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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

KENNETH SUN, M.D.
LICENSE NO. 25MA06318400

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

Administrative Action

COMPLAINT

CHRISTOPHER S. PORRINO, Attorney General of New Jersey, by David M. Puteska, Deputy Attorney General, appearing, with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, by way of Complaint, says as follows:

GENERAL ALLEGATIONS

1. Pursuant to N.J.S.A. 52:17A-4(h), Complainant, Christopher S. Porrino, 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").

2. 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.

3. Respondent, Kenneth Sun, M.D., is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA06318400. At all times relevant hereto Respondent maintained a medical practice, New Jersey Progressive Pain Solutions, LLC located in Phillipsburg, New Jersey. Upon information and belief, Respondent also maintained a medical office in the State of Pennsylvania where he is also licensed to practice medicine.

4. On December 28, 2016, the Board entered a Consent Order in which Respondent agreed to the temporary suspension of his medical license pending either a negotiated settlement or the filing of a Complaint and plenary hearing on the allegations therein.

5. Fentanyl is a synthetic opioid prescription analgesic that is fifty times more potent than heroin, and one hundred times more potent than morphine. The use of fentanyl 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.

6. Based upon the dangers and potential for abuse that could lead to severe psychic or physical dependence, 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).

"TIRF" Class of Fentanyl Substances

7. Transmucosal immediate release fentanyl ("TIRF") medicines are formulations of fentanyl that deliver fentanyl to their users via the oral mucosa nearly instantaneously. There are

currently six approved TIRF medications, three of which, Subsys, Actiq, and Fentora, are at issue in this matter.

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

9. 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: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, and 1600 mcg fentanyl solution.

10. 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: 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg fentanyl solution.

11. The only Food and Drug Administration ("FDA") approved indication for all TIRF substances, 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.

12. TIRF medicines are available only through the TIRF Risk Evaluation and Mitigation Strategy ("REMS") Access program ("TIRF REMS Access Program" or "Program"), a restricted distribution program required by the FDA.

13. The TIRF REMS Access Program governs the health care industry's access to TIRF medications. All physicians who seek to prescribe TIRF substances to outpatients must, by law, first enroll in the TIRF REMS Access Program. Unless a physician enrolls in the Program, an authorized pharmacy may not fill prescriptions for TIRF medications written by a non-enrolled physician.

14. In order to enroll, and thus, gain the ability to prescribe TIRF medications to his outpatients, a physician must satisfy several requirements. He must (a) review the TIRF REMS Access education materials, including a document called "Full Prescribing Information" for each TIRF substance; (b) successfully complete the "Knowledge Assessment", a quiz designed to test his knowledge of TIRF substances; (c) complete and sign a "Prescriber Enrollment Form"; and (d) complete and sign "Patient-Prescriber Agreement Form" with each patient to whom the physician seeks to prescribe a TIRF substance.

15. Upon satisfaction of these requirements, the TIRF REMS Access Program provides the physician written confirmation that he is permitted to prescribe TIRF substances. That confirmation letter reminds the physician of the Program's requirement that, before prescribing the substance 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

16. In or about October 2013, Respondent enrolled in the TIRF REMS Access Program.[1] In so doing, he completed and submitted the Prescriber Enrollment Form, read the Full Prescribing Information for all TIRF substances, including Subsys, Actiq and Fentora, and successfully completed the Knowledge Assessment.

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

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

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

18. By enrolling in the Program, the Respondent acknowledged having read the Full Prescribing Information for Subsys, Actiq and Fentora, which although slightly different depending upon the specific drug, state, among other things, as follows:

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL

Respiratory Depression

Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS, including following use in opioid non-tolerant patients and improper dosing.

. . .

Medication Errors

Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose. . . . When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to SUBSYS.

Abuse Potential

SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

. . .

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

. . .

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

19. By enrolling in the Program, the 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.

The only exception is for Actiq and its generic equivalents, which are approved for cancer patients 16 years and older.

