being prescribed for the management of breakthrough CANCER pain."[23] (Emphasis in original.)

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[22] In addition to prescribing Subsys, Respondent also regularly prescribed M.B., throughout her treatment, various strengths and combinations of opioids including tapentadol (Nuncynta), fentanyl patches, and hydromorphone (Exalgo and Dilaudid), and well as the benzodiazepine, diazepam (Valium).

[23] Information provided by Respondent to M.B.'s insurance carrier indicates that he prescribed Subsys "for pain related to a metal rod from wrist palsy/pain related to rejection of a steel rod [sic]."

151. Nevertheless, Respondent continued prescribing Subsys, in steadily increasing doses, through December 16, 2014, when he and M.B. finally executed the PPAF. On that same date, Respondent prescribed M.B. Subsys at 400mcg, with instructions that she consume the drug at this strength four times daily.

152. In signing the PPAF, Respondent acknowledged, among other things, that: (a) the initial dose of Subsys, which he had already prescribed to M.B. since December 6, 2012, was the lowest dose available; (b) he had reviewed with M.B. the "appropriate use" of Subsys; and (c) he had also reviewed with M.B. the Subsys Medication Guide.

153. Among other notices, the Subsys Medication Guide contains the following unequivocal warnings: "Do not use SUBSYS unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" and "Do not switch from SUBSYS to other medicines that contain fentanyl without talking with your healthcare provider. . . . Your healthcare provider will prescribe a starting dose of SUBSYS that may be different than other fentanyl containing medicines you may have been taking."

154. In signing the PPAF on December 16, 2014, Respondent represented that he understood the risks associated with Subsys and its proper and improper uses, and also represented and agreed that he would comply with all Program requirements. Nevertheless, from that date forward, Respondent continued prescribing M.B. Subsys, among other drugs.

155. Additionally, M.B.'s treatment record further provides evidence of Respondent's ineffective prescription drug monitoring and insufficient supervision of M.B.'s use of opioid medications, including Subsys. This includes, as the following:

a. On December 23, 2014, Keystone Lab reported to Respondent that, although M.B. had tested positive for regularly prescribed medications, including Subsys,

she had also tested positive for unprescribed benzodiazepines, alprazolam (Xanax) and lorazepam.

b. On April 4, 2015, Keystone Lab again reported that although M.B. had tested positive for prescribed medications, she also tested positive for numerous unprescribed medications, including Xanax; a barbiturate (phenobarbital); a tricyclic antidepressant (imipramine), and muscle relaxant (cyclobenzaprine).

c. On May 4, 2016, Acutis Diagnostics similarly reported to Respondent that M.B. had tested positive for an unprescribed benzodiazepine (lorazepam).

d. Notwithstanding the foregoing monitoring reports associating M.B. with the use of benzodiazepines, antidepressants, and muscle relaxants not authorized by Respondent, he continued prescribing M.B. Subsys, among other opioids, with no documented discussion, let alone treatment plan, addressing possible drug misuse, abuse or diversion. Nor did Respondent regularly review M.B.'s prescription history through the NJPMP.

156. As detailed above, and more fully in Respondent's records for M.B., Respondent improperly treated M.B. with a high-risk pharmacological plan of care. Respondent's prescribing regime created a risk of harm to M.B. 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 REMS agreement and grossly outside the standard of care.

157. 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, safety, and welfare 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. the issuing 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: 
Michael Antenucci
Deputy Attorney General

Dated: November 23, 2020