BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: David James Smith, M.D. Physician's and Surgeon's Certificate No. G 66777 Respondent.	Case No. 800-2018-042234

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on January 21, 2022.

IT IS SO ORDERED December 22, 2021.

MEDICAL BOARD OF CALIFORNIA

Richard E. Thorp, M.D., Chair
Panel B

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MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation against:

DAVID JAMES SMITH, M.D., Respondent

Physician's and Surgeon's Certificate No. G 66777

Case No. 800-2018-042234

OAH No. 2021040832

PROPOSED DECISION

Abraham M. Levy, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on October 4 through 8, and 11, 2021, by video conference.

Joseph F. McKenna, III, Deputy Attorney General, represented complainant William Prasifka, Executive Director of the Medical Board of California (board), Department of Consumer Affairs.

Matthew D. Rifat, Attorney at Law, the Law Offices of Matthew D. Rifat, represented respondent David James Smith, M.D.

Oral and documentary evidence was received. The record was closed, and the matter was submitted on October 11, 2021.

SUMMARY

Complainant alleges that respondent committed gross negligence and repeated negligent acts relating to his treatment and care of three pain management patients. Based on the evidence of record as whole, respondent departed from applicable standards of care in his use of the fentanyl and ketamine in intrathecal pump therapy, his failure to obtain psychological evaluations before proceeding with the implantation of the devices in two of the patients and scheduling the third for a trial pump, and he incorrectly programmed the pump of two of the patients. Respondent further failed to maintain adequate and accurate records and engaged in unprofessional conduct. To ensure public protection respondent is prohibited from performing intrathecal therapy, or advising other medical providers regarding intrathecal therapy, during the duration of the time he remains on probation imposed in the prior discipline in Case No. 800-2015-013651, which became effective August 25, 2020.

PROTECTIVE ORDER

A protective order has been issued on the undersigned's motion without objection sealing Exhibits A to J, and P, Q, R, and S, because it is impractical to redact the private information in these exhibits. At complainant's request the name of the patient at the second page of Exhibit 5 has been redacted. A reviewing court, parties to this matter, and a government agency decision maker or designee under Government Code section 11517 may review materials subject to the protective order provided that this material is protected from disclosure to the public.

FACTUAL FINDINGS

Jurisdictional Matters

1. Complainant filed the Accusation in this matter on December 22, 2020. Respondent filed a timely Notice of Defense. The accusation alleges that respondent engaged in misconduct relating to his treatment of three pain management patients. At the hearing, on complainant's motion without objection, line 14 of the accusation was interlineated to read: "Respondent failed to consider and/or obtain a psychological evaluation prior to scheduling implantation of an intrathecal pump trial in Patient C."

License History and Prior Discipline

2. On August 21, 1989, the board issued Physician's and Surgeon's Certificate Number G 66777 to respondent. The certificate is current, and will expire on January 31, 2023, unless renewed.

3. Respondent has one prior instance of discipline. Effective August 25, 2020, in the case entitled *In the Matter of the First Amended Accusation Against David James Smith, M.D.*, Case Number 800-2015-013651, respondent's license was disciplined and placed on probation for seven years for committing gross negligence, repeated negligent acts, incompetence, excessive prescribing, failing to maintain adequate and accurate records, and unprofessional conduct in his care and treatment of five patients. The terms of probation require respondent to complete a clinical competence course, a medical record keeping course, a prescription practices course, and be subject to physician monitoring, among other terms and conditions. Respondent is also prohibited from performing intrathecal pain procedures until after

he has completed the clinical competence course. Respondent's performance of intrathecal (IT or IT therapy) procedures is also at issue in this matter.

Respondent's Practice and Intrathecal Therapy

4. Respondent is a board-certified specialist in pain management and is the Medical Director and owner/operator of San Diego Comprehensive Pain Management Clinic (SDCPMC or respondent's clinic), and the Medical Director of Pacific Surgical Institute of Pain Management. At issue in this matter, as it was, in part, in the prior matter for which he was disciplined, is his use of intrathecal pumps in the delivery of narcotic drugs to relieve chronic pain. It is not disputed that the three patients at issue in this matter suffered from pain, and they treated with respondent to manage and relieve their pain.

5. An intrathecal pump is a medical device that delivers drugs directly into the space between the spinal cord and the protective sheath surrounding the spinal cord for targeted drug delivery. An intrathecal pump delivers medicine directly into the cerebrospinal fluid and requires a smaller amount of medication compared to medication taken orally due to bypassing of the systematic path that oral medication must travel in the body.

An intrathecal pump is programmable, and it stores information about medication in its memory. As part of the process that respondent used to program the pumps at issue in this matter, respondent used Excel spread sheets to identify in detail the concentrations of the drugs and their total daily administered dosages. As described in detail in this decision, respondent did not dispute he incorrectly programmed the drugs delivered to two of the patients.

An intrathecal pump is programmed to slowly release medication over a period of time and can be programmed to release different amounts of medication at different times of the day. When the intrathecal pump's reservoir is almost empty, the medication is refilled by insertion of a needle through the skin and into the fill port on top of the pump's reservoir.

Medical Evidence and Expert Testimony

6. Respondent's care and pain management treatment of the three patients at issue in this matter are found in the patient records received as evidence in addition to respondent's statements at his interview with the Health Quality Investigation Unit (HQIU) of the Division of Investigation. It is not disputed that the three patients at issue in this matter suffered from chronic pain, and it was medically necessary they receive treatment to manage and relieve their pain.

7. Mark Steven Wallace, M.D., reviewed the applicable materials of record and rendered opinions as an expert in this matter at HQIU's request. He prepared reports summarizing his opinions for each of the three patients. Jack M. Berger, M.D., was asked to review applicable materials and rendered opinions in this matter at respondent's request. He also prepared reports summarizing his opinions which were received as evidence.

8. From these sources the following is a summary of the patient records and the opinions of both experts:

Patient A

9. On December 12, 2016, Patient A, a 54-year-old female, saw respondent at SDCPMC for a consultation regarding implantation of an intrathecal pump. David

Dobecki, M.D., who was treating Patient A for pain management referred Patient A to respondent because he believed Patient A might benefit from an IT pump.

10. At this initial visit, Patient A reported to the nurse practitioner who conducted the initial interview that she has comprehensive regional pain syndrome (CRPS) and Reflex Sympathetic Dystrophy (RSD) of the right arm and cervical and lumbar spine. Patient A also said she has a history of failed therapies including injection therapies, and she was "tired" of using fentanyl patches and oral medications that didn't work. Fentanyl patches are applied to the skin and used to relieve severe pain.

For pain she was using a fentanyl patch 100 mcg/hour and taking 10 mg/325 mg of Percocet four times a day. She rated her pain level as "7/10" on a pain scale of 0-10. Percocet is a brand name for oxycodone-acetaminophen used for the management of moderate to severe pain. It is an opioid and Schedule II controlled substance pursuant to Health and Safety Code section 11055, and a dangerous drug pursuant to Business and Professions Code section 4022.

11. Patient A also reported she had been diagnosed with depression, and she has a "nervous twitch." As part of her medical history Patient A said her mother suffered from "mental illness" and had a "nervous breakdown." Patient A was taking a variety of antidepressant and antianxiety medications including Cymbalta, Prozac, and trazadone, at the time of her initial visit at SDCPMC. These three drugs are antidepressants and are classified as dangerous drugs pursuant to Business and Professions Code section 4022.

12. The record from this date does not identify if Patient A was treating for depression and does not identify the clinician who was treating her. In an

authorization record for respondent to obtain Patient A's "psychotherapy notes as necessary" respondent identified Dr. Nicole Duarte as a treating clinician, in addition to Dr. Dobecki. It is unclear from the record whether this clinician is a psychologist or psychiatrist or therapist and there is no documentation that respondent or his office contacted her. Respondent however obtained Patient A's records from Dr. Dobecki and made them part of respondent's chart.

13. A subsequent progress note made well after Patient A's initial visit with respondent and dated August 10, 2018, identifies Anne Cox, M.D., as her psychiatrist and that this doctor recommended that Patient A's ketamine be increased in the IT pump to treat her depression. In that August 10, 2018, note, respondent reported she has had depression since she was an adolescent and that she only mildly responded to antidepressants. Respondent's records for Patient A did not contain any records from Dr. Cox.

14. On December 12, 2016, Patient A completed and signed a number of intake documents at SDCPMC including, informed consent forms and a patient authorization form permitting respondent to obtain "psychotherapy notes" from Patient A's treating clinical psychologist. Respondent did not obtain any such notes, or at the least the record does not reflect that Patient A's psychotherapy notes were obtained.

15. On April 25, 2017, Patient A returned to SDCPMC and met with respondent to ask him questions about IT pump therapy before moving forward with implantation of an IT pump. Respondent had a lengthy discussion with Patient A and discussed the risks and benefits of an intrathecal pump trial. Because other treatment modalities had failed, Patient A decided to move forward with the therapy. Respondent calendared the implantation of the catheter for the trial IT pump for May

2, 2017. (The IT pump trial does not involve implanting the pump itself in the patient but places the reservoir externally. A catheter is threaded to the spinal cord sac from this external reservoir.)

16. At this visit, respondent did not discuss or document discussing with Patient A having her undergo a psychological evaluation before beginning the pump trial or the implantation of the pump.

17. On May 2, 2017, respondent surgically implanted a percutaneous catheter in Patient A at Pacific Surgical Institute. Later at respondent's clinic, an external pump used for the trial was filled with the following intrathecal medication: fentanyl 25 mg/ml (1 ml), ketamine 20 mg/ml (1 ml), and Marcaine 5 mg/ml (1 ml). These medications were used through Patient A's treatment during the time alleged in the accusation. Fentanyl is a Schedule II controlled substances pursuant to Health and Safety Code section 11055, and a dangerous drug pursuant to Business and Professions Code section 4022. Ketamine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, and a dangerous drug pursuant to Business and Professions Code section 4022. Marcaine, the brand name for bupivacaine, is an anesthetic medication generally given in a medical setting for local or regional anesthesia or analgesia for surgery. Marcaine is a prescription medication and is a dangerous drug pursuant to Business and Professions Code section 4022.

18. The operative procedure report from May 2, 2017, documented that Patient A had undergone "psychological testing" and that she had been "cleared to proceed with the pump trial." The operative procedure note further documented that Patient A had "no contraindications of depression, substance abuse or other psychological preclusions" that would preclude her from the trial. As an "HCPC Code" the following documentation is found relating to the psychological clearance:

"Depression Scr Not Documented Reason Not Given." It is noted that in Patient A's May 3, 2017, note this HCPC coding is repeated.

19. In the operative report respondent wrote that he "will increase the infusion rate slowly and sequentially per clinic protocol until pain relief occurs."

20. Except for this reference to "psychological testing," Patient A's records do not identify the clinician who conducted this testing or when it was done. As noted, Patient A's chart from SDCPMC does not contain information to confirm that Patient A ever underwent any psychological testing before the trial for the purposes of being cleared to proceed with the intrathecal pump trial.

21. To address the inconsistency in Patient A's records at the hearing, respondent testified Patient A had both a psychiatrist and psychologist. But he then stated he talked to her "psychiatrist" *after* the trial. It is thus concluded that respondent's reference in his operative procedure report that Patient A underwent psychological testing and was cleared to proceed with the IT pump trial is a misstatement and his operative procedure report is inaccurate.

22. Between May 3, 2017, and May 5, 2017, Patient A returned to SDCPMC to have the medication rate increased during the pump trial. On each date, Patient A signed an "Informed Consent For Intraspinal Drug Therapy Via The Intrathecal Infusion Device." For some reason this informed consent documentation that Patient A signed did not contain any reference or information about the use of intrathecal ketamine during the trial.

Respondent increased the fentanyl infusion rate on May 3 when he increased the rate from 0.2 mg to 0.3 mg and on May 5, 2017, from 0.3 mg to 0.4 mg without explanation. On May 5, 2017, Patient A rated her pain level as 4/10.

23. On May 9, 2017, the IT pump trial ended, and respondent explanted the percutaneous catheter from Patient A.

24. Later that same day on May 9, 2017, as recorded in Patient A's May 19, 2017, office visit notes, Patient A stated she had "extreme relief" from pain. But, she experienced withdrawals and sickness once the trial pump was explanted, and she had to go to the emergency room for treatment.

25. On May 19, 2017, Patient A returned to SDCPMC for a pre-op evaluation for implantation of a permanent intrathecal pump. The progress note for this visit documented Patient A's visit to the emergency department due to "withdrawals" and sickness after the seven day pump trial ended.

26. On June 13, 2017, respondent surgically implanted a Medtronic 20-ml Synchromed II infusion pump in Patient A under general anesthesia. The surgical procedure was performed at Pacific Surgical Institute. According to the operative procedure report, the pump was programmed by a Medtronic representative and then placed inside patient A.

27. Later that same day, Patient A went to SDCPMC to have the new pump reprogrammed and filled with intrathecal medications. The initial formula of intrathecal medication is documented as fentanyl, ketamine, and Marcaine. The initial rate of fentanyl was set at 2.402 mg per day.