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

20. On October 8, 2014 and September 8, 2016, the Respondent renewed his enrollment in the TIRF REMS Access Program, and, in so doing, once again completed and signed the above-mentioned Prescriber Enrollment Form and successfully completed the Knowledge Assessment.

21. In furtherance of investigation and to better understand the risks inherent in the prescribing of TIRF substances, the Attorney General sought expert review by Lewis S. Nelson,

M.D., an addiction specialist who leads the Emergency Department at University Hospital. Dr. Nelson has explained that in addition to TIRF substances' "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."

22. Unless enrolled in the Access Program described above, a physician will not be able to prescribe TIRF substances to outpatients. It follows that any physician who, after completing the steps required to enroll in the Program, 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 explains, this conclusion is well-founded: "An 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." The overwhelming weight of the currently available medical evidence confirms that the only safe and medically recognized indication for the use of a TIRF substance is for the management of breakthrough pain in opioid-tolerant cancer paints.

COUNT I

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

24. Respondent's relationship with Insys began on March 30, 2012, when Michelle Breitenbach, an Insys sales representative, called him to discuss Subsys. Shortly thereafter, on April 10, 2012, the Respondent wrote his very first Subsys prescription.

25. In the weeks that followed, the Respondent and Breitenbach continued to exchange calls and emails, and met face-to-face. The Respondent soon expressed interest in participating in Insys' speaker program, and, on June 26, 2012, he e-mailed Breitenbach his curriculum vitae for consideration. Insys scheduled him to attend a virtual speaker training at the end of July, 2012.

26. When he informed Breitenbach that he could not attend the July 2012 speaker training, Breitenbach reported to her supervisors that the Respondent had told her that "**he owes [her] a few scripts** for missing the web training [.]" (emphasis added). While his request to become a speaker was pending, the Respondent issued ten Subsys prescriptions, and, thereafter, Insys offered the Respondent the opportunity to be a speaker. The Respondent subsequently participated in five speaker programs in 2012, for which he received $8,000 in speaking payments from Insys. In exchange, the Respondent wrote 39 Subsys prescriptions that year, generating $93,185.31 in revenue for Insys.

27. In January 2013, Insys arranged an expense paid trip for Respondent to Scottsdale Arizona to participate as part of its "Advisory Board." Insys paid for Respondent's airfare, ground transportation, hotel room at the Scottsdale Plaza Resort and all meals. Respondent was not even required to tip his baggage carriers or housekeepers as Insys prepaid all "baggage handling and housekeeping gratuities."

28. Also, in January 2013, Respondent entered into a "Consulting Agreement" with Insys. The initial agreement provided for Respondent to receive $2,500 "honorarium" for his attendance at a virtual speaker live consultant meeting. All travel expenses were also paid by Insys.

29. The January 2013 consulting agreement was amended in writing on at least two occasions. In January 2014, Respondent was paid $500 to attend a 1-hour teleconference. In February 2014, Respondent was paid $2,500 for attending a one-day meeting. In each case, any expenses incurred by Respondent were fully reimbursed.

30. In September 2013, Respondent entered into a separate "Speaker Agreement" with Insys. Pursuant to the terms of this agreement, Respondent received $2,500 for a one-day meeting in Chicago, Illinois. All expenses incurred by Respondent to attend this meeting, i.e. airfare, hotel, meals, were reimbursed by Insys. The purpose of the meeting was to provide Respondent with training on "Insys Therapeutics-approved speaker program slides."

31. Pursuant to the Speaker Agreement Respondent also received $1,600 for each in-person Insys Speaker Program that he completed along with an extra $800 for any additional programs conducted within the same day. Any expenses incurred by Respondent related to these programs were fully reimbursed by Insys.

