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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 **VIVIENNE MATALON, M.D.** **LICENSE NO. 25MA05359600** TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	Administrative Action **VERIFIED COMPLAINT**

CHRISTOPHER S. PORRINO, Attorney General of New Jersey, by Christopher Salloum, Deputy Attorney General, appearing, with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, by way of Verified 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. Pursuant to N.J.S.A. 45:1-22, the Board may enter a temporary order of suspension of licensure, pending the conclusion of plenary proceedings, upon consideration of a "duly verified application of the Attorney General" that alleges that the Respondent engaged in an act or practice that violates any act or regulation administered by the Board, provided, however, that the Attorney General's application "palpably demonstrates a clear and imminent danger to the public health, safety and welfare[.]"

4. The Respondent, Vivienne Matalon, M.D., is licensed to practice medicine and surgery in the State of New Jersey, and possesses license number 25MA05359600.

5. The Respondent maintains an office for the practice of medicine and surgery called TLC Healthcare, whose address is 2070 Springdale Road, Suite 100, Cherry Hill, New Jersey 08003-2043. The Respondent also maintains an office at 1 Market Street, Suite 1-C, Camden, New Jersey.

New Jersey's Opiate Epidemic

6. Like the rest of the Nation, the State of New Jersey is suffering from a grave public health crisis: an epidemic of opiate

abuse and addiction. Between 2010 and 2014, 15,036 people in New Jersey died from heroin or prescription opioid related deaths. In 2012, there were more than 33,507 admissions to State-licensed or certified substance abuse treatment programs due to opioid abuse. In 2013, 2014, and 2015, there were 33,445, 28,653, and 35,529 such admissions, respectively. For many, the path to opiate addiction begins with legally prescribed pain medications. Prescription opioid death rates in the United States, for example, have more than quadrupled since 1999, and such death rates exceed those due to motor vehicle crashes.

7. Fentanyl, a synthetic opioid prescription analgesic that is fifty times more potent than heroin, and one hundred times more potent than morphine, has played an exacerbating role in the epidemic. In March 2015, the United States Drug Enforcement Administration issued nationwide alerts that identified fentanyl as a significant threat to public health and safety. In New Jersey, fentanyl-related deaths tripled from 2013 to 2014, and fentanyl has caused more deaths in New Jersey during the first six months of 2015 alone than during all of 2014.

8. Like other opioids, the use of fentanyl in any form can lead to severe physical and/or psychological dependence, and may also result in sedation, nausea, vomiting, respiratory depression, circulatory depression, substance abuse and addiction, and/or death.

9. 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. 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).

The Highly-Potent "TIRF" Class of Fentanyl Substances

10. Transmucosal immediate release fentanyl ("TIRF") medicines are formulations of fentanyl that instantly deliver fentanyl to their users via the oral mucosa. There are currently six approved TIRF medications, of which only one, Subsys, is at issue in this matter.

11. 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. See, e.g., Exhibit A, at TIRF52, attached to the Certification of Christopher Salloum, Deputy Attorney General ("Salloum Cert.")[1].

12. The only approved indication for all TIRF substances, including Subsys, is for the management of breakthrough pain in

[1] Unless otherwise specified, all exhibits referenced herein are attached to the Salloum Cert.

patients with cancer who are already receiving, and who are tolerant to, regular opioid therapy for their underlying persistent cancer pain. See Exhibit A, at TIRF03; Exhibit C at 2.

13. The Food and Drug Administration ("FDA") has explained that the indication for TIRF substances is "narrow" for the following reasons:

> [T]he population identified has a specific need for a treatment to address cancer-associated breakthrough pain, which is characterized by a quick onset, often high severity, and relatively short duration. These formulations of fentanyl are designed to have a relatively rapid rise to [maximum concentration] and a relative short duration of effect. Fentanyl is a very potent opioid that can cause respiratory depression in microgram quantities. For this reason, the indication also reflects the need for patients to be opioid-tolerant, a physiological state in which patients are more tolerant to the CNS depression and respiratory depression associated with opioids.
>
> Salloum Cert., Exhibit C, at 2.

14. Because of the "risk for misuse, abuse, addiction, overdose, and serious complications due to medication errors," 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. See generally Salloum Cert., Exhibit A.

15. As its name suggests, 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. See generally Salloum Cert., Exhibit A.

16. In order to enroll, and thus, gain the ability to prescribe TIRF medications to her outpatients, a physician must satisfy several requirements. She must (a) review the TIRF REMS Access education materials, including a document called "Full Prescribing Information"; (b) successfully complete the "Knowledge Assessment", a quiz designed to test her 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. See Salloum Cert., Exhibit A, at TIRF15-TIRF16.