28. From this time to August 2017, the exact drug concentrations programmed into Patient A's pump were inaccurate. During this time the actual drug concentrations contained in the pump were lower than the pump's programmed amount of drug concentration because respondent incorrectly programmed the initial fentanyl drug concentrations, per the report in Patient A's chart, at 50 mg/ml of

fentanyl when the concentration actually used was 25 mg/ml of fentanyl as recorded and documented in another document, an Excel spreadsheet. This second document accurately recorded the drug concentration. As a result of this discrepancy as complainant's expert Dr. Wallace testified, this meant that if Patient A was treated by a third party doctor at a hospital or elsewhere and this doctor interrogated the pump this could have led to this doctor prescribing a drug that could have caused Patient A to overdose.

29. Respondent must have seen that the initial concentration of fentanyl was incorrectly programmed into the pump and corrected the initial concentration rate on August 30, 2017, to reflect the correct concentration as 25 mg/ml of fentanyl. Respondent did not notate in Patient A's records that he made this correction however and why he made it.

30. After the IT pump was implanted, Patient A returned to SDCPMC on June 16, 2017, for a follow up visit. The notes states that Patient A "reports today for a re-evaluation and possible rate increase." Patient A reported discomfort at the incision site and described her pain as "8/10" on a pain scale of 0 to 10.

Respondent reprogrammed the pump and increased the daily dose of fentanyl to 3.752 mg per day. He did not notate why he increased the daily dose of fentanyl at this rate. The Medtronic drug calculation spreadsheet documenting this particular medication rate change is actually dated "6/17/2017," one day after the progress note.

At this visit, Patient A also completed an intrathecal pump questionnaire and signed an informed consent document.

31. On June 21, 2017, Patient A returned to SDCPMC for a follow up visit. The note again states that Patient A "reports today for a re-evaluation and possible rate

increase." She complained about pain in her cervical and lumbar spine and she described the pain was constant. She also reported a reduction in pain and described her pain level as "5/10." Even though she said the pain level decreased, Patient A wanted another increase to get her pain below 5/10. Apparently at her request, Patient A's daily dose of fentanyl was again increased to 4.750 mg per day. Respondent did not document a rationale for why he was increasing the fentanyl rate to this amount.

Respondent scheduled her to return in two days. She signed an informed consent document for IT that identified ketamine as one of the drugs used in the therapy. The document is incorrectly dated "June 21, 2016".

32. At Patient A's June 23, 2017, visit, the note records that Patient A "presents today for a rate increase and staple removals." She noted she was able to knit again, which she was not able to do for a while. But at the same time, she described her pain similarly as she described it in her last visit as "constant." The language in the note exactly tracks the language from the prior notes in terms of describing Patient A's pain complaints. Patient A said her pain level was at 5/10. Respondent increased the rate of fentanyl to 5.750 mg per day. Respondent did not record his rationale for this increase.

33. On June 26, 2017, Patient A returned for a follow up visit. Patient A reported that the last increase of fentanyl was effective, and that she was able to walk further without noticing any increased pain. Respondent's note again records Patient A's pain complaints in the exact same language found in the two prior notes. Patient A described her pain as constant and at a 5/10 level. Again, despite reporting reduced pain, Patient A wanted another increase of fentanyl. Her daily dose of fentanyl was increased to 6.746 mg per day at this visit. During a fifteen-day period Patient A's daily dose of intrathecal fentanyl more than tripled. According to Dr. Dobecki's progress

note from the same date, Patient A said she discontinued the fentanyl patch but wanted to continue pain medications as needed until the pump was adjusted.

34. Patient A returned to respondent's office on June 28, 2017, with the same complaints of pain. The note records that she reports today for "re-evaluation and possible rate increase." At this visit however she reported her pain level to be at 8/10 indicating significant improvement at the same time she said she noted an increase in pain from her last visit. She stated the last increase on June 26, 2017, was effective and she was able to walk further than she had walked in three months. The dose of fentanyl was increased to 7.757 mg per day without a documented rationale for this increase.

35. On June 30, 2017, Patient A went to respondent's office as a walk-in "for an increase in her intrathecal rate." She stated the recent increase really helped her mobility and function, and she was able to do more activities of daily living (ADLs) and be more active. The rate was increased to 8.7457 mg of fentanyl per day without rationale or explanation.

36. On July 7, 2017, Patient A presented to respondent's office for a routine follow-up "requesting for [*sic*] an increase to her intrathecal rate." She described her pain level as 8/10 but also described her pain as "constant, sharp, aching, cramping, hot, burning, pins and needle, pressure like, and stabbing." She added that she was experiencing pain that was "constant stabbing, throbbing, tingling, electrical, muscle tightness, muscle spasms, swelling and weakness." The pain to her back, upper and lower extremities, and hip and neck worsened when she bent, increased her activities, climbed stairs, sat or stood for a long time. She also reported she was more active. Without rationale or explanation her rate was increased to 9.756 mg of fentanyl per day.

37. Patient A returned to see respondent on July 14, 2017, and she was "requesting for [*sic*] an increase to her intrathecal rate." Her pain symptoms are documented to be similar to the pain condition she detailed at her last visit with a pain level at 8/10 and with the ability to do more ADLs. (The note appears to be an exact repopulation from the July 8, 2017, note.) Without rationale or explanation her rate was increased to 10.745 mg of fentanyl per day.

38. Eight days later on July 26, 2017, on a walk-in basis Patient A returned to respondent's office "for an increase to her intrathecal rate." She stated the last increase was very effective, and she said she was like a new woman with 50 percent relief since the IT pump implant. She described her pain as 8/10. Without rationale or explanation her rate was increased to 12.746 mg of fentanyl per day.

39. On August 11, 2017, again on a walk-in basis Patient A returned to respondent's office "for an increase to her intrathecal rate." She again stated the last increase was very effective, and she said she was like a new woman with 50 percent relief since the IT pump implant. She described her pain level as 4/10. Without rationale or explanation respondent increased Patient A's rate to 13.748 mg of fentanyl per day but did not provide a rationale for doing this. This 13.748 mg amount of fentanyl amounted to an approximate 470 percent increase from the initial starting dose of intrathecal fentanyl since she began IT pump therapy.

40. Respondent's next visit was August 30, 2017, for a pump refill. The note for this visit records that she experienced 50 percent relief due to the pump. Patient A described her pain level as 4/10, and she was independent with her ADLs and was active daily. The note documents that the pump was refilled as part of the regular maintenance of the pump and to ensure that the pump was controlling Patient A's chronic pain, she was improving by the measure of her daily functioning, and to

prevent abrupt "med withdrawal" and exacerbation of her chronic pain. The note recites that the pump was determined to be medically necessary before it was implanted because Patient A failed all other therapy modalities, she had success during the pump trial and was thoroughly educated about the therapy and consented to it. The note continues that the pump was analyzed and refilled. Respondent assessed Patient A with multiple physical conditions affecting her neck and back. He also assessed her with uncomplicated opioid dependence. Subsequently, in Patient A's September 13, 2017, note respondent referenced the impression of uncomplicated opioid dependence made since August 30, 2017.

41. Without rationale or explanation respondent reduced Patient's A's IT pump rate by *exactly* 50 percent to 6.874 mg of fentanyl per day from 13.748 mg of fentanyl per day. It is noted as discussed above per the report from this visit the initial concentration rate for fentanyl was reduced to 25 mg/ml from the incorrect programmed concentration of 50 mg/ml recorded from Patient A's prior visits. This correctly programmed reduction also reflects a 50 percent change.

42. Here, it is reasonable to infer that respondent discovered after he interrogated Patient A's pump on August 30, 2017, that the initial programmed concentration rate was incorrect, and he adjusted Patient A's initial concentration rate accordingly. He then failed to record this adjustment or his rationale for it in this note. In his testimony, respondent said that he recognized the programming error and reduced the rate by 50 percent without documenting why he did this.

43. On September 13, 2017, Patient A returned to respondent's clinic for "re-evaluation." She said she was in a lot of pain and wanted an IT pump increase. She reported her pain level as 7/10 but described her pain condition as she similarly described it at her prior visits. She said she was not able to do her ADLs as she had

been able to do them previously.[1] Without rationale or explanation her rate was increased from 6.874 mg to 8.869 mg of fentanyl per day.

44. Two days later, on September 15, 2017, Patient A returned for re-evaluation of her treatment plan. She wanted respondent to review her MRI of her right hip because the treatment she received was ineffective. She denied she wanted a pump rate increase. At respondent's order, she was given an intramuscular injection of Decadron and respondent provided her with a prescription for a 30-day supply of naproxen one tablet per day.

45. At Patient A's next visit with respondent on September 29, 2017, she was seen for a telemetry and analysis after she had an MRI to determine whether the pump restarted after her MRI and for a possible rate increase. She identified her pain level as 7/10 with the same pain symptoms she described in her prior visits. Patient A said she has increased pain in her lumbar spine. She said that overall the pump has improved her quality of life. Without explanation or rationale respondent increased her rate from 8.869 mg of fentanyl per day to 10.863 per day.

46. On October 4, 2017, Patient A saw respondent for medication management. She wanted respondent to prescribe her pain medications because Dr. Dobecki was no longer prescribing her pain medications. She was advised a "CURES"[2]

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[1] At this visit in a questionnaire under the heading "Pump Related Concerns" Patient A wanted to know if the pump became dislodged after she fell, and she wanted to know her current infusion rate.

[2] The Controlled Substance Utilization Review and Evaluation System (CURES) is a program operated by the California Department of Justice (DOJ). (Health & Saf.

report would be run, and she said she was not asking for a rate increase. Respondent ordered an intramuscular injection of Decadron, a medication used to treat arthritis among other conditions. He also prescribed her the following pain medications: 60 pills of 15 mg oxycodone, 60 pills of naproxen, 500 mg Medrol Pak, and 30 pills of omeprazole 20 mg. Oxycodone is an opioid and Schedule II controlled substance. Naproxen is a non-steroidal anti-inflammatory drug used to treat pain. Medrol Pak is a medication used to treat arthritis. Omeprazole is a medication to treat acid reflux.

47. Patient A saw respondent next on October 12, 2017, for reevaluation and review of her October 9, 2017, MRI. The impressions of this MRI showed moderate to severe degenerative changes to Patient A's right hip with significant loss of cartilage in the hip area. Respondent referred Patient A to an orthopedic surgeon for evaluation. At this visit, respondent had Patient A undergo a drug screen.

48. On October 16, 2017, Patient A returned to respondent's office for a pump refill. Patient A described her pain level as 5/10 with "about 50 percent relief." She said the pump had given her great relief, and she felt like a new person, but her hip was bothering her. Patient A said her use of oxycodone has been effective. Respondent recorded that she was taking two pills of 15 mg oxycodone daily and naproxen pills. Without explanation or rationale respondent increased fentanyl dosing to 11.853 mg per day.

Code,§ 11165.) California law requires dispensing pharmacies to report to the DOJ the dispensing of Schedule II, III, and IV controlled substances. (Health & Saf. Code, § 11165, subd. (d).)

49. Patient A's next appointment was November 3, 2017. At this appointment she reported her pain as 6/10 with the pain pump and 10/10 without it. She did not ask for an increase in the fentanyl rate. But without explanation or rationale the nurse practitioner wrote a prescription for 60 pills of 20 mg oxycodone and the dosage was increased from 15 mg. Respondent reported that the oral medication was not effective in relieving her right hip pain. Respondent assessed her with uncomplicated opioid dependence and CRPS osteoarthritis and bursitis to her right hip.

50. At her November 22, 2017, appointment Patient A returned for a pump refill and mediation refill. She said with the oral medications and the pump she has been able to obtain 60 percent relief. Patient A said her right hip pain was increasing. His assessment of Patient A included CRPS, a number of orthopedic conditions, and uncomplicated opioid dependence. Another prescription for a 60 pills of 20 mg oxycodone was written to start December 3, 2017. Her fentanyl rate remained unchanged.

51. On December 29, 2017, Patient A saw respondent for her pump refill and medication refill. She stated she was scheduled for hip replacement surgery on February 8, 2018. She described her pain as 5/10 and it was repeated that she felt like a new person with the pump, and the oral medications have relieved her pain by 50 percent. His assessment of Patient A identified the same conditions noted above. For his plan, he wrote prescriptions for the pharmacy to compound for the pump refill and a prescription effective January 2, 2018, was written for 60 pills of 20 mg oxycodone. The daily dose of fentanyl remained unchanged.

52. By the end of 2017, respondent had increased Patient A's fentanyl rate approximately 14 times despite sustained improvement in her reported pain levels while her rate of intrathecal ketamine in the pump remained constant, and while

respondent prescribed oxycodone to her. Patient A also reported no side effects from the medications she was taking, and she reported her overall pain conditions improved.