32. During the course of his relationship with Insys, Respondent was frequently reminded of the need to keep prescribing Subsys. Emails reveal that Insys sales representative Michelle Breitenbach would make sure that the Respondent was aware that his prescribing was being monitored. For example, when Breitenbach's supervisor, Jeff Pearlman, informed her via email on March 27, 2015 that the Respondent was "$30K short still just of breaking even" for that quarter, she forwarded that email to him. When Lindencare, a mail-order pharmacy that supplied Subsys to many patients, contacted Breitenbach expressing concern that "we have not seen many scripts from [the Respondent]," she forwarded him that email too. In addition, more often than not, whenever Breitenbach received an email from a supervisor informing her that the Respondent had written a Subsys prescription for a "low strength," i.e. not as profitable, Breitenbach would contact the

Respondent. When Insys obtained Subsys insurance coverage for the Respondent's patients, Breitenbach would forward emails conveying the news of the coverage approval to the Respondent.

33. On March 16, 2013, for example, Breitenbach forwarded Respondent an email she received that Insys had obtained approval for patient E.C., discussed in Count VII below, and exclaimed as follows: "Keep them rolling. Ps please send to Lindencare :)." When Lindencare required that the Respondent write new Subsys prescriptions, for one reason or another, Lindencare would contact Insys, and Insys, in turn, would inform the Respondent.

34. The currently known payments from Insys to Respondent reveal that virtually every month from 2012 to 2016, Respondent received payments from Insys. During this same time period, Respondent wrote hundreds of prescriptions for Subsys generating millions of dollars in profits for Insys.

35. The following chart illustrates Respondent's monthly Subsys prescribing, the payments he received and the resulting revenue generated to Insys:

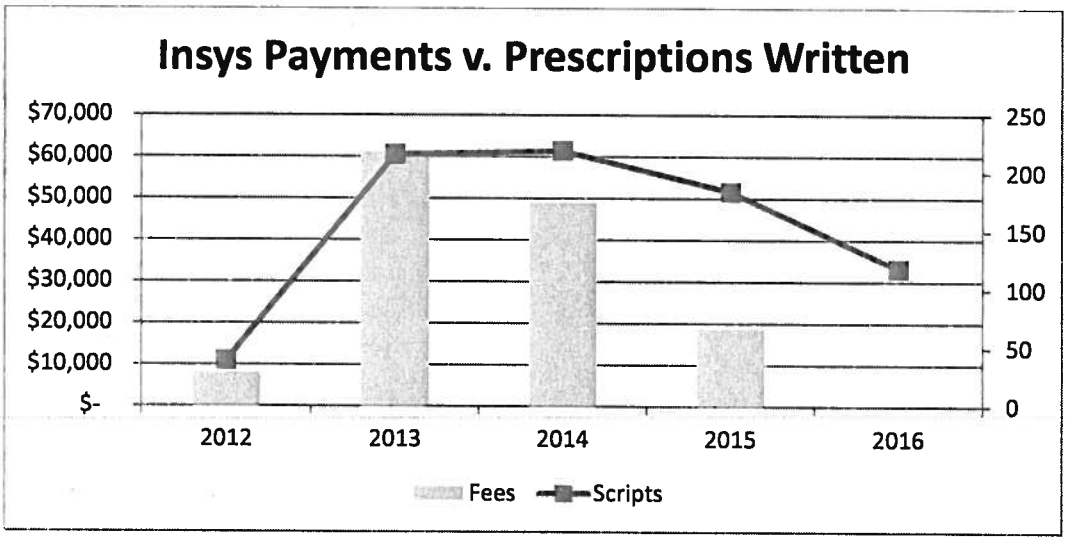
Month	**Subsys Prescriptions written by Respondent**	**Insys Payments to Respondent**	**Revenue Generated to Insys**
April 2012	1	$0	$1,286
May 2012	0	$2.50	$0
June 2012	2	$0	$2,573
July 2012	0	$9.32	$0
August 2012	6	$2.94	$8,058
September 2012	4	$5.14	$7,115
October 2012	12	$4,807.28	$25,769
November 2012	10	$3,206.69	$34,592
December 2012	4	$23.22	$13,793
2012 Total	**39**	**$8,057.09**	**$93,185**
January 2013	8	$3,225.47	$18,745
February 2013	5	$1,661.42	$21,751
March 2013	9	$33.46	$31,670
April 2013	21	$12,021.11	$57,153
May 2013	26	$1,606.88	$83,991