17. Upon satisfaction of these requirements, the TIRF REMS Access Program provides the physician written confirmation that she 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, she 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." See, e.g., Exhibit B at B09.

The Respondent Enrolls in the TIRF REMS Access Program

18. On September 14, 2013, the Respondent enrolled in the TIRF REMS Access Program. In so doing, she completed and submitted the Prescriber Enrollment Form, read the Full Prescribing Information for all TIRF substances, including Subsys, and successfully completed the Knowledge Assessment. See generally, e.g., Exhibit B, at B1-B16.

19. By completing and submitting the "Prescriber Enrollment Form", the Respondent, in her capacity as a professional licensed by this Board, 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 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.

Exhibit B at B10-B11.

20. By enrolling in the Program, the Respondent acknowledged having read the Full Prescribing Information for Subsys, which states, 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.

. . .

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.

Exhibit A, at TIRF28, TIRF29.

21. 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

Salloum Cert., Exhibit A, at TIRF3 and TIRF4.

22. On September 4, 2015, the Respondent renewed her 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. See Exhibit B, at B12-B16.

23. By enrolling in the TIRF REMS Access Program and thereby promising to abide by the Program's restrictions and requirements, the Respondent became empowered to prescribe, and thus assumed the great responsibility for prescribing, TIRF medications consistent with the narrow indication for which Subsys was approved and the Program's requirements and restrictions.

COUNT ONE

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

25. On August 13, 2014, S.F., a thirty-year-old female with special needs, became the Respondent's patient. See Exhibit D, at SF06.

26. On August 13, 2014, S.F. and her mother informed the Respondent that S.F. had a prior history of opiate abuse and addiction. The Respondent acknowledged S.F.'s prior history of substance abuse, promised S.F. and her mother that she would treat S.F.'s chronic pain using alternative treatment methods. See Exhibit E, at ¶¶ 3-4.

27. Despite being specifically informed that S.F. had a prior history of substance abuse, the Respondent did not note S.F.'s prior history of substance abuse in any of her progress notes, and

began to treat S.F.'s chronic pain with opiates soon thereafter. See generally Exhibit D.

28. Although the Respondent diagnosed S.F. with, and purportedly treated her for, a wide variety of medical conditions, including, without limitation, chronic pain, diabetes, fibromyalgia, and urinary tract infection, at no time during the Respondent's care and treatment of S.F. did the Respondent diagnose S.F. with, or treat S.F. for, cancer or breakthrough cancer pain. See generally Exhibit D.

29. Notwithstanding that S.F. did not have cancer and, therefore, did not suffer from breakthrough cancer pain, the Respondent placed S.F. on a pain management medication regimen that included, among other opioids, Subsys. See generally Exhibit D.

30. The manner in which the Respondent induced S.F. to take Subsys is described, in part, as follows:

a. On December 8, 2014, during a regularly scheduled follow-up visit, the Respondent informed S.F. and her father of the existence of a "new drug that could be used to treat [S.F.'s] chronic pain" and also informed S.F. and her father that, during the next scheduled appointment, a sales representative from "the company that makes the drug" would be present to teach them all about the new medication. During this visit, the Respondent did not inform S.F. of the name of this new medication. See Exhibit F, at ¶3.

b. On January 5, 2015, the Respondent, S.F., and S.F.'s father met with Ms. Melina Ebu-Isaak, a representative from Insys, the company that produces Subsys, at the Respondent's office. See Exhibit F, at ¶4.

c. During this visit, the Respondent and Ms. Ebu-Isaak explained to S.F. that Subsys would help S.F. greatly with her chronic pain, demonstrated to S.F. how Subsys should be consumed, and noted that Subsys would be mailed directly to S.F.'s home. Neither Ms. Ebu-Isaak nor the Respondent informed S.F. and her father that Subsys was an opiate-based medication. Nor did they explain the risks or dangers associated with Subsys's use and misuse. Exhibit F, at ¶¶4-5.

31. On January 5, 2015, the Respondent executed and submitted the Program's Patient-Prescriber Agreement Form. In so doing, the Respondent acknowledged, among other things, that (a) the initial dose of Subys, the TIRF medication that she intended to prescribe for S.F., is the lowest dose available; (b) she had reviewed with S.F. the "appropriate use" of Subsys; and that (c) she had also reviewed with S.F. the Subsys Medication Guide. Among other things, that Medication Guide contains the following unequivocal warning: "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." See Exhibit B at B18-B20; Exhibit A at TIRF 52

32. By submitting this Patient-Prescriber Agreement Form, as well as the Prescriber Enrollment Form that she had completed on September 14, 2013, the Respondent, in her capacity as a professional licensed by the Board, represented that she understood the risks associated with Subsys and its proper uses, and also represented and agreed that she would comply with all Program requirements.