53. On January 24, 2018, Patient A returned to respondent's office for a pump refill and refill of her oxycodone. She noted her February 6, 2018, hip surgery and wanted to discuss with respondent her post-operation medications. She described her pain level as 5/10. But, she stated that the IT pump therapy exercises and injection therapy were only "partially beneficial." At the same time, she said the IT therapy has helped reduce her CRPS and radiating nerve pain by 70 percent. She also said she was dependent on others for her ADLs. Respondent's assessment of Patient A included the same conditions previously noted. His plan involved refilling her pain pump with the prescribed compounded amount of medications and refilling the oxycodone prescription. He increased the number of oxycodone pills to 120 to start February 1, 2018. He did not explain the reason or rationale for this increase in the number of pills. The daily rate of fentanyl remained unchanged. Patient A signed a new Informed Consent for Opioid Maintenance document.

54. On March 2, 2018, after her hip surgery, Patient A returned to respondent's office for pump refills and for a refill of oxycodone. She reported great improvement as a result of the IT therapy and the hip surgery and physical therapy. She rated her pain level at 4/10. The medication regimen, intrathecal medication formula, and daily dosing rate remained unchanged at 11.853 mg of fentanyl per day.

55. Apparently, soon after her March 2, 2018, visit with respondent, Patient A fell at her home when she put her full weight on her right leg. She experienced excruciating pain and wasn't able to walk. EMS was called, and she was taken to the University of California San Diego (UCSD) Medical Center. She was assessed with an

"acute fracture" of her hip more specifically a "proximal medial femur fracture that went all the way down to distal to the lesser trochanter about 1-2 cm" and on March 5, 2018, underwent a "[r]ight open reduction internal fixation of proximal femur fracture with cerclage wires." Her post-operative care plan included two weeks of physical therapy.

56. During the hospital stay Patient A was administered pain medications with several physicians noting she was on a very high dose IT opioid regimen and she was opioid tolerant. As a result, UCSD doctors fine-tuned pain management for her during her hospital stay, which included the administration of opioids and ketamine.

57. On March 30, 2018, Patient A returned to respondent's office for a pump refill. Despite her fall on March 2, and seven-day hospitalization, she denied any recent history of falls or falls within the last six months. Her surgical history did not include the surgery she underwent on March 5, 2018, to repair her hip fracture. Patient A was noted to be using a cane as an assistive device. Patient A stated that she obtained 60 percent pain relief and was able to perform her ADLs. She noted she was also able to knit in her free time.

58. At this visit a nurse practitioner under respondent's supervision refilled the IT pump with fentanyl, ketamine, and Marcaine with the daily rate of intrathecal fentanyl at 11.853 mg per day. Her assessment and plan identified her conditions previously noted, including uncomplicated opioid dependence. The assessment did not identify her March 2, 2018, hip fracture and procedure to repair it. Respondent wrote another prescription for 120 pills of oxycodone for her.

59. About 30 to 45 minutes after her pump was refilled at SDCPMC, Patient A suffered an acute drug overdose when her husband was driving her home from the

visit. After the IT pump was refilled, and she left SDCPMC, she became sedated. Her husband stated "she was just staring, and she did not know how to move." She also did not know her birthday or the date. Concerned, her husband called 911 after he talked to respondent, who advised him to call 911.

60. At the hearing in this matter, Patient A stated she lost consciousness. In his testimony respondent disputed this and denied that Patient A lost consciousness. Emergency Medical Technicians (EMTs) responded and administered Narcan by IV to Patient A to revive her. Narcan is a medication designed to rapidly reverse opioid overdose.

The EMTs transported her to UCSD Medical Center's Emergency Department. Patient A reported she regained consciousness when she woke up in the ambulance. She was admitted overnight to UCSD Medical Center for observation.

61. The admitting emergency room doctor, Hannah Wanberg, M.D., called respondent and spoke with him. Respondent told Dr. Wanberg "sometimes with exchange a little extra fentanyl can get into system. Happens rarely but is a known side effect." He added "this will quickly wear off and there was no change to her intrathecal pump, and it was functioning today without leak or malfunction."

62. Timothy Furnish, M.D., an attending pain management specialist at the hospital, assessed that a small amount of fentanyl inadvertently was deposited subcutaneously during the refill. Patient A was advised that the medication concentrations in the IT pump were extremely high, and that because of this, every time her pump is refilled there is the potential of an overdose and a risk of death from overdose. To highlight his concern, Patient A testified, Dr. Furnish told her she had

enough fentanyl in her pump to kill the entire emergency room.[3] Dr. Furnish's statement is considered as administrative hearsay pursuant to Government Code section 11513 because it supplements and explains his concern documented in the hospital record that respondent faced the potential of an overdose every time her pump is refilled.

63. After Patient A's pump was refilled at respondent's clinic, respondent did not observe her to assess whether she experienced any adverse reactions to the medications. In his interview during the Health Quality Assurance Investigation (HQIU) into this matter respondent said it was "customary" at his clinic to observe patients for 20 minutes after their pumps were filled. He added that he did not "necessarily document [that the observations occurred]."

64. On May 4, 2018, Patient A returned to see respondent for a pump refill. In the questionnaire she completed for the visit she said she wanted to "discuss [the] last refill/OD." She discussed with respondent her overdose and said she experienced no side effects and that the pump was working for her. She said the pump significantly reduced her back pain and improved her quality of life, and she has reduced her oral pain medications by half since the pump was implanted. Per the assessment and plan for her, respondent recorded that he had a lengthy discussion with Patient A about "the overly narcotized incident" following her refill on March 30, 2018, and she was

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[3] On November 30, 2017, it is noted Dr. Furnish performed a pre-operative pain management consultation related to her hip replacement surgery. He noted that Patient A with her IT pump therapy was on an "EXTREMELY high dose IT fentanyl plus ketamine and bupivacaine." (His emphasis.)

aware of the risk of proceeding with the therapy and the benefits outweighed the risks to her.

65. Finally, the progress note indicates that Patient A was scheduled to return the following month for a pump refill, on June 8, 2018. On or about June 8, 2018, Patient A had her pump refilled, according to documents found in Patient A's medical record from SDCPMC. Specifically, a telemetry report, a Medtronic drug calculation spreadsheet, and a handwritten prescription appear to show that Patient A's pump was refilled on or about June 8, 2018.

66. Patient A has remained respondent's patient and has continued IT therapy. She testified in this matter for respondent and said that the IT pump therapy has allowed her to achieve a good quality of life. As an example, she said she walked five miles the day before she testified. She described respondent as a "miracle worker." Regarding the incident where she overdosed, as mentioned above, Patient A said she lost consciousness and, as mentioned above, she said Dr. Furnish told her she had enough fentanyl in her pump to kill the entire emergency room.

67. Respondent was interviewed regarding his treatment of Patient A on August 21, 2019. He was asked about the intrathecal fentanyl dosing he had prescribed to Patient A, and whether he considered the dosing as low, medium, or high. Respondent stated that he had patients who ranged from 2.4 mg per day, up to 25 mg per day. He explained that "[e]verybody is different ... I suppose it depends on their pharmacokinetics and their metabolism." Respondent was also asked questions about Patient A's overdose on March 30, 2018. Respondent speculated that "little drops" could have come out of the tip of the needle when it was pulled out, which then got into the patient's subcutaneous tissue. He then added, "[i]t's rare, but it can happen." Respondent stated that it was "customary" at SDCPMC to observe patients

for 20 minutes after their pump was filled. Respondent was asked whether observations are documented, to which he replied, "[w]e don't necessarily document that." In this hearing respondent testified as a result of Patient A's overdose he changed his procedure and has now implemented a 45-minute observation period after a pump refill.

TESTIMONY OF MARK STEVEN WALLACE M.D. REGARDING PATIENT A

68. Complainant called Mark Steven Wallace, M.D. as an expert. Dr. Wallace was asked to review the materials of record admitted as evidence and render opinions regarding respondent's care and treatment of Patient A.

Dr. Wallace is Professor of Anesthesiology and Chief of the Division of Pain Medicine, and Director of Clinical Research Services, Division of Clinical Research, Clinical and Translational Research Institute, Department of Anesthesiology at UCSD. He has held the position of Chief of the Division of Pain Medicine since 2010. This Division was established in 2010, and he was instrumental in creating it when he proposed it as a division within the Department of Anesthesiology.

69. Respondent oversees 14 faculty members in this division. The program consists of a very active clinical practice to treat patients with care that ranges from psychiatric therapies to implantable devices. A component of the program is a clinical approach program. Three directors report directly to him.

Prior to his appointment as Director of Clinical Research Services, Dr. Wallace served as Program Director for the Center for Pain and Palliative Medicine and Professor of Clinical Anesthesiology from 2005 to 2019.

70. Dr. Wallace obtained his M.D. degree from Creighton University School of Medicine. He completed an internship in general surgery at Washington Hospital Center in Washington D.C., a residency in anesthesiology at the University of Maryland Hospital in Baltimore, a National Institutes of Health Grant Fellowship at UCSD, and a Pain Fellowship also at UCSD.

71. Dr. Wallace received clinical training in all aspects of pain management, and he participated in research in the development of intrathecal pain management with Tony Yaksh, Ph.D.

72. Dr. Wallace is the author of 159 peer reviewed original articles in the field of pain management from 1993 to 2021. Among these articles, he was coauthor with Dr. Yaksh of the first comprehensive study of intraspinal medicine delivery in 2000. In 2007 and 2012 for the Polyanalgesic Consensus Conference (PACC) he and other authors reported on their recommendations for the management of pain by intrathecal drug delivery. PACC is an international organization that endeavors to identify standards for intrathecal drug delivery.

73. In addition to his authorship of peer reviewed articles Dr. Wallace is the author of numerous abstracts and chapters in books in the field of pain management. Notably, for the issues in this hearing, among these Dr. Wallace wrote a chapter entitled "Human Spinal Drug Delivery: Methods and Technology" (Spinal Drug Delivery, Elsevier, New York (1999). In this chapter Dr. Wallace addressed standards to select patients for spinal drug delivery treatment by their psychosocial status and comorbidities.

74. Dr. Wallace is a member of many professional societies in the field of pain management including the North American Neuromodulation Society and the

International Neuromodulation Society and the American Academy of Pain Medicine. At UCSD he has held numerous appointments. In 2018 Dr. Wallace was the Chair of UCSD's Opioid Task Force and in 2020 was the Co-Chair of the Addiction Pain Medicine Council. Since 2002 Dr. Wallace has actively participated as an editor of publications in the field of pain management and as a member of committees and workgroups in the field.

75. Dr. Wallace is also the investigator of numerous studies and drug trials in the field and the recipient of grants to study the efficacy of pain control treatments.

76. Dr. Wallace is a Diplomate of the National Board of Medical Examiners, the American Board of Anesthesiology with added qualification in Pain Management and the American Board of Pain Medicine. He is licensed to practice medicine in California.

77. At UCSD, Dr. Wallace spends 50 to 60 percent of his time in direct patient care: three days of patient clinical care which involves new patients, treatment planning and medication management. The rest of his time involves implantation of pain management devices.

In this clinical practice at UCSD Dr. Wallace works on intrathecal pumps. He is the primary doctor at the clinic for intrathecal pumps and deals with them daily.

78. Dr. Wallace is familiar with the applicable standards of care and the definitions of extreme and simple departures from the standard of care. He prepared reports summarizing his opinions for each of the patients at issue in this matter. His testimony was consistent with the reports.

His testimony is summarized as follows:

79. Based on his review of the the evidence of record in this matter Dr. Wallace identified four medical issues where he found respondent departed from applicable standards of care in his treatment of Patient A. He found that he departed from the standards of care when respondent incorrectly programmed Patient A's initial drug concentrations into the pump; he did not have Patient A undergo a psychological evaluation to assess whether she was an appropriate candidate for intrathecal drug therapy; he administered excessively high doses of intrathecal fentanyl; and he administered ketamine in the pump.

80. Regarding respondent's programming error, Dr. Wallace stated the standard of care requires that exact concentrations of the drugs be programmed into the pump, and respondent departed from this standard by not programming the exact concentrations accurately. As he put it these doses must be accurate because it is not uncommon for pain patients to require emergency care in other institutions. Inaccurate concentrations can result in either an overdose or an underdose if the pump needed to be refilled in another institution.

81. In Patient A's case, if a doctor at another institution relied upon the incorrectly programmed drug concentrations for Patient A, in his opinion this would likely have resulted in a drug overdose and harmed Patient A. For this reason, Dr. Wallace concluded that respondent's programming error constituted an extreme departure from the standard of care.

82. With respect to the medical issue concerning respondent's evaluation and selection of Patient A as an appropriate patient for intrathecal drug therapy, Dr. Wallace identified the standard of care as follows: The standard of care requires that patients identified for intrathecal drug therapy undergo a psychological evaluation to identify any psychosocial barriers they may have that would serve as barriers to

successful outcomes. Dr. Wallace found that respondent departed from this standard of care by not obtaining a psychological evaluation of Patient A before she began intrathecal therapy. He found the departure to be extreme.