Month	Subsys Prescriptions written by Respondent	Insys Payments to Respondent	Revenue Generated to Insys
June 2013	23	$3,277.52	$92,082
July 2013	20	$4,904.85	$90,529
August 2013	21	$10,511.86	$93,532
September 2013	18	$12,100.00	$77,323
October 2013	26	$8,071.65	$117,470
November 2013	21	$3,700.00	$105,886
December 2013	18	$0	$86,629
2013 Total	**216**	**$61,114.22**	**$876,761**
January 2014	18	$2,154.22	$109,657
February 2014	19	$9,125.66	$100,268
March 2014	19	$1,698.00	$111,201
April 2014	17	$5,608.36	$98,550
May 2014	18	$4,477.27	$110,089
June 2014	19	$2,611.55	$109,445
July 2014	23	$13.85	$133,853
August 2014	16	$109.43	$109,197
September 2014	17	$4,478.03	$105,006
October 2014	20	$8,927.60	$130,000
November 2014	19	$9,748.65	$112,421
December 2014	14	$0	$111,716
2014 Totals	**219**	**$48,952.62**	**$1,341,403**
January 2015	16	$4,594.41	$140,863
February 2015	12	$2,212.96	$85,790
March 2015	17	$0	$110,011
April 2015	18	$6,634.38	$116,268
May 2015	15	$2,214.25	$101,210
June 2015	13	$2,208.75	$96,219
July 2015[2]	18		$131,329
August 2015	13		$98,293
September 2015	15		$120,556
October 2015	14		$105,746
November 2015	19	$780.00	$139,000
December 2015	14		$107,956
2015 Totals	**184**	**$18,644.75**	**$1,353,241**

[2]Upon information and belief, Respondent received additional payments from Insys after July 2015.

Month	Subsys Prescriptions written by Respondent	Insys Payments to Respondent	Revenue Generated to Insys
January 2016	13		$110,930
February 2016	10		$99,225
March 2016	13		$112,190
April 2016	10		$93,495
May 2016	11		$103,286
June 2016	12		$113,077
July 2016	12		$115,693
August 2016	10		$107,281
September 2016	11		$118,515
October 2016	10		$95,087
2016 Totals	**118**		**$1,068,779**
Grand Total	**776**	**$136,768.68**	**$4,733,369**

36. As this graph represents, Respondent's Subsys prescribing increased dramatically from 2013 onward during the same period he received as much as $12,000 a month from Insys:



37. As detailed in the following counts, Respondent frequently wrote prescriptions for Subsys to patients who did not have breakthrough cancer patient and/or who were on stable pain management prescribing routines. These scripts were written in contravention of the TIRF/REMS program and Respondent's agreement to abide by its terms when prescribing Subsys.

38. Respondent's actions described herein constitute the use or employment of fraud, deception, and misrepresentation in violation of N.J.S.A. 45:1-21(b); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(e); and 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, 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)) and/or demonstrates the 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

39. The Attorney General repeats and re-alleges the General Allegations and those of Count I as if fully set forth herein.

40. J.M. was a fifty-eight year old male who became Respondent's patient in November 2014 with a history of colon cancer, chronic back pain and post-chemotherapy-related peripheral neuropathy with pain in the lower legs and feet, hands, and tongue.[3]

41. Before he became Respondent's patient, J.M.'s pain was managed by G. Farrokh Maneksha, M.D., of ACP Pain Clinic ("ACP") in Stony Brook, New York.

42. At the time Respondent assumed the responsibility for managing J.M.'s pain, J.M. had been on a stable pain management regime that effectively controlled his pain in the years following the conclusion of his chemotherapy and the resolution of his colon cancer in 2011.

43. Beginning in October 2012, Dr. Maneksha's regular pain management regime for J.M. included the following opioids: (1) fentanyl transdermal patch 100 mcg – 125 mcg; (2)

[3] Pursuant to Board policy regarding public documents, reference to any patient name shall be by initials only. The identity of the patients is known to Respondent.