33. On January 5, 2015, the Respondent prescribed S.F. 120 dosage units of Subsys, 200mcg, the second-lowest strength available, with instructions that S.F. consume Subsys four times daily. On that same date, the Respondent also provided S.F. with another prescription for Subsys, dated January 26, 2015, for 120 dosage units of Subsys, 600mcg, with instructions that S.F. consume Subsys at this strength four times daily. See Exhibit D, at SF97, SF103.

34. For the next fourteen months, the Respondent continued S.F. on a pain management regimen that included the use of Subsys, 600mcg, four times a day until August 2015, and, thereafter, the use of Subsys, 600mcg, six times a day. See generally Exhibit D, at SF103-SF246.

35. On March 17, 2016, the Respondent issued S.F. her final prescription for Subsys. See Exhibit D, at SF246.

36. Eight days later, on March 25, 2016, S.F. died at the age of thirty-two. See Exhibit G, at 01.

37. The postmortem toxicology examination revealed that S.F. had significant levels of fentanyl metabolites in her blood at the time of her death, and the autopsy report listed the cause of death as "Adverse Effect of Drugs." See Exhibit G, at 03-05, and 01.

38. The Respondent's conduct, as described above, constitutes: (a) the use or employment of fraud, deception, and misrepresentation; (b) professional misconduct; (c) gross negligence that endangered the life, health, safety, and welfare of S.F.; (d) repeated acts of negligence, malpractice, or incompetence; (e) the indiscriminate prescribing of controlled dangerous substances; and (f) violations of the statutes and regulations administered by the Board, including, but not limited to, N.J.A.C. 13:35-7.1A and N.J.A.C. 13:35-7.6. Such conduct thereby empowers the Board to suspend or revoke the Respondent's license to practice medicine and surgery in this State pursuant to N.J.S.A. 45:1-21(b), (c), (d), (e), (h) and (m).

39. The Respondent's conduct, as described herein, palpably demonstrates that her continued practice of medicine and surgery presents a clear and imminent danger to the public health, safety, and welfare within the meaning of N.J.S.A. 45:1-22.

COUNT TWO

40. The Attorney General repeats and re-alleges the General Allegations and the allegations of Count One above as if fully set forth verbatim herein.

41. On May 31, 2013, M.C., a sixty-one-year-old female, became the Respondent's patient. See Exhibit H, at MBC15.

42. Although M.C.'s past medical history included a cancer diagnosis, at all times relevant hereto, M.C. did not suffer from cancer or breakthrough cancer pain. See e.g., Exhibit H, at MBC 49-50; MBC228.

43. Notwithstanding that M.C. did not have cancer, and therefore, did not suffer from breakthrough cancer pain, the Respondent placed M.C. on a pain management medication regimen that included Subsys. See, e.g., Exhibit H, at MBC89-90; MBC111.

44. On December 10, 2014, the Respondent and M.C. executed the Program's Patient-Prescriber Agreement Form. In so doing, the Respondent acknowledged, among other things, that (a) the initial dose of Subsys, the TIRF medication that she intended to prescribe for M.C., is the lowest dose available; and (b) she had reviewed with M.C. the "appropriate use" of Subsys and its Medication Guide. See Exhibit B, at B24-B26.

45. By executing and submitting this Patient-Prescriber Agreement Form, as well as the Prescriber Enrollment Form that she had completed on September 14, 2013, the Respondent, in her capacity as a medical professional licensed by the Board, represented that she understood the risks associated with Subsys and its proper uses, and also represented and agreed that she would comply with all Program requirements.

46. Following the submission of this Patient-Prescriber Agreement Form, on December 10, 2014, the Respondent prescribed M.C. thirty dosage units of Subsys, 200mcg, the second-lowest strength available, with instructions that M.C. consume Subsys once daily. Also on that date, the Respondent issued M.C. a second prescription for Subsys, dated December 12, 2014, for 120 dosage units of Subsys, 200mcg, with instructions that M.C. consume Subsys four times daily, effectively prescribing M.C. 400mcg of Subsys. See Exhibit H, at MBC89-90.

47. Almost one month later, on January 7, 2015, the Respondent discontinued prescribing Subsys for M.C. after M.C. reported that she was experiencing side effects from Subsys, including "nausea, vomiting, and dizziness everytime [sic] she used Subsys." The Respondent's progress note for that date states that: "[M.C.] stated that she tried 5 doses [of Subsys] and it did not help relieve her pain." See Exhibit H, at MBC97.