83. Dr. Wallace testified that specialists in the field of intrathecal drug therapy widely accept that a psychological evaluation is necessary before starting the therapy. It is also PACC's recommendation. The reason a psychological evaluation is needed is that intrathecal therapy is very invasive, the therapy involves a lot of healthcare reliance, and it is costly. The provider in effect "marries" the IT therapy patient. There needs to be assurance that the patient identified for such therapy will be reliable and psychosocially stable, and also the patient has realistic expectations of outcomes. Dr. Wallace said, as an example of the importance of a psychological evaluation, that it is unrealistic and dangerous for a patient to have an expectation that he or she would have no pain. Otherwise, it opens the patient up to the excessive use of medications with the risk. In addition, it is important that any psychological and social issues are known and addressed to ensure positive outcomes as best as possible.

84. Dr. Wallace addressed respondent's statement in his May 2, 2017, operative report for the implant of the trial pump catheter that Patient A had undergone "psychological testing" and that she had been "cleared to proceed with the pump trial." Dr. Wallace dismissed respondent's statement in the report because he found no indication in Patient A's records that Patient A underwent psychological testing.

85. Concerning whether depression by itself is a contraindication for IT therapy, Dr. Wallace stated that a diagnosis of depression by itself is not a contraindication for such therapy. But he said Patient A reported depression and was

under medication management for it, and she reported her mother's mental health history as recorded in her notes made it important that she undergo this psychological evaluation before proceeding with either the pump trial or the implantation of the pump. Dr. Wallace commented that family history always indicates an increased risk of mental health issues. Dr. Wallace believes that this evaluation needed to be done before the pump trial.

86. The third medical issue Dr. Wallace identified is whether respondent complied with the standard of care with the management of IT therapy for Patient A. He stated that the standard of care requires the doctor to use small doses of drugs in IT therapy because the drug is targeted for delivery in the spinal cord and not systemically throughout the body. To highlight his point, Dr. Wallace stressed that fentanyl is a hundred times more potent than morphine, and a small amount of solution outside the pump can pose a risk to the patient. He stated that published guidelines for IT therapy exist but he did not rely only these guidelines in formulating his opinion on this issue.

87. Dr. Wallace found that respondent departed from this standard of care because he used excessively high doses of intrathecal fentanyl in Patient A. The dosages he administered to Patient A exceeded the amount of fentanyl used for cardiac anesthesia and far exceeded the standard of care.

88. In his experience as a practitioner and researcher in the field of IT therapy and pain management Dr. Wallace said he never saw the amount of fentanyl administered to any patient in an intrathecal pump that respondent administered to Patient A. He added that you don't start with fentanyl as the "driver drug." He found the departure to be extreme. He further found that his prescription and administration of this amount of fentanyl caused Patient A harm when she faced a life-threatening

consequence when she overdosed when a small amount of fentanyl was administered outside the pocket.

89. Dr. Wallace acknowledged there is no known upper limit to the intrathecal use of fentanyl, but he quickly pointed out that does not mean there is no limit. He stressed that while there is no known upper limit this makes clinical judgment an important requirement and, fundamentally, he questions respondent's clinical judgment by starting Patient A on such a high amount of fentanyl and titrating her up. By doing this he did not give Patient A the chance to see if with lower dosage her pain level would have improved, and she would be able to better function.

90. To illustrate that Patient A was administered exceedingly high dosages of fentanyl Dr. Wallace noted that Patient A experienced withdrawals after the pump trial ended and before the pump was implanted. As a result, Patient A needed to go to the emergency room. He suspects that this was because respondent was administering very high dosages to Patient A and she developed an acute dependence.

91. Dr. Wallace found respondent's clinical judgment lacking because he repeatedly, even during the pump trial, increased the dosages without explanation. During the pump trial period respondent increased the fentanyl infusion rate on May 3, 2017, from 0.2 to 0.3 mg of fentanyl and on May 5, 2017, from 0.3 mg to 0.4 mg without explanation.

92. Once the IT pump was implanted Dr. Wallace started Patient A at an excessively high dosage and then titrated the dosages up. This amounted to a huge step in the fentanyl drug dosage he delivered to Patient A, and Dr. Wallace repeated that by starting Patient A at such a high dosage he didn't give Patient A the chance to

see if she was able to function at a lower dose. Dr. Wallace said he was not critical of respondent's titration of the drug but of the "huge" doses of fentanyl he was using.

93. During the hearing Dr. Wallace went through Patient A's records for the period after the pump was implanted. He noted respondent repeatedly increased the dosages of fentanyl without explaining why he increased these dosages in the amounts he did. Respondent routinely increased the dosages when respondent came to his clinic and asked for these increases. In 2017, Dr. Wallace noted that respondent increased the rate of fentanyl 14 times even when Patient A reported improved pain levels.

94. In August 2017 without explanation, respondent reduced Patient A's dosage of fentanyl by half from 13.7 mg of fentanyl to 6.86 mg of fentanyl. Dr. Wallace said this was a big reduction and seemed to show that respondent recognized he had made a programming error, which he needed to correct.

95. In 2018, respondent increased the fentanyl dosages even where Patient A reported her pain level improved at 5/10 on January 24, 2018, and on March 2, 2018, where she reported her pain level at 4/10.

96. Patient A's overdose on March 30, 2018, highlighted Dr. Wallace's concern regarding the high dosage of fentanyl respondent administered to Patient A. He agreed that a small amount of fentanyl outside the pump pocket made her unresponsive and required the administration of Narcan to Patient A, and her emergency hospitalization.

97. The fourth medical issue Dr. Wallace discussed involved respondent's use of ketamine intrathecally for Patient A. The standard of care Dr. Wallace identified requires that drugs used for intrathecal therapy be safe. Ketamine is not a safe drug to

use in IT therapy. It has been shown to be toxic to the spinal cord with unacceptable risk/benefit to the patient. Respondent's use of ketamine for IT therapy for Patient A represented an extreme departure from the standard of care. Dr. Wallace based his opinion on this issue on his education, training, clinical experience, and knowledge of the literature, and interaction with colleagues and his day to day clinical care of intrathecal patients.

98. Dr. Wallace testified that ketamine's safety is not a "gray area" because of the evidence of ketamine's toxicity when used in IT therapy. He referenced a study done at UCSD in the late 1990s and in early 2000. He also cited a 2002 study "Kedlaya Reynolds and Waldman epidural and intrathecal analgesic for cancer pain best practices 2002." The authors of this study expressed concern for the long-term safety of ketamine in intrathecal therapy and cited a post-mortem of a cancer patient with basically "holes in the spinal cord" from ketamine IT therapy. Dr. Wallace said that this finding was consistent with dog and sheep models. Because of these dog and sheep models the Food and Drug Administration put the brakes on clinical trials of ketamine in humans because of the toxicities of ketamine in the IT therapy found in the dogs and sheep. In other words, clinical human trials of ketamine in IT therapy were deemed unsafe.

99. Dr. Wallace found support for his opinion in an article respondent made part of the record about the long-term effects of ketamine use and which respondent's expert cited. Respondent cited the article to show the value of ketamine therapy. The July 2018 article is entitled "Consensus Guidelines on the Use of Intravenous Ketamine Infusions for Chronic Pain From the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Academy of Anesthesiologists."

100. The authors of this study on the IV use of ketamine (as opposed to the IT use of ketamine) summarized their conclusion as follows:

> Larger studies evaluating a wider variety of conditions are needed to better quantify efficacy, improve patient selection, refine the therapeutic dose range, determine the effectiveness of non-intravenous ketamine alternatives, and develop a greater understanding of the long-term risks of repeated treatments.

The authors noted the absence of double-blind studies to properly assess these long-term risks.

101. Dr. Wallace is aware of only two case reports where ketamine was used in IT therapy, and both reports involved cancer patients. In general, more aggressive pain management treatments can be warranted for a terminal cancer patient.

102. In support of his opinion on redirect, Dr. Wallace cited a study respondent's expert Dr. Berger referenced in his report regarding the potential neurotoxicity of ketamine. According to this study "Epidural and intrathecal analgesia for cancer pain" there are long term safety concerns for ketamine's use in IT therapy. Ketamine can create holes in the spinal cord. In fact, out of concern for the safety of ketamine in IT therapy, the FDA halted human clinical studies of ketamine in IT therapy.

103. On cross-examination Dr. Wallace was asked to explain why, if ketamine is not safe for IT therapy use, the Centers for Medicare & Medicaid Services (CMS) has authorized as a local coverage determination (LCD) the use of ketamine in IT pump therapy. Dr. Wallace responded that the LCD does not establish the standard of care.

104. Dr. Wallace also addressed the articles respondent's expert cited in his report to support his opinion that ketamine is safe to use in IT therapy. Dr. Wallace said he is familiar with all the articles Dr. Berger referenced and none of them mention ketamine. He noted that ketamine was removed from the 2012 PACC guidelines.

TESTIMONY OF JACK M BERGER M.D. REGARDING PATIENT A

105. Respondent called Jack M. Berger M.D. as an expert witness. Dr. Berger reviewed the applicable evidence of record in this matter and prepared reports regarding respondent's care of each of the patients at issue in this matter. He acknowledged respondent helped him by finding records to dispute Dr. Wallace's assertions. Dr. Berger said he needed respondent's help to do this. He is familiar with the applicable standards of care and the definitions of simple and extreme departures from standards of care. His testimony is materially consistent with the reports he prepared regarding his evaluation of respondent's treatment of the three patients. His testimony is summarized as follows:

106. Dr. Berger received his M.D. degree in 1978 from the University of Bologna in Italy. He completed residencies in anesthesiology at Los Angeles County University of Southern California Medical Center in 1981, and at UCLA Medical Center in 1982. He became board certified by the American Board of Anesthesiology in 1984 with added qualifications in Pain Management in 1994, and by the American Board of Pain Management, an organization that disbanded in 2019. He has served as a consultant for the board, performed medical-legal evaluations, and served about 15 years ago as a reviewer for the Motion Picture Health Insurance regarding Anesthesia and Pain Management Claims.

107. Dr. Berger served as Professor of Anesthesiology, the Director of the Regional Anesthesia Resident Training, and Program Director for Regional Anesthesia Fellowship until 2020 at the Keck School of Medicine, University of Southern California (USC). He is now Professor Emeritus of Clinical Anesthesiology. He described himself as "sort of retired" and he works one to two days a week at the county hospital.

Dr. Berger has further served as Clinical Director of Pain Management at USC University Hospital and Norris Comprehensive Cancer Hospital and Chairman of the Department of Anesthesiology and Vice Chair at Charter Community Hospital, among other professional affiliations.

Dr. Berger is a member of numerous professional societies in the field of pain management and has served on many leadership positions and committees.

108. Dr. Berger has actively been involved in research in the field of pain management and has been the co-author of many published papers and abstracts through 2021. He also has written book chapters for textbooks in the pain management field. Dr. Berger has been a frequent presenter in continuing medical education for health professionals in pain management.

109. Dr. Berger has had experience caring for patients with intrathecal pump therapy. He was one of the earliest implanters of IT pumps in the 1980s. He has been involved in the maintenance of IT pumps, and the kinds of drugs that go into them. He estimates he has implanted between 40 to 50 pumps. He said of these about three or four had ketamine in their pumps.

110. Based on his review of the materials provided to him, Dr. Berger testified that respondent did not depart from the standards of care regarding the need to have a psychological evaluation of Patient A before proceeding with IT trial therapy; the

doses of fentanyl he administered to Patient A; and his use of ketamine. Dr. Berger did not dispute that respondent departed from the standard of care in his programming error, but he found that to be a simple departure from the standard of care.

111. With respect to the need to have Patient A undergo a psychological evaluation before proceeding with IT therapy, Dr. Berger disagreed with Dr. Wallace that respondent needed to have this done before Patient A proceeded with the pump trial. But he seemed to agree with Dr. Wallace regarding the applicable standard of care to an extent. Depending on a patient's presentation, Dr. Berger said that the standard of care may require a psychological evaluation. He noted that there is disagreement within the pain management community regarding the need for this consult. But he stressed that if a physician obtains such an evaluation it is his/her job to decide what to do with the information from this evaluation. In this sense the physician does not obtain the psychological evaluation to "clear" the patient for IT therapy.

112. Concerning Patient A, Dr. Berger did not directly address whether respondent departed from the standard of care when he did not obtain a psychological evaluation before the trial or before he implanted the pump. Instead, he noted simply in his report that Patient A was under the care of both a psychiatrist and a therapist. By this statement he appears to suggest that the fact that Patient A was under the care of mental health professionals obviated the need for respondent to obtain an evaluation.

113. But it must be noted there is no documentation in Patient A's chart that she was under the care of a psychiatrist and therapist either before the trial pump or before the pump was implanted. In his testimony, Dr. Berger said that he based his

understanding that Patient A was under the care of a psychiatrist and psychologist from his discussion with respondent.