Dilaudid, 4mg, prn. This regime remained more-or-less unchanged for nearly two years. Dr. Maneksha's records consistently reflect that J.M.'s pain was tolerable under this regime.

44. The efficacy of this pain management regime, coupled with his imminent retirement from his labor-intensive and pain-exacerbating job, caused J.M. to request in July 2014 that he be weaned off opioid medications, and Dr. Maneksha and J.M. discussed Suboxone.

45. During his penultimate ACP office visit in August 2014, J.M. emphasized his desire to reduce his dependency on opioids. He had "started weaning himself off the Dilaudid" and had "only taken half the month's supply", prompting Dr. Maneksha to conclude that J.M. "does not need a prescription this month" and instead "will try to cut down further and then reduce fentanyl patches."

46. By September 2, 2014, the date of his final office visit with Dr. Maneksha, J.M. had made significant progress in reducing his pain medicine intake. He reported to Dr. Maneksha that he had made a "conscience [*sic*] effort to decrease oral dilaudid lst [*sic*] month and was able to decrease to three per day" and that he "can tolerate the pain at this time with some additional advil PRN."

47. By letter dated September 8, 2014, Dr. Maneksha referred J.M., who was in the process of relocating to Pennsylvania following retirement, to the Respondent for continued pain management. The referral letter specifically noted that J.M. was "stable" on his current pain management regimen and was attempting to reduce his opioid intake. Shortly thereafter, Dr. Maneksha transmitted to Respondent J.M.'s medical records, which reflect his impression that, although J.M. had previously been diagnosed with cancer, J.M.'s current pain should be classified as "non-malignant pain."

48. On November 5, 2014, J.M. became Respondent's patient. Despite having been specifically informed of the efficacy and stability of J.M.'s current pain medication regime, Respondent significantly modified that regime on that very same day by prescribing Subsys to J.M.

49. By November 2014, Respondent had received more than $100,000 from Insys including over $13,000 in the two months immediately preceding J.M.'s first Subsys prescription.

50. Respondent stated in the corresponding progress note that "[p]atient has failed multiple prn medications so far", registered him for the TIRF REMS Program, and issued him a one-month prescription for Subsys, 100 mcg, for "severe pain." The Respondent's notes do not acknowledge that J.M. had experienced tolerable analgesia under his old regime, nor do they explain how or why J.M.'s pain, somehow, in less than two months, had transformed from being stable and tolerable, for years, on a less potent opioid pain management medication regime to being so excruciating that Respondent was forced to conclude that the great risks associated with Subsys do not outweigh the benefits to J.M. The notes also do not reflect that Respondent contacted Dr. Maneksha to discuss the appropriateness of the dramatic change in pain management treatment.

51. On November 4, 2015, Respondent's patient records reflect communication with J.M.'s insurance carrier for pre-authorization which states that the purpose of the Subsys was for the "treatment of breakthrough cancer pain" indicating also that the expected length of this therapy was "indefinite."

52. Each of Respondent's patient records for J.M. from December 2014 to September 2016 includes a notation by Respondent that J.M. "has not yet attempted the Subsys." Yet, Respondent continues to prescribe Subsys each month, increasing the prescription to 400mcg, by September 2016. Respondent's records do not reflect that J.M. showed marked improvement on

Subsys. Indeed, the records show that J.M. had reported that he was experiencing "poor symptom control" for at least one year, and indicate that the Subsys was never utilized

53. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.)); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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

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

55. B.B. was a female patient of Respondent with a history of substance abuse, opioid overdose, and attempted suicide by opioid overdose. She has been Respondent's patient since at

least 2004, when he began to treat her for chronic severe pain of her feet stemming from a March 2003 accident during which a six foot cabinet "fell on her right thigh, ultimately sliding down and landing, or resting, on her right ankle."