48. On April 29, 2015, the Respondent, once again, placed M.C. on a pain management regimen that included Subsys, prescribing her 120 dosage units of Subsys, 200mcg, with instructions that M.C. consume Subsys four times daily. See, e.g., Exhibit H, at MBC111.

49. Five months later, on September 29, 2015, the Respondent, once again, discontinued prescribing Subsys to M.C. after M.C. reported that Subsys caused her "too many side effects." See Exhibit H, at MBC138.

50. The Respondent's medical records for M.C. contain pervasive misrepresentations regarding M.C.'s medical conditions, including, but not limited to, false diagnoses of cancer. Although some, but not all, of the Respondent's progress notes for M.C. reflect a diagnosis of cancer, other aspects of the Respondent's medical records for M.C., and the medical records from the oncology group that had been treating M.C. for cancer, reflect that M.C. has been cancer free since September 2005. Illustrative of the pervasive nature of such misrepresentations are the following examples:

a. By letter dated December 18, 2013, before the Respondent prescribed M.C. Subsys, Norman H. Siegel, M.D., informed the Respondent that M.C. had suffered from cancer, but had been disease free since receiving a stem cell transplant in September 2005. Dr. Siegel concluded that: "From our standpoint, [M.C.] has no evidence of recurrent disease and will return in one year for fellow up." The Respondent included this letter in the medical record that she maintained for M.C. See Exhibit H, at MBC49-50.

b. Despite the fact that, as indicated by Dr. Siegel's letter, M.C. did not have cancer from, at the very least, May 31, 2013, the date that M.C. became the Respondent's patient, and December 18, 2013, the date of Dr. Siegel's letter, the Respondent noted in some, but not all, of her progress notes for this

timeframe a present diagnosis of cancer. See e.g., Exhibit H, at MBC19, MBC29, MBC34, MBC36, and MBC42.

c. Also during this time frame, the Respondent submitted at least one form to an insurance carrier on behalf of M.C. in which she represented that she had diagnosed M.C. with cancer. See, e.g., Exhibit H, at MBC37.

d. By letter dated February 4, 2015, after the Respondent had prescribed M.C. Subsys, Howard I. Kesselheim, D.O., a physician from the same oncology group that had treated M.C. for her prior history of cancer, informed the Respondent that M.C. continued to remain cancer free. Dr. Kesselheim explained the Respondent that "[M.C.] is doing quite well from the standpoint of her lymphoma. She is now ten years since completion of her program and remains free of disease." In addition, Dr. Kesselheim noted that "[M.C.] has no complaints related to appetite, pain, energy, or sleep." See Exhibit H, at MBC228. The Respondent did not include this letter in the medical record that she maintained for M.C. See Exhibit H, at MBC01-MBC214.

e. Despite the fact that, as indicated by Dr. Kesselheim's and Dr. Siegel's letters, M.C. did not have cancer from, at the very least, December 18, 2013, the date of Dr. Siegel's letter, and February 4, 2015, the date of Dr. Kesselheim's letter, the Respondent noted in some, but not all, of her progress notes for this timeframe a present diagnosis of cancer. See, e.g.,

Exhibit H, at MBC69, MBC79, MBC100, MBC111, MBC130, MBC140, MBC144, MBC150, MBC169, and MBC173.

51. The Respondent's conduct, as described above, constitutes: (a) the use or employment of fraud, deception, and misrepresentation; (b) professional misconduct; (c) gross negligence that endangered the life, health, safety, and welfare of M.C.; (d) repeated acts of negligence, malpractice, or incompetence; (e) the indiscriminate prescribing of controlled dangerous substances; and (f) violations of the statutes and regulations administered by the Board, including, but not limited to, N.J.A.C. 13:35-7.1A and N.J.A.C. 13:35-7.6. Such conduct thereby empowers the Board to suspend or revoke the Respondent's license to practice medicine and surgery in this State pursuant to N.J.S.A. 45:1-21(b), (c), (d), (e), (h) and (m).

52. The Respondent's conduct, as described herein, palpably demonstrates that her continued practice of medicine and surgery presents a clear and imminent danger to the public health, safety, and welfare within the meaning of N.J.S.A. 45:1-22.

COUNT THREE

53. The Attorney General repeats and re-alleges the General Allegations and the allegations of Counts One and Two above as if fully set forth verbatim herein.

54. On June 16, 2009, L.A., a twenty-five-year-old female, became the Respondent's patient. See Exhibit I, at LA20.

55. Although the Respondent diagnosed L.A. with, and purportedly treated her for, a wide variety of medical conditions, including, without limitation, rheumatoid arthritis and Crohn's disease, at no time during her care and treatment of L.A. did the Respondent diagnose L.A. with, or treat L.A. for, cancer or breakthrough cancer pain. See, e.g., Exhibit I, at LA563.