114. With respect to respondent's dosing of fentanyl, Dr. Berger did not agree with Dr. Wallace that the dosages were excessive, and that respondent breached the standard of care. Dr. Berger emphasized the importance of judgment in setting the dosing levels citing the PACC 2017 guidelines which he quoted as follows: "Algorithms [predicting appropriate dosing levels] are based on evidence and consensus on safety. The *patient's physician and good clinical* judgment should guide individual patient care [his emphasis]." He found that respondent's exercised sound clinical judgment in his dosing of fentanyl.

115. In his testimony Dr. Berger elaborated on the importance of clinical judgement. In his view a physician's clinical judgment, as far as dosing levels are concerned, cannot be questioned as long as the physician documents his reasoning for the dosing. He testified as follows:

> And that they [pain management doctors], based on the physician's own experience and their judgment, they can go outside of those [consensus] guidelines because they are familiar with what they are doing, and it's appropriate. And as long as they document the appropriateness of that in their thought process, no one can judge them. And that's what I say, the patient's physician in good clinical judgment should guide individual patient care, and that's what they say.

116. Dr. Berger explained the clinical judgment is to find the appropriate dosage level based on the patient's response. Because the opioid or combination of drugs are delivered directly to spinal cord where the pain fibers are, there is little systemic effect from the medications. Dr. Berger stressed that because the medications are delivered within the intrathecal sac and make contact with the spinal cord, there is less impact on the body's system than if the drug was delivered systemically. Dr. Berger commented that a drug delivered directly to the brain can have significant effects.

117. Dr. Berger added that, in dosing, factors for the practitioner to consider include the patient's age, height, and sensitivity to the drug. This requires starting with one drug or two drugs for use as determined in a trial period and then slowly increasing the dosage amounts or adding a drug while monitoring the patient. Dr. Berger said finding the appropriate fentanyl dosing level is not an exact science. If the practitioner finds that the patient is not responding to one drug, then a second drug may be added, or the drug changed.

118. In his analysis, Dr. Berger further noted there is no maximum dose of fentanyl for IT pump therapy and, as he wrote in his report (concerning Patient B), "[t]he metabolism of intrathecal fentanyl is not completely understood." As he put it, no one knows what the dose should be because the drug is so soluble there can be high concentrations without the drug "precipitating" out. Dr. Berger said the "max dose" is the dose that provides relief without side effects.

119. To address the appropriate dose, respondent correctly, in Dr. Berger's view, had Patient A undergo a trial of fentanyl, and based on her response, respondent decided to implant the IT pump using a similar concentration of fentanyl. He commented that she was not "opioid naïve" meaning she was tolerant of the effects of

opioids. Respondent then slowly increased the dose to find the best possible relief without side effects. Dr. Berger acknowledged that the concentrations were "relatively high," but he said respondent very carefully in his view monitored Patient A. He was also careful in the titration of the drug, and he frequently saw Patient A, and increased the doses based on Patient A's description of her condition and with her agreement

120. Dr. Berger stressed the IT pump gave Patient A significant pain relief. It allowed her to return to ADLs, and she decreased the oral pain medications she took, and she was able to enjoy a quality of life she was missing before the implant. He noted that, as Patient A testified, she was able to walk five miles the day before she testified.

121. Dr. Berger dismissed Dr. Wallace's concern that the fentanyl concentrations in Patient A's pump were dangerous. Dr. Berger recognized that the drug concentrations in a pump in general are high, but he said this was because of the two-month time period between pump refills.

122. Dr. Berger also criticized Dr. Wallace for comparing respondent's fentanyl dosing levels to the high end of cardiac anesthesia. This comparison ignores the metabolic and pharmacological differences between fentanyl delivered by IV therapy and by IT therapy.

123. Concerning Dr. Wallace's opinion on the issue of the use of ketamine, Dr. Berger disagreed that ketamine should be absolutely prohibited in IT therapy. Dr. Berger found that respondent acted within the standard of care in using ketamine in Patient A's IT therapy.

124. Dr. Berger testified that respondent correctly determined that ketamine was appropriate for Patient A. It enhanced the effect of fentanyl without increasing the

dosage. As a combined therapy, the drug provided the best relief for all patients with minimal side effects. Dr. Berger noted that a small amount may help with depression - though not clinical depression - because of the patient's frustration with coping with chronic pain.

125. Dr. Berger recognized there is debate regarding ketamine's neurotoxicity at low doses. He said some studies say it is neurotoxic and others say it is not. He believes that very low doses of ketamine would not cause toxicity.

Dr. Berger, however, in his report was not as certain that respondent's use of ketamine was within the standard of care. He wrote that respondent's use of ketamine at low doses "*does not appear* to have been outside the standard of care (emphasis added)." This contrasts sharply with the certainty he expressed on this issue in his testimony.

126. Dr. Berger cited ketamine's use in treating depression and comprehensive regional pain syndrome and thus it was appropriate to treat Patient A's CRPS and RSD. In his report he cited studies involving ketamine's use in managing pain in cancer patients.

127. Concerning respondent's programming error, Dr. Berger did not address this in his report, but he testified that he regarded the error as a simple departure from the standard of care considering the dosing discrepancies were small and would not have resulted in patient harm.

Patient B

128. On May 13, 2015, respondent first saw Patient B, a then-60-year-old female resident at a skilled nursing home, for a consultation for a pain management.

Patient B was transferred to this facility after she was hospitalized due to her altered mental state from a possible overdose of methadone. Patient B was taking methadone 10 mg orally three times a day. Methadone is a synthetic opiate primarily used in the detoxification and maintenance of patients who are dependent on opiates, and the treatment of patients with chronic, severe pain. It is Schedule II controlled substances pursuant to Health and Safety Code section 11055, and a dangerous drug pursuant to Business and Professions Code section 4022.

129. Respondent reported Patient B's medical history to include schizophrenia, a history of opioid abuse, anxiety, depression, C3-4 spinal injury, and traumatic brain injury secondary to domestic abuse. Patient B, it is noted, was diagnosed with schizoaffective disorder.[4]

130. Patient B had been under the care of a psychiatrist for many years, and she had recently been transferred to the nursing home following a recent hospital admission due to a possible overdose of methadone. Respondent remained under the care of psychiatrist Laurence Saben, M.D.

131. In his consultation report dated May 13, 2015, respondent documented Patient B's medical complaints included chronic pain in her spine, legs, knees, and hands; and that her past pain medications included fentanyl patches and Roxicodone.

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[4] To show the degree of Patient B's mental health condition at the time Patient B sought treatment with respondent, complainant called R. Lee Wagner, M.D., a pain management doctor. On October 6, 2017, Patient B consulted with Dr. Wagner. Dr. Wagner had the opportunity to clinically observe Patient B and assessed her "with major mental health problems."

Roxicodone, a trade name for oxycodone, is a Schedule II controlled substances pursuant to Health and Safety Code section 11055, and a dangerous drug pursuant to Business and Professions Code section 4022. Patient B took methadone for pain. She told respondent that it was ineffective. Respondent also recorded Patient's B medical and psychiatric history.

132. Respondent found that Patient B had "most likely" engaged in opioid abuse, and that an overdose had occurred because of her response to Narcan given by paramedics. Respondent then concluded that "[Patient B] is an excellent candidate for an infusion pump," and that when she was discharged from the nursing home he would "attempt to get her in for an intrathecal pump trial which should prevent any future abuses or accidental or intentional overdoses."

133. Despite Patient B's opioid abuse history, respondent did not discuss or document discussing with her the need to undergo a psychological evaluation before considering her for an intrathecal pump trial.

134. Between May 26, 2015, and August 6, 2015, Patient B saw respondent for follow up visits and pain medication refills of fentanyl patches and Roxicodone. In Patient B's May 26, 2015, note respondent recorded that Patient B was suffering from depression, anxiety, mood swings, and nervousness, and that she was "not acting in appropriate manner. She is in mild distress. . . . Her recent memory is not intact. Her mood and affect exhibits [*sic*] paranoia and shows anxiety."

135. On July 24, 2015 respondent "tried" Patient B on a peripheral nerve stimulator. In the same order he wrote that Patient B will return to the surgical center on August 18, 2015, to implant an IT opioid pump and for her to return on August 21, 2015, for assessment and explant on August 25, 2015. Respondent did not record

whether the nerve stimulator helped Patient B. During this time frame, respondent did not discuss or document discussing with Patient B the need to undergo a psychological evaluation before considering her for an intrathecal pump trial. Patient B's transport for the implant was to be arranged by ambulance.

136. On August 18, 2015, respondent surgically implanted a catheter for the pump trial. An external pump used for the trial was filled with the following intrathecal medication: fentanyl 25 mg/ml, and Marcaine 5 mg/ml (1 ml).

137. Respondent in an August 18, 2015, operative procedure note, noted that the pump trial was being used "to determine the appropriateness of a Medtronic Synchromed II infusion pump as [Patient B] has failed all conservative methods." Respondent wrote in his report that was going to "increase the infusion rate slowly and sequentially per clinic protocol until pain relief occurs."

138. In this operative report respondent did not state Patient B had undergone a psychological evaluation prior to the start of pump trial. In fact, Patient B did not undergo such an evaluation before the pump trial.

139. In a note dated August 20, 2015, respondent recorded that nursing staff at the nursing facility reported that Patient B's schizoaffective behaviors worsened since the pump trial had begun two days earlier. Patient B reported swelling and paralysis. She was again noted to have paranoia and anxiety. Respondent reminded Patient B about her August 21, 2015, appointment.

140. Patient B saw respondent on August 21, 2015, according to a short progress note. This note records simply that Patient B had reported to SDCPMC for "pump trial EXPLANT." Under the "Follow Up" subheading in the note respondent notated "No follow up."

141. The next note is dated November 3, 2015, and records that respondent surgically implanted a second pump trial for Patient B. No explanation is given why there was a gap in Patient B's treatment with respondent between August 21, 2015, and November 3, 2015, or why there was a second pump trial. An external pump used for the trial was filled with the following intrathecal medications: fentanyl 25 mg/ml, and Marcaine 5 mg/ml. The report states that respondent will "increase the infusion rate slowly and sequentially per clinic protocol until pain relief occurs."

This note does not record that Patient B had undergone "psychological testing" before the second pump trial.

142. On November 6, 2015, Patient B returned to SDCPMC for a follow up. She reported her pain level as 3/10 at the time but complained of generalized pain upon movement. Respondent increased the pump trial rate from 0.2 mg to 0.3 mg per day.

On November 10, 2015, Patient B saw respondent for a follow up visit. She reported 70 percent relief from pump and rated her pain level as 3/10 and 9/10 without the pump. She indicated she would like to proceed with implantation of the pump. Respondent explanted the percutaneous catheter from Patient B. Patient B stated that she wanted to proceed with the implantation of a permanent intrathecal pump, according to the progress note for the visit.

Respondent documented that respondent was to be assessed for a MRSA culture before the pump was implanted.

143. In a document captioned Pain Medicine Follow Up note dated December 13, 2015, respondent recorded that he saw Patient B in the hallway at his clinic.[5] He said Patient B was excited for the pump implant which was set for December 17, 2015, after two "successful trials." He stated that she "has gone through psychiatric clearance." There are no details regarding this clearance.

144. On December 17, 2015, respondent implanted an IT pump in Patient B at Pacific Surgical Institute. He did not document in his operative report that Patient B underwent a psychiatric or psychological evaluation, notwithstanding the December 13, 2015, note discussed immediately above.

145. Among Patient B's records that respondent submitted as evidence is a handwritten note that is barely legible. Respondent represented that Dr. Saben, Patient B's psychiatrist, wrote the note to clear Patient B for the pump implantation. The note does not identify Dr. Saben. It is included with the fax cover page from San Diego Post-Acute, one of the facilities in which Patient B resided. The fax cover sheet states "Psych clearance for pain pump implant." It does not identify that Dr. Saben or his office sent the note.

146. The note is not among Dr. Saben's records for Patient B that Dr. Saben certified in June 2018 was a complete record of his treatment of Patient B. No explanation was offered why this note was not among his records. Further, the note is

[5] For reasons that were not explained this record is among Patient B's records respondent submitted as evidence, but is not among the records respondent submitted to HQIU.

not among Patient B's medical records that respondent sent to HQIU on August 3, 2018, and which respondent certified consisted of Patient B's complete records.

147. Regarding the note itself it appears to be dated December 2, 2015. An effort was made to read it, but it is mostly illegible. The language "pt is able to [illegible] pump. . . " is the only language that is discernible.

148. After the pump was implanted on December 17, 2015, later that same day, Patient B reported to SDCPMC to have the new pump reprogrammed and filled with intrathecal drugs. The initial formula of intrathecal medication appears to have been fentanyl 25 mg/ml, and Marcaine 5 mg/ml. The initial daily dose of fentanyl was 1.997 mg per day.

149. On December 21, 2015, Patient B returned to respondent's clinic for analysis with programming. There are two notes for this date. One note records that the rate was increased from 0.2 mg to 0.3 mg. A second note with this date records that the rate was increased from 1.997 mg/day to 3.248 mg/day. The later rate refers to the fentanyl infusion rate. It is not clear what the first rate of 0.3 mg rate references.