56. Respondent's progress notes for B.B. dated before May 31, 2013, the date Respondent first issued her a Subsys prescription, establish that, although B.B. was suffering from chronic pain, her pain management medication regimen, which included Lyrica, 75mg, MS Contin,15mg XR tablet and Nucynta 50mg tablet, prn, had effectively managed her pain.

57. By May 2013, Respondent had received almost $25,000 from Insys including over $12,000 in the month immediately preceding his first Subsys prescription to B.B.

58. On May 31, 2013, Respondent issued B.B. her first prescription for Subsys, 200mcg, the second-lowest dose available. Although the progress note for B.B.'s visit on that date states that "[p]atient reports prn medications take 1-2 hrs to take effect," Respondent's progress notes for at least the six immediately-preceding office visits do not reflect that B.B. had been prescribed a short-acting opioid or that her previous pain medications were ineffective. Respondent's medical records also do not indicate that B.B. had, in fact, suffered from breakthrough pain. Finally, there is also no suggestion in the medical records that B.B. showed marked improvement in her management of breakthrough pain due to Respondent's prescribing of Subsys. To the contrary, Respondent's records reveal that B.B. had reported, for months, that she was experiencing "poor symptom control" and "worsening" pain on Subsys. Despite this, Respondent maintained B.B. on Subsys through at least September 2016, and increased her dose to 400mcg.

59. Respondent also ignored at least four explicit warnings he received from ExpressScripts informing him that B.B. was consuming nefazodone HCL and Subsys simultaneously, and reiterating the Subsys black box warning for a "risk of potentially fatal

respiratory depression in patients receiving concomitant treatment with cytochrome eP450 3A4 inhibitors such as nefazodone."

60. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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

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

62. J.L. is male patient whom Respondent has treated since 2007 for chronic low back pain, and then neck and upper extremity pain related to a work injury.

63. Prior to first prescribing J.L. Subsys on November 19, 2013, Respondent had managed J.L.'s pain on a medication regimen that consisted of Dilaudid 4mg and Opana ER 40mg. His medical records for J.L. predating November 2013 reflect that J.L.'s chronic pain had been effectively managed by that regimen.

64. By November 2013, Respondent had received over $65,000 from Insys including a total of $30,683 in the three months immediately preceding J.L.'s first Subsys prescription.

65. Respondent's progress note for J.L.'s visit on November 19, 2013 reflects that, after years of being relatively stable on his previous pain management regimen, the nature of J.L.'s pain and pain management needs purportedly suddenly changed. The neck pain that Respondent described in a June 2013 hospital record as "residual" suddenly became the paramount focus of Respondent's treatment plans for J.L. Respondent's treatment record for this date shows little to no rationale for beginning J.L. on Subsys including no indication of breakthrough pain.

66. In May 2014, J.L. stopped utilizing Subsys—and Respondent had thus stopped prescribing it—for about eleven months "due to lack of efficacy."

67. When Respondent restarted J.L. on Subsys in April 2015, he placed him on 200 mcg, the second-lowest dose available; notably, Respondent did not document in his records why he decided to re-prescribe J.L. Subsys, and merely stated that J.L. "is reporting that Subsys was helping in the past although benefits had plateaued."

68. Respondent maintained J.L. on Subsys until January, 2016 when J.L.'s insurance determined that it would no longer pay.

69. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in

violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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

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

71. S.W. is a male patient whom Respondent began treating on July 27, 2012 for chronic back pain and leg pain stemming from a work-related injury that occurred in December 2011. Before Respondent first prescribed S.W. Subsys on May 14, 2013, his records reflect that S.W.'s pain had been effectively managed on a medication regimen that consisted of long and short-term acting opioids, and the records predating May 2013 suggest that S.W. had not been experiencing breakthrough pain episodes.

72. By May 2013, Respondent had received almost $25,000 from Insys including over $12,000 in the month immediately preceding S.W.'s first Subsys prescription.

73. Respondent's May 14, 2013 progress note suggests that S.W. had been suffering from breakthrough pain episodes, without explaining what might have caused the sudden change. Respondent noted, for the first time, in his May 14, 2013 progress note that S.W.'s "[p]ertinent medical conditions include cancer (prior kidney) and obesity."

74. Respondent's records reflect that, even with the added Subsys, S.W.'s pain management regimen was yielding "poor symptom control" and worsening pain. Despite this Respondent maintained S.W. on Subsys until his insurance denied coverage in late 2015.

75. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in

violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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

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

77. At the time of her initial consultation with Respondent on April 16, 2013, patient J.V. was seventy-three years old and had been suffering from chronic pain associated with rheumatoid arthritis for forty years. Records from her primary care physician, John Bernard, M.D., reveal that she previously had a long-term opioid abuse problem, and also had a history of leukemia, which went into remission in 2008.

78. During J.V.'s first office visit, Respondent noted that she was already on a pain management regimen for rheumatoid arthritis that included a substantial amount of opioids but that she had "admit[ted] to taking more meds than prescribed causing her to "recall[] three memorable episodes of narcotic withdrawal[.]"

79. Despite J.V.'s admitted history of substance abuse and noncompliance with prior pain management medication regimens, Respondent, on J.V.'s first office visit in April 2013, prescribed her Subsys, 200 mcg, the second-lowest dose available, for her pain, and he continued her on Subsys through December 2013, eventually titrating her dose upward to 600 mcg.

80. By April 2013, Respondent had received almost $13,000 from Insys. This number would rise to almost $70,000 by the end of 2013.

81. Nowhere in patient J.V.'s medical records does the Respondent explain, why, despite the information about the dangers of TIRF substances that he acknowledged understanding, he

prescribed this elderly patient with a history of opioid abuse a TIRF substance, at high doses, for a lengthy period of time.

82. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.)); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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

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

84. E.C., a female with a lengthy history of alcohol abuse, was diagnosed with lung cancer in 2011. Respondent began treating E.C., then approximately fifty-three years old, for pain

management in 2012. Following a course of cancer-related treatment that included chemotherapy, on or about September 18, 2012, E.C.'s oncologist, Hayman Salib, M.D., concluded that the lung cancer had resolved.

85. Nearly six months after E.C.'s lung cancer had resolved, on March 8, 2013, Respondent prescribed her 100 mcg of Subsys for "severe pain" episodes. Respondent's progress note for that date neither states that the Subsys was being prescribed for "breakthrough cancer pain" nor suggests that E.C. was, in fact, suffering from breakthrough cancer pain. Instead, his notes indicate that E.C. was experiencing chronic persistent pain, or, in Respondent's own words, daily episodes of pain that "last 12 hours."

86. By March 2013 Respondent had received almost $13,000 from Insys. This number would rise to almost $70,000 by the end of 2013.

87. Notwithstanding that, at the time of her first Subsys prescription, E.C. did not have cancer, Respondent represented to an insurance carrier on a prior authorization request form dated March 15, 2013 that the diagnosis for which he prescribed E.C. Subsys was "breakthrough cancer pain" and "malignant neoplasm of bronchus."

88. Respondent maintained E.C. on Subsys for three years, eventually titrating the dose upward to 800mcg.

89. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT VIII

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

91. K.K. is a female patient who suffers from chronic pain and who had cervical cancer in her late twenties. Records obtained from K.K.'s obstetrician and gynecologist, Christopher Mann, M.D., reveal that she was diagnosed with cervical cancer in 1998, and underwent a hysterectomy soon thereafter, resulting in the resolution of K.K.'s cancer.

92. Eleven years later, in May 2009, K.K. was referred to Respondent for the management of, among other things, chronic back pain. In a May 26, 2009 letter to K.K.'s primary care physician, Laura Kropf, D.O., Respondent explained that K.K. was suffering from chronic back and shoulder pain, as well as foot pain related to an accident she sustained a few years earlier. Notably, the Respondent did not attribute her pain to her prior history of cervical cancer.