56. Notwithstanding that L.A. did not have cancer, and, therefore, did not suffer from breakthrough cancer pain, the Respondent prescribed L.A. Subsys. See Exhibit I at LA559.

57. On April 14, 2015, the Respondent and L.A. executed and submitted the Program's Patient-Prescriber Agreement Form. In so doing, the Respondent acknowledged, among other things, that (a) the initial dose of Subsys, the TIRF medication that she intended to prescribe L.A., is the lowest dose available; (b) she had reviewed with L.A. the "appropriate use" of Subsys, and its Medication Guide. See Exhibit B, at B21-B23.

58. By executing and submitting this Patient-Prescriber Agreement Form, as well as the Prescriber Enrollment Form that she had completed on September 14, 2013, the Respondent represented, in her capacity as a medical professional licensed by the Board, that she understood the risks associated with Subsys and its proper use, and also represented and agreed that she would comply with all Program requirements.

59. Following the completion of these forms, on April 14, 2015, the Respondent prescribed L.A. 30 dosage units of Subsys, 400mcg, with instructions that L.A. consume one dose daily. See Exhibit I, at LA559.

60. Soon thereafter, on April 15, 2015, L.A.'s insurance carrier denied coverage of Subsys because the Respondent had prescribed L.A. Subsys for a reason that is not medically accepted. See Exhibit I at, LA564.

61. On April 29, 2015, the Respondent submitted a letter to the insurance carrier appealing the denial on behalf of L.A. In that letter, the Respondent related, in pertinent part, the following information:

> I have treated [L.A.] in my clinic since November 29, 2009. Ms. [L.A.] is a 31 year old woman with severe Juvenile Rheumatoid Arthritis, Wilson's Thyroid and Crohn's Disease. She has difficulty swallowing and digesting oral medications, and she is in almost constant severe pain.
>
> . . .
>
> A combination of Oxycontin, Methadone, Oxycodone, and Klonopin, at the highest dose available, tends to abate Ms. [L.A.'s] pain fairly well. However severe breakthrough pain continues to be a problem with a frequency that is debilitating to this unfortunate patient. Injectable pain relievers are not an option for this patient.
>
> Due to the severity of Ms. [L.A.'s] illness and pain, and due to the limited number of medications available to her, I write this letter recommending that coverage be approved for Subsys as a medical necessity for offering this patient as much quality of life as possible.

Exhibit J, at LA563

62. On May 7, 2015, the insurance carrier notified the Respondent that it had denied the appeal, and once again explained that it could not cover "Subsys for treatment of chronic pain and chronic pain syndrome not due to breakthrough cancer pain." See Exhibit I, at LA649.

63. The Respondent's conduct, as described above, constitutes: (a) the use or employment of fraud, deception, and misrepresentation; (b) professional misconduct; (c) gross negligence that endangered the life, health, safety, and welfare of L.A.; (d) repeated acts of negligence, malpractice, or incompetence; (e) the indiscriminate prescribing of controlled dangerous substances; and (f) violations of the statutes and regulations administered by the Board, including, but not limited to, N.J.A.C. 13:35-7.1A and N.J.A.C. 13:35-7.6. Such conduct thereby empowers the Board to suspend or revoke the Respondent's license to practice medicine and surgery in this State pursuant to N.J.S.A. 45:1-21(b), (c), (d), (e), (h) and (m).

64. The Respondent's conduct, as described herein, palpably demonstrates that her continued practice of medicine and surgery presents a clear and imminent danger to the public health, safety, and welfare within the meaning of N.J.S.A. 45:1-22.

WHEREFORE, the Attorney General respectfully demands that the Board:

1. Temporarily suspend, or otherwise limit, the Respondent's license to practice medicine and surgery in the State of New Jersey pending the conclusion of plenary proceedings in this matter, pursuant to N.J.S.A. 45:1-22;

2. Suspend or revoke the Respondent's license to practice medicine and surgery in this State, pursuant to N.J.S.A. 45:1-21;

3. Assess civil penalties against the Respondent pursuant to N.J.S.A. 45:1-22(b) and N.J.S.A. 45:1-25;

4. Assess costs, including, but not limited to, costs of investigation and attorneys' fees, pursuant to N.J.S.A. 45:1-25; and

5. Order such other and further relief as the Board shall deem just and appropriate.

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY

By: _____
Christopher Salloum
Deputy Attorney General

Dated: 10/13/2016