A note dated December 28, 2015, records that respondent removed the staples from the procedure. Patient B reported that her pain level was 2/10.

150. On December 31, 2015, Patient B returned to SDCPMC for a follow up visit. Patient B requested an increase of fentanyl because she said her pain level was 9/10. Per her request, respondent increased Patient B's daily dose of fentanyl to 4.242 mg per day. In 14 days, respondent doubled Patient B's daily dose of fentanyl from 1.997 mg per day to 4.242 mg per day without explanation.

151. In 2015, according to Patient B's records, Patient B consistently was documented to suffer from depression, anxiety, mood swings, and nervousness. She was further recorded to have memory problems and exhibit paranoia.

152. On January 15, 2016, respondent saw Patient B at the San Diego Post Acute Center and increased her daily dose of fentanyl to 5.498 mg per day.[6] As recorded in a Pain Medicine Follow Up Note respondent stated that Patient B's pain level decreased from "a 7 to approximately a 2." He nonetheless increased the fentanyl rate "to further decrease" her pain. Patient B reported some knee pain due to a recent fall, but she said she was able to perform ADLs.

153. Patient B next saw Sharon Thompson, M.D., at respondent's clinic on February 17, 2016. She reported her pain level as 7/10 because she fell in the shower and hurt her knees, wrist, and back. Dr. Thompson increased her daily dose of fentanyl to 6.006 mg of fentanyl per day.

154. On March 11, 2016, Patient B requested another "slight" increase of intrathecal fentanyl in her pump. Patient B reported pain at approximately "1-2" (out of 10 on pain scale). Respondent increased her daily dose of fentanyl to "7.0" mg per day.

155. On March 24, 2016, Patient B returned for a routine IT pump refill. She reported she has fallen four times in the last month and reported swelling to the left foot. She asked respondent for help in finding a new primary care doctor. Under his assessment and plan for Patient B, respondent identified the ICD codes for Patient B

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[6] This is one of several skilled nursing facilities where Patient B resided during the time she treated with respondent.

which included "Schizo affective schizophrenia"; "Traumatic brain injury"; and "Traumatic brain injury with loss of consciousness of unspecified duration, sequela." The pump was not refilled on this occasion.

156. On April 29, 2016, Patient B went to respondent's clinic for a pump refill. She described her pain level as 3/10. She stated that the pump has helped reduce her pain by 70 to 80 percent.

157. On July 1, 2016, Patient B reported to SDCPMC for a pump refill. Patient B rated her pain at "1-3 on a scale of 10." Respondent also recorded Patient B's reported pain scale as 3/10. Without explanation in the progress note, and despite that Patient B's pain level remained in the 3/10 range and according to her she was functioning well and able to do her ADLs, respondent increased her daily dose of fentanyl to 7.503 mg per day from 6.993 mg per day. In this note respondent identified that Patient B had the following conditions by ICD codes: "Anxiety and depression"; "Opioid dependence continuous"; and "Long term current use of opiate analgesic" in addition to physical based conditions.

158. Patient B's intrathecal pump was refilled on August 26, 2016. She described her pain at this visit as 6/10. She said she was experiencing increased pain due to an incident at the skilled nursing facility where she resided. She repeated that the pump was working, and she was able to perform her self-care activities independently. After the pump was refilled respondent maintained Patient B on the daily rate of fentanyl of 7.503 mg.

159. On October 26, 2016, Patient B reported to SDCPMC for a pump refill. The intrathecal medication formula, drug concentration, and daily rate remained

unchanged. Patient B reported she was very fatigued due to a lack of sleep from being transferred between facilities.

160. However, the drug concentration values contained in the corresponding telemetry report differed from the actual concentration values reported in the corresponding Medtronic drug calculation spreadsheet. The intrathecal pump print-out on this date records that Patient B was supposed to be receiving concentrations of fentanyl 25 mg/ml, and bupivacaine 5 mg/ml with a daily dose of fentanyl at 7.503 mg/day and bupivacaine 1.5007 mg/day.

161. However, this was incorrect. Per the separate sheet captioned "Medtronic Drug Calculations" the actual fentanyl dose Patient B was receiving was Fentanyl 6.7570 mg/day and bupivacaine at 0.15008 mg/day; the concentrations for these drugs respectively were 22.5 mg/ml and the bupivacaine was 0.5 mg/ml. There is no indication in Patient B's records that respondent noticed this error throughout Patient B's treatment with him.

162. In 2016, Patient B consistently reported that she was suffering from depression, anxiety, mood swings, and nervousness, according to the progress notes from SDCPMC. The progress notes document that Patient B had memory problems, she exhibited paranoia and had been diagnosed with schizophrenia, and that she had a history of prescription opioid abuse and opioid dependence.

163. Included in Patient B's records is a lease agreement she signed for an independent living facility on December 23, 2016. Respondent in his testimony stated that this showed Patient B was functioning well enough due to the course of pain management to be able to live independently.

164. On January 4, 2017, Patient B returned to SDCPMC to have the pump refilled. She reported her pain level at 10/10. Respondent noted Patient B was barely able to ambulate and used a wheelchair.

165. The refill date was scheduled for December 24, 2016, but she was unable to make her appointment because she was hospitalized for a condition or problem that was not identified in this note. Respondent noted he or his office communicated with the hospital, and Patient B's treating doctor at the hospital regarding the intrathecal pump. Because the refill date had passed the pump was noted as empty and as a result respondent decreased the rate from 7.503 to 3.506 mg per day of fentanyl.

166. Respondent instructed Patient B, and her caregiver, to bring all of her medications to the next visit so that a medication reconciliation can be done.

167. According to the Medtronics Drug Calculations sheet for this visit Patient B's fentanyl and Marcaine rates were 3.155 and 0.070, not as 3.506 and 0.7013 as respondent programmed the pump.

168. On February 23, 2017, Patient B returned to SDCPMC reporting pain to multiple body parts she said she sustained due to physical altercations she had with her roommates at several long-term care facilities. Patient B wanted to discuss with respondent her treatment options and develop a plan of care to prevent falls. She also reported she was living at an independent living facility and had fallen due to the poor condition of the property. Patient B's daily dose of fentanyl was increased to 3.994 mg per day at this visit from 3.506 mg per day.

169. On March 10, 2017, Patient B reported to SDCPMC for a pump refill. She reported her pain level as 5/10 but said that she was able to function well and perform her ADLs. The pump was refilled.

170. At this visit the pump was refilled with fentanyl and Marcaine. In addition, for reasons respondent did not explain, respondent added ketamine to the intrathecal medication formula. The formula for these medications was as follows: a concentration of fentanyl 25 mg/ml (16 ml), ketamine 20 mg/ml (2 ml), and Marcaine 5 mg/ml (2 ml) or 3.994 mg of fentanyl per day, 0.7989 mg of Marcaine per day, and 3.196 mg of ketamine per day.

171. But, according to the corresponding Medtronic Drug Calculation sheet this formulation was incorrect. According to the sheet for this date the "Absolute rate/day" was 2.804 mg of fentanyl 0.70 of bupivacaine per day and 0.28 mg of ketamine per day with fentanyl as the driver drug as 3.506 per day. Dr. Wallace, however, in his report calculated this figure as 3.195 mg of fentanyl per day 0.80 mg of bupivacaine per day and 0.32 mg of ketamine per day. Whatever the amount or discrepancy respondent did not dispute that the pump was programmed incorrectly.

172. After this date there are no further records documenting that Patient B treated with respondent. Per the CURES report for Patient B, on May 9, 2017, and June 27, 2017, respondent prescribed fentanyl and ketamine through a nurse practitioner working under respondent's supervision. There are no corresponding progress notes or other documents in Patient B's medical record documenting that her pump was refilled on those dates at SDCPMC.

173. According to respondent's interview with HQIU respondent sent a van to the facility where Patient B was residing to pick her up and have her brought to his

clinic to have the pump refilled. Respondent also said he sent an Uber transport for Patient B.

174. In a letter dated August 10, 2017, respondent signed a discharge letter informing Patient B that, effective August 10, 2017, he was discharging her from his care.

DR. WALLACE'S TESTIMONY REGARDING PATIENT B

175. In his testimony regarding Patient B, Dr. Wallace identified the same four medical issues he identified in respondent's care of Patient A: Did respondent comply with the standard of care in evaluating and selecting Patient B for IT therapy? Did he comply with the standard of care in the management of IT therapy for Patient B? Did he comply with the standard of care by using ketamine in the IT therapy? Did he comply with the standard of care in calculating and programming the drug doses to be delivered in the IT pump? The same standards of care applied.

176. Regarding respondent's programming error Dr. Wallace found that respondent departed from the standard of care, and he found this departure extreme. He found the same issue with programming errors he found with Patient A. Dr. Wallace reasoned that this departure was extreme because the discrepancies noted in the way respondent programed the pump concentrations would likely have resulted in drug overdose and patient harm in the event that the drug concentrations programmed into the pump were used.

177. With respect to the medical issue Dr. Wallace identified concerning respondent's evaluation and selection of Patient B as an appropriate patient for intrathecal drug therapy, Dr. Wallace found that respondent departed from the standard of care which required Patient B to have undergone a psychological

evaluation. Dr. Wallace stated that such an evaluation was especially important for Patient B given her mental health history and her history of drug use.

178. As Dr. Wallace expressed, in response to questions regarding the handwritten note purportedly from Dr. Saben, a psychological evaluation is not a clearance to proceed with the IT therapy. It should provide information regarding the patient's physical and mental aspects of pain to manage the patient's pain. The note from Dr. Saben, assuming it was from Dr. Saben, does not provide this information. Based on his review of the records Dr. Wallace determined that the departure was extreme.

179. In his analysis Dr. Wallace found the following of Patient B's history noteworthy: She had previously overdosed and had a history of opioid abuse; she had a traumatic brain injury with cognitive impairment; and she had severe mental health disturbances: schizophrenia, as respondent identified it, or schizoaffective disorder, and she was suffering from major depression. In addition, and just based on Patient B's behavior during the first trial, there were red flags respondent should have recognized. These red flags included somatic complaints of swelling and paralysis as well as reports of worsening of her schizoaffective symptoms since starting the pump trial. In Dr. Wallace's opinion, in light of these red flags, respondent should have stopped proceeding with intrathecal therapy and referred Patient B for psychiatric care.

180. Patients, Dr. Wallace testified, with such mental health conditions, can be very challenging because for IT therapy to succeed patients with these severe mental health conditions have to have such mental health conditions under good control. He commented that a pump for a person with schizophrenia can worsen the symptoms of schizophrenia.

181. Given her mental health conditions, Dr. Wallace stated he felt respondent needed the hand-to-hand participation of a therapist to even consider IT therapy for Patient B, and as a threshold matter respondent should have determined whether Patient B was even psychologically able to have a pump.

182. As part of his analysis and conclusion Dr. Wallace reviewed Patient B's records from Dr. Saben, which Dr. Saben submitted to HQIU. Dr. Wallace testified he found nothing in these records to indicate that Dr. Saben evaluated Patient B before the pump trial or the implant of the pump.

183. At the hearing Dr. Wallace was asked about the handwritten note purportedly from Dr. Saben from December 2015. As noted above, respondent did not include this note in the records he submitted as part of the HQIU investigation and the note is not found in Dr. Saben's records for Patient B. Dr. Wallace reviewed this note and dismissed it. He said the note is worthless because it does not contain information to evaluate Patient B's psychosocial state to assess whether it was appropriate for respondent to proceed with IT pump therapy for Patient B. He said respondent should have referred Patient A to the psychiatrist or a psychologist and obtained a full evaluation. Instead, as he put it "all we have is a scribbled note."

184. Dr. Wallace elaborated on his comment on redirect. He said to have a handwritten note is worthless because the purpose is to give information of the patient's psychosocial state. The decision whether to proceed with IT therapy requires collaborative care with a mental health provider. This is not a yes or no determination, and it not a clearance. It is an evaluation because pain medicine doctors have to deal with the physical and mental aspects of pain.

185. Concerning the third issue Dr. Wallace identified, respondent's management of IT therapy for Patient B to treat her chronic pain, Dr. Wallace found that respondent departed from the standard of care, and he found the departure to be extreme.

In his analysis of this issue Dr. Wallace stated, as he stated in his analysis of the same issue for Patient A, that respondent used fentanyl doses that exceeded the doses used for cardiac anesthesia, and in his view far exceeded the standard of care limits. He described the doses as excessive and extreme for IT therapy using fentanyl. The dosages respondent used were in his view beyond reasoning and breached the point of targeted intrathecal therapy. Such doses contravened the purpose of IT targeted therapy, which is designed to use a fraction of the dose that would be required for the systemic use to treat chronic pain.

186. Dr. Wallace stated that the starting daily rate of 1.997 was very high and not justified. Further the rate increases to 7 mg from November 2015 to March 2016 were also very high. Respondent increased the daily rate of fentanyl from 1.997 mg per day to 7 mg per day.

187. Regarding respondent's use of ketamine Dr. Wallace repeated that respondent's use of ketamine for IT therapy breached the standard of care and represented an extreme departure from the standard of care for the reasons he gave regarding his administration of the drug to Patient A.

DR. BERGER'S TESTIMONY REGARDING PATIENT B

188. Dr. Berger addressed each of the issues Dr. Wallace identified and found that respondent only departed from the standard of care on one issue: his error in

programming Patient B's pump. He found the departure to be a simple departure from the standard of care.

189. Concerning respondent's dosing of fentanyl to Patient B, Dr. Berger believes that he did not breach the standard of care because he exercised sound clinical judgment in dosing and closely monitored and followed Patient B. As a result, Patient B showed improvement in her pain levels, was able to do her ADLs, and even was able to transition to an independent living facility as documented in the lease agreement she signed.

190. Regarding the psychological assessment of Patient B, Dr. Berger said that respondent complied with the standard of care because, as he wrote in his report, Patient B was under the care of a psychiatrist and therapist and this is noted twice in the medical records. He said that a psychological evaluation was not needed before the pump trial.

191. Dr. Berger commented that active mental illness is not a contraindication for a pump. He emphasized that it is the job of the pain management doctor based on his interaction and answers he/she obtains to specific questions from a patient to decide whether the patient is an appropriate candidate for IT therapy.

192. While he seemed to recognize the importance of psychological evaluation for certain patients before IT therapy, Dr. Berger paradoxically seemed to minimize the necessity for a psychological evaluation for any patient. He noted that the pump, as he put it, takes away the need for the patient to take oral medications because the pump delivers the medications.

193. Regarding the use of ketamine in IT therapy for Patient B, he restated that respondent did not breach the standard of care for the same reasons he gave regarding Patient A.

194. On the issue of respondent's programming error for Patient B, Dr. Berger found there was a departure from the standard of care, but the departure was a simple departure. He said it wasn't an extreme departure because there wasn't an extreme difference in the concentrations due to the error that made a huge difference in the pump output.

Patient C

195. On February 17, 2018, Patient C, a then-72-year-old female, was referred to respondent for a pain management consultation. Patient C had a long history of pain, had been involved in an automobile accident on October 2, 2017, and had not received any treatment beyond oral pain medications.

196. At this visit she described her pain level as 7/10 on the pain scale. Patient C had been taking morphine sulfate (MS Contin) and Norco at the time of the initial visit. MS-Contin is an opioid used to treat the symptoms of acute pain and chronic severe pain. MS-Contin is a brand name for morphine sulfate controlled-release. Norco is an opioid used for the management of moderate to severe pain. Norco is a brand name for hydrocodone-acetaminophen. Both drugs are Schedule II opioid controlled substances pursuant to Health and Safety Code section 11055, and dangerous drugs pursuant to Business and Professions Code section 4022.

197. Patient C stated as recorded in her chart that these medications were effective in controlling her pain and improving her function. She reported anxiety and trouble sleeping but denied depression. She reported she has fibromyalgia.

Respondent performed a physical evaluation, ordered imaging studies, and issued prescriptions for 180 pills of 30 mg immediate release morphine, and 30 pills of 10 mg/325 mg Norco, in addition to a dose pack of Savella, which was prescribed per Patient C to treat her fibromyalgia. Patient C was scheduled to return for a follow up appointment. Respondent diagnosed her with uncomplicated opioid dependence long term, current use of opiate analgesic, and orthopedic conditions in her back, knees, and neck.

198. On March 20, 2018, Patient C returned to SDCPMC for her follow-up appointment. Patient C reported an increasing in low back pain and knee pain, she described her pain level as 7/10. She stated that her medication regimen was "completely ineffective," and that she wanted to discuss a treatment plan. Respondent identified among the medications she was taking: fluoxetine and the benzodiazepine clonazepam which she was taking three times a day.

199. Respondent discontinued MS Contin and Norco due to the patient reporting the medication was ineffective and issued a prescription for Morphine Sulfate Immediate Release (MS-IR). This drug is an opioid used to treat moderate to severe pain and a Schedule II opioid controlled substances pursuant to Health and Safety Code section 11055, and dangerous drug pursuant to Business and Professions Code section 4022.

200. After respondent left the exam room, as recorded under the Assessment and Plan heading of the progress note, Patient C stated that the new prescription will not be effective and that her only two options were "to overtake medications or to commit suicide because we give her not [*sic*] other options." Patient C was advised to follow prescription information and to call SDCPMC for an earlier appointment if the new medication remained "ineffective."

201. Under this same portion of the progress note respondent recommended to Patient C that she proceed with an intrathecal pump trial the following month with the procedure to be done on April 24, 2018. A pre-op packet was reviewed and signed by Patient C, and she was given a list of medications that would be used in the pump trial. It is not documented in the note whether respondent was told about Patient C's comments after he left the exam room. He did not document discussing with Patient C the need to obtain a psychological evaluation and clearance prior to considering her for an intrathecal pump. Respondent did not document in this note, or in a subsequent note, whether he discussed with Patient C her threat of suicide.

202. On April 6, 2018, Patient C returned to SDCPMC for an early refill of her medication. Patient C reported that she had "overused" her medication because the prescribed dose was "not sufficient." According to the progress note for the visit, Patient C was out of her medication 13 days early; this was the "second time" that she had run out early; despite counseling she continued to be non-compliant; and she "needed to try other treatment modalities beyond oral medication given her repeated non-compliance." Respondent then informed Patient C "that her option was to undergo an intrathecal pump trial on 04/09/18." Patient C agreed, and she was given a small prescription of MS-IR "to prevent withdrawal over the weekend."

203. On April 18, 2018, Patient C returned to SDCPMC for re-evaluation and medication refill. According to the progress note for the visit, Patient C reported that she did not want to go through with the pump trial because she felt that the "possible complications" outweighed the benefits. Patient C stated that she had been on morphine (oral) for "almost 2 decades" and that no other treatment plan worked for her pain. Under the "Assessment and Plan" portion of the progress note, it was documented that due to non-compliance "an intrathecal pump trial was

recommended." It was further documented that Patient C "refused to undergo an intrathecal pump trial for compliancy," and that "no oral pain medication" was prescribed to Patient C that day due to "non-compliance with treatment plan."

204. On April 24, 2018, Patient C sent a letter to the board complaining that respondent gave her no choice but to have the pump, and he stopped the morphine. Based on information she obtained from the internet she felt the pump and the drugs were unsafe noting that there have been reported deaths and paralysis from IT pump therapy. She added the therapy would not even treat her fibromyalgia. In a subsequent email to a board analyst, Patient C stated she did not want to punish respondent, and she felt respondent did not do anything wrong.

205. Included in Patient C's records is an undated handwritten note she wrote to respondent. In this note, in summary, Patient C expressed frustration and desperation regarding her pain condition and stressed that she needed morphine to function and begged respondent to not discontinue the medication.

DR. WALLACE'S TESTIMONY REGARDING RESPONDENT'S TREATMENT OF PATIENT C

206. Dr. Wallace testified that respondent breached the standard of care regarding obtaining a psychological evaluation for Patient C before considering her for IT pump therapy. Dr. Wallace said that respondent was pushing her into IT therapy, and he said this evaluation was needed because Patient C exhibited these "red flags": She was on high dose opioids with little pain control, and she was non-compliant with the prescribed opioid use. Dr. Wallace described the degree of departure as extreme.

DR. BERGER'S TESTIMONY REGARDING RESPONDENT'S TREATMENT OF PATIENT C

207. Dr. Berger disagreed that respondent departed from the standard of care because the standard of care does not require a psychological evaluation before a pump trial as has been noted above. Further he did not agree with Dr. Wallace that respondent pressured Patient C to have the pump. He said Patient C had time to consider whether the pump trial was appropriate for her.

Respondent's Testimony

208. Respondent's testimony is summarized as follows: Respondent is the largest implanter of pumps in San Diego as a standalone physician. Since 1994 he estimates he has implanted about 700 pumps. For over 25 years, he has been a pain management practitioner, focused on interventional pain medicine. He is a Diplomate of the American Board of Physical and Rehabilitation Medicine, the American Academy of Pain Medicine, and the American Board of Pain Medicine, and an Associate Member of the American Association of Neuromuscular and Electrodiagnostic Medicine. In addition to his licensure in California he has been licensed to practice medicine in Nevada since 2018.

209. Respondent obtained his M.D. from the Northwestern University School of Medicine in 1988. Respondent completed an internship in internal medicine at UCLA Wadsworth Veterans Administration, and then a three-year residency program in physical medicine and rehabilitation, which encompassed several subspecialties including pain medicine; prosthetics for amputees (both upper and lower extremities, above and below knee, and above and below elbow); traumatic brain injury; stroke

rehabilitation; pediatric aspects (cerebral palsy, birth defects and myelomeningocele defects); and sports medicine.

210. Respondent testified that Patients A, B, and C tried many pain therapy modalities before the IT therapy, and these less invasive treatments more or less failed. He said he doesn't rush a patient to have IT therapy, but the trial pump is a simple procedure and minimally invasive. Because it is minimally invasive, he can adjust dosages. At the same time, respondent said that the permanent pump is better than the external trial pump to fine tune drugs.

211. As a general matter, respondent said when you implant a pump you marry a patient, and this raises the patient's dependency on the provider. He described the relationship with the IT therapy patient as a collaboration. He talks to patients to see if rate increases are warranted. As long as there are no red flags, and the patient is improving, he will increase the drug infusion rates. It is not a first line therapy.

212. Respondent discussed in detail his treatment of Patient A. He methodically went through Patient A's records and described the adjustments he made in medication rates to address her pain condition.

Due to the IT therapy formulas, he said Patient A achieved excellent results without side effects. He said the rate increases were not unusual and done methodically until a steady state was reached. Respondent said he reduced the rate by 50 percent because he recognized the inaccurate programming.

213. In terms of her positive response to the IT therapy, respondent said she was a model patient: She achieved significant pain relief, was able to increase her mobility, have a social life, and perform her ADLs. He noted, as Patient A testified, she was even able to knit, an activity she was not able to do before the therapy. As an

indication the IT therapy was effective, respondent emphasized she discontinued the fentanyl patch on June 26, 2017.

214. Respondent said that Patient A was not able to discontinue her oral opioid pain medications due to her hip problems. He said the pain was breakthrough pain due to the loss of cartilage in her hip, and IT therapy does not manage such pain.

215. Regarding the circumstances of Patient A's overdose, respondent said Patient A's husband called him on his cell phone after she left the clinic, and respondent directed him to take Patient A to the emergency room. Respondent said Patient A overdosed because a drop of fentanyl during the refill entered Patient A's system subcutaneously. He said such occurrences are rare.

216. Respondent emphasized that Patient A did not lose consciousness. He said the drop of fentanyl caused Patient A to experience a "change" or "decrease" in consciousness. In his progress note where he documented that he discussed the incident with her, he referred to Patient A's overdose as "the overly narcotized incident." In contrast, Patient A testified she lost consciousness and hospital records confirm this.

217. Respondent said that as a result of the incident he now requires patients who have had pumps refilled to wait for 45 minutes to make sure there are no negative side effects.

218. After the incident, Patient A wanted to continue with the IT therapy and as mentioned earlier, she remains respondent's patient and has continued IT therapy.

219. Respondent agreed with Dr. Wallace that fentanyl in IT therapy can lead to adverse consequences as Patient A experienced. But he added that the benefits and

risks need to be weighed. He stressed that very few doctors devote themselves to IT therapy, and a doctor has to be vigilant in how to deliver the therapy. As he stated it you can't minimize the risk to zero.

230. Respondent did not agree with Dr. Wallace that, at one point, Patient A developed an opioid dependence from the IT therapy after the trial pump ended. She reported she had to go to the emergency room after the trial pump was explanted. Respondent said however she experienced withdrawals due to the fentanyl patch and the oral medications, and not from the IT therapy.

221. Regarding his care and treatment of Patient B, respondent said there was no evidence she was at the skilled nursing facility due to an acute psychiatric issue. She accidentally overdosed on methadone. He also did not see her history of opioid abuse as a contraindication to IT therapy. Respondent did not think, based on her presentation, she was unstable despite her history. He believed she was able to follow up. In her case, respondent said she accidently took too much methadone and lost consciousness because of her problem with pain control.

222. Respondent felt Patient B was an excellent candidate for an infusion pump because it allowed for the delivery of the pain medications without taking oral medications and avoided potential abuse. It is rare for a pain patient to be a good candidate for a pump, but Patient B bounced around the system a lot. In order to manage her pain so it can be controlled without her abusing pain medications the pump was an appropriate vehicle.

223. Respondent recognized that Patient B presented a challenge, and a psychiatric clearance was needed. He said he obtained this clearance from Dr. Saben. As confirmation of this evaluation, as discussed above, he referenced a document

captioned "Pain Medicine Follow up" dated December 13, 2015, which states that Patient B had gone through "psychiatric clearance."

224. Respondent said that Patient B's paranoia and anxiety as recorded in the progress notes did not change his opinion that she was an excellent candidate for IT therapy. It suggested to him that he needed to go slowly and make sure her psychiatrist was on board.

225. In his testimony respondent went through Patient B's records in detail. He described Patient B's condition as not linear. Her pain condition improved, then worsened, and he adjusted the drugs accordingly and monitored her closely. But he commented for over a year Patient B was able to be more active. Then her pain level increased to 9/10 which respondent attributed to her overactivity. This occurs he said in pain patients who suddenly can move more due to pain relief. Respondent also said she was experiencing neuropathic pain from a fall. Drugs delivered intrathecally have limited ability to relieve this type of pain.

226. Respondent discharged her after a year and after she refused to take a taxi service he sent for her. He acknowledged this was not a good outcome, but by the time he mailed the discharge letter to her, he had been treating her for close to two years.

227. Regarding Patient C, respondent denied that he pressured her to get the pump implant. He didn't recommend that she undergo a psychiatric or psychological evaluation because she decided against having the pump implant and such an evaluation was not needed. Respondent testified it was not brought to his attention

that she threatened suicide outside the exam room due to the change in her medications. He said he first learned about this at his HQIU interview.[7]

228. Respondent addressed his use of ketamine intrathecally for Patients A and B. He said he started to use ketamine because of the comorbidity from depression. He thought he could use it to address pain, and after speaking to other doctors he began using it at very low doses. He said CMS's website stated it can be used intrathecally.

Based on his research respondent testified he didn't see evidence of central nervous system toxicity intrathecally in humans. He found no evidence of spinal cord toxicity in 2015 to 2016.

229. Regarding fentanyl respondent hired graduate students to research fentanyl's metabolization, and he conducted his own research. The drug is lipophilic and binds quickly to receptors, which means that at low doses when used intrathecally it is safe.

230. Respondent recognized the programming errors regarding Patient A's and B's pumps. He stressed he took steps to ensure this does not happen again. He hired a mathematician from UCSD who helped develop an accurate Excel spreadsheet he now uses where the drugs formulas are correctly recorded.

231. Concerning the matter of psychological evaluations for Patients A and B, respondent said Patient A had both a psychiatrist and a psychologist, and he talked to her psychiatrist after the trial to make sure he/she was ok with the trial. He didn't see

[7] It is noted here that the record of Patient B's comment is in her records.

her mental health to be an issue and didn't see her mother's history to be a factor. Per Patient A's records, respondent did not record that Patient A had both a psychiatrist and psychologist or that he spoke to Patient A's psychiatrist. The only reference that she had a psychiatrist is a note dated August 10, 2018, which identifies Anne Cox, M.D. as Patient A's psychiatrist. Respondent said that Patient A underwent this testing prior to the implant should be reflected in Patient A's psychiatric records. He said his statement in the May 2, 2017, operative report that she was cleared to proceed with the "trial" was a poor choice of words.

232. Respondent recognized that he should have documented this in Patient A's chart. He said that, as a result of the 2020 medical record keeping course, he was required to take under his probation, he now documents charts better.

233. Regarding Patient B, as mentioned, respondent testified he did obtain a psychological evaluation of Patient B before the pump was implanted, but he did not record he obtained this psychiatric evaluation from Dr. Saben. In addition, Dr. Saben's records which were received as evidence do not confirm he ever conducted a psychiatric evaluation of respondent. The note respondent submitted as evidence purportedly from Dr. Saben is materially illegible. A note described as a "Follow Up Note" dated December 13, 2015, records that Patient B was given psychiatric clearance to proceed with the implant on December 17, 2015, but does not contain any details, including who performed this clearance.

234. Respondent has complied with the terms of his probation. Virginia Addis, a board inspector who is respondent's probation monitor, testified and confirmed this.

235. Respondent stated he has completed the clinical competence assessment course and can now perform surgical procedures related to intrathecal pumps. He also, as mentioned, completed the required medical record keeping course.

Character Evidence

236. Respondent called Sharron Thompson, M.D., and Marc Rouff, M.D. Their testimony is summarized as follows:

237. Dr. Thompson is board certified in physical and rehabilitation medicine. She has worked with respondent since 2008 and worked with him essentially full time between 2015 and 2018. She has filled pumps at respondent's clinic and has utilized fentanyl in IT therapy at his clinic. Dr. Thompson does not implant pumps.

Based on her experience working with respondent, and her experience working with other doctors at other practices, Dr. Thompson feels respondent is very well informed and an excellent clinician. He always does his best for patients and has never pressured patients to get pumps. She said that respondent always obtains psychological evaluations of patients before implanting pumps into them. Dr. Thompson added that respondent is very attentive to pump patients. They are high priority patients to him. He makes sure they are aware they will need to see him frequently. Dr. Thompson never saw respondent exercise poor clinical judgment.

238. Dr. Rouff worked at respondent's clinic until recently. He is board certified in physical and rehabilitation medicine. He was first licensed to practice medicine in 2020. Based on his interactions with respondent he believes that respondent is a compassionate and caring doctor who has the best interests of his pain management patients in mind.

Parties' Arguments

239. Complainant in closing argued that Dr. Wallace's opinions regarding respondent's conduct should be fully accepted against Dr. Berger's, and causes for discipline found. Dr. Wallace's opinions should be relied upon because he is a leading expert in the field of IT therapy and actively practices IT therapy. He heads a program at UCSD in IT therapy and has published extensively in the field. His research has been cited by authoritative sources. Dr. Berger's experience in the area of IT therapy does not compare to Dr. Wallace's; his experience with IT therapy is limited. In contrast to Dr. Wallace, Dr. Berger has never published on the topic of IT therapy. Complainant also questioned Dr. Berger's knowledge of the applicable definition of extreme departure because for conduct to constitute an extreme departure, harm to the patient is not a required factor. In addition, complainant questioned Dr. Berger's objectivity because he relied upon respondent to prepare his reports.

240. As a matter of discipline, complainant asks that respondent be prohibited from practicing intrathecal therapy during the remaining term of probation under Case Number 800-2015-013651.

241. Respondent stated that he is the largest provider of pain pumps in Southern California and has been utilizing the therapy for many years. As a result of his experience in IT therapy, he has developed sound clinical judgment. He accused Dr. Wallace of being in an "ivory tower." He said Dr. Wallace lives in a world of "consensus speed limits." Respondent said there is no consensus regarding dosing of fentanyl. The evidence is thus not clear regarding the standard of care, or that respondent departed from it. Respondent stressed that he closely monitored both patients and adjusted their doses based on their responses to the medications and their functioning. He

stated that ketamine is not prohibited as drug in IT therapy, and as proof of this CMS permits its use in IT therapy.

242. Regarding the psychological evaluation issue, respondent claimed he talked to Patient A's psychiatrist and simply failed to document he had. He was aware Patient A was under psychiatric care. Concerning Patient B there was no evidence she was schizophrenic. He disagreed that she was suffering from delusions when she said she was assaulted.

With respect to the incorrect programming, respondent stated his failure to program accurately was not an extreme departure from the standard of care but a simple departure.

243. In his closing argument respondent asserted the first time that Business and Professions Code section 2220.05, subdivision (a)(3), as a defense to the charge of excessive prescribing. This section provides that a physician will not be prosecuted for excessive prescribing for patients with "intractable pain." It is not clear from the record whether Patients A and B were suffering from "intractable pain," as opposed to chronic pain, and respondent made no argument regarding the applicability of this section to the facts of this case. Consistent with respondent's burden of proving such an argument, respondent's argument is not considered because he failed to present this evidence.

244. In summary respondent believes no purpose would be served in imposing discipline because respondent is on probation. He also said no purpose would be served by revoking his license.

245. Complainant replied that while there is no known upper limit for fentanyl dosing in IT therapy, Dr. Wallace did not rely only on the consensus guidelines to

support his opinion. Further, complainant disagreed with respondent that Patient B did not have serious mental health issues. Respondent recorded that Patient B suffered from schizophrenia; he thus thought Patient B had a serious mental health condition.

Complainant stated that respondent does not want to accept responsibility for his programming error. The departure was not a simple departure because the error could have resulted in incorrect dosing of the patients.

246. Complainant concluded by stating that this action is not a "do over" of the prior discipline. The only shared issue between the present matter and the prior discipline concerns the programming error. Complainant reiterated that probation with a practice restriction is the appropriate remedy for public protection.

Evaluation of Evidence

247. In determining the facts of this case, the credibility of both expert witnesses has been considered.

In resolving the conflicts in their testimony in this matter, consideration has been given to the qualifications and credibility of both experts, including any biases they have that could color their opinions and their review of the evidence, the reasons for their opinions, and the factual bases of their opinions. California courts have repeatedly underscored that an expert's opinion is only as good as the facts and reasons upon which that opinion is based. (*Kennemur v. State of California* (1982) 133 Cal.App.3d 907, 924.)

FIRST AND SECOND CAUSES FOR DISCIPLINE

248. The accusation asserts under the First and Second Causes for Discipline that respondent committed gross and simple negligence in his care and treatment of

Patients A, and B, and only gross negligence in his care and treatment of Patient C. To the extent cause is found that respondent committed acts of gross negligence in his care and treatment of Patients A and B, respondent is found to have also committed repeated negligent acts.

249. The accusation first alleges that respondent engaged in gross negligence when he failed to obtain psychological evaluations of Patients A and B before implanting intrathecal pumps, and when he failed to consider and/or obtain a psychological evaluation of Patient C before scheduling her for an IT pump.

250. Dr. Wallace's testimony that respondent departed from the standard of care and committed extreme departures when he failed to obtain psychological evaluations for Patients A, B, and C is found persuasive, and it is supported by the credible evidence of record.

Dr. Wallace explained clearly that the standard of care requires that this psychological evaluation be performed before the implantation of the pump, and this standard applies to trial pumps. The reason for this is that the pain management doctor must be assured that the patient has the psychosocial stability to follow up with care considering the serious nature of IT therapy, and also that the patient has realistic expectations of the goals of pain management.

251. Each of the three patients had mental health issues that required them to be evaluated to ensure they were appropriate candidates for IT therapy: Patient A suffered from depression and was treating for it; Patient B had a history of serious mental illness: she overdosed on methadone and was in a series of skilled nursing facilities. She also suffered from schizophrenia or schizoaffective disorder and depression and opioid abuse. Patient C had a history of anxiety and sleep problems,

but also overused her opioid pain medications when she saw respondent and was opioid dependent. At respondent's clinic, Patient C threatened to kill herself if respondent did not refill her pain medications.

252. Respondent did not obtain psychological evaluations for any of these patients. His testimony that he talked to Patient A's psychiatrist after the pump trial is simply not credible. There is no documentation in Patient A's records to confirm this conversation. In addition, no effort was made to substantiate this conversation from Patient A's psychiatrist. If this psychiatrist had cleared Patient A for IT therapy, it is reasonable to expect that he/she would have noted it.

253. Regarding Patient B the record does not support a conclusion that Dr. Saben evaluated Patient B. Dr. Wallace found that the "scribbled note," supposedly from Dr. Saben, was worthless because it does not contain information to identify Patient B's psychosocial state. It is illegible for the most part. This note is further viewed with suspicion because it is not among Dr. Saben's records that he submitted to HQIU and which he certified as the complete records for Patient B. The note is also not among the records respondent submitted to HQIU. It appears in records that respondent submitted as evidence in this hearing. No explanation was offered as to how respondent came into possession of this note after he certified he submitted Patient B's complete records to HQIU. The note further does not contain Dr. Saben's name. Additionally, no effort was made to substantiate that Dr. Saben wrote this note. If he wrote the note, it is reasonable to expect Dr. Saben could easily confirm it.

254. The December 13, 2015, "Follow Up" note is similarly problematic as a record that Patient B underwent a psychiatric evaluation. It is a record of a conversation respondent had with Patient B when he ran into her in the hallway at his clinic. He told Patient B she was psychiatrically cleared to proceed with the implant. It

does not identify Dr. Saben or contain other information regarding this clearance. Further, no other records document that Patient B needed to undergo this evaluation before the implant. It is similarly not among the records respondent sent to HQIU.

255. With respect to Patient C, respondent did not obtain an evaluation before scheduling her for the trial pump. Dr. Wallace's testimony here is found persuasive that this evaluation was needed whether before the trial pump or before the permanent pump was implanted. Due to the importance of the evaluation to assess the appropriateness of the therapy for a patient, Dr. Wallace's testimony here makes sense. Respondent, in his testimony that he didn't think an evaluation was needed because Patient C did not proceed with the trial, ignored the standard of care. This standard required him to have Patient C undergo this evaluation *before* proceeding with IT therapy. He scheduled Patient C for the trial pump without a psychological evaluation.

256. The accusation also alleges that respondent routinely used excessively high doses of intrathecal fentanyl in Patient A's and Patient B's pumps, and this conduct constituted gross negligence.

257. Dr. Wallace's testimony on