93. In the years since that initial consultation, Respondent continued to see K.K. for the management of her chronic pain. Until he first prescribed K.K. Subsys, his records continued to reflect that her decades-old and now-resolved cancer diagnosis was not the etiology of K.K.'s pain. Instead, the records note that her chronic back pain is caused by lumbar degenerative disc and facet disease.

94. On October 8, 2013, Respondent prescribed her Subsys, 200 mcg, the second- lowest dose available. At the time that he first prescribed her Subsys, Respondent's records do not indicate that K.K. had been taking around-the-clock opioid medication for chronic pain, strongly suggesting that K.K. was not opioid tolerant. In addition, Respondent's progress note for that date does not reflect a diagnosis of breakthrough cancer pain.

95. By October 2013 Respondent had received over $57,000 from Insys including more than $22,000 in the two months immediately preceding K.K's first Subsys prescription.

96. Respondent continued K.K. on TIRF substances, including Subsys and Actiq through at least September 2016. Notwithstanding that K.K. had a hysterectomy in the late nineties and that his medical records do not reflect treatment for "breakthrough cancer pain," Respondent represented to an insurance carrier, on a pre-authorization form dated March 4, 2015, that the purpose for which Subsys was being prescribed to K.K. was for "chronic breakthrough cancer pain" and for "malignant neoplasm of pelvic bones."

97. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.)); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the failure to be of good moral character as required for licensing as a physician pursuant to N.J.S.A. 45:9-6.

COUNT IX

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

99. J.P. is a female chronic pain patient. J.P. was diagnosed with breast cancer in 2009. Following a course of successful chemotherapy, J.P.'s breast cancer resolved in late 2010, and has not returned since.

100. Following his initial consultation with J.P. on or about October 21, 2011, nearly a year after J.P.'s breast cancer had resolved, Respondent mailed a letter to J.P.'s primary care physician noting his impression that J.P. suffered from peripheral neuropathy, abdominal pain, incidental herniated cervical discs, incidental cervical spinal stenosis, and possible neuropathic pain of the abdominal wall. Respondent did not attribute her pain to her prior history of cancer, which the Respondent noted as part of J.P.'s significant past medical history. Nor did he describe

J.P. as suffering from breakthrough pain episodes. Instead, Respondent characterized J.P.'s pain as "unrelenting." Notably, Respondent concluded that he "would like [J.P.] to taper one" of two opioids that she was taking at the time, Dilaudid and Nucynta, "[r]ather than pursue both . . . indefinitely." In addition, he also encouraged J.P. to "decrease her Dilaudid use" and limit her Nucynta consumption to a maximum of four a day.

101. On April 10, 2012, Respondent prescribed J.P. Subsys. The Respondent titrated J.P.'s Subsys dose to 400mcg, and maintained her on TIRF substances, including Subsys and Fentora, until at least September 2016. His records consistently note that the purpose of his decision to prescribe Subsys and Fentora to J.P. was for the treatment of "chronic intractable pain." Indeed, Respondent expressly wrote, on at least sixteen of the Subsys prescriptions he issued to J.P., that the prescription was for "chronic intractable pain."

102. As noted above, Respondent was first contacted by Insys' sales representative about Subsys in March 2012.

103. Notwithstanding that J.P.'s breast cancer had resolved six years earlier, on February 4, 2016, Respondent represented to Express Scripts that she was suffering from "cancer related pain."

104. Respondent's actions described herein constitute 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); repeated acts of negligence in violation of N.J.S.A. 45:1-21(d); professional or occupational misconduct in violation of N.J.S.A. 45:1-21(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, 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); preparation of an inaccurate patient record in violation of N.J.A.C. 13:35-6.5; failure to perform an appropriate history, 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; and 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.)); the issuing of prescriptions of controlled dangerous substances indiscriminately or without good cause in violation of N.J.S.A. 45:1-21(m); and/or demonstrate the 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. Revoking or suspending Respondent's license to practice medicine 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 in the individual counts above, pursuant to N.J.S.A. 45:1-25;

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.

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY

By: _____
David M. Puteska
Deputy Attorney General

Dated: October 14, 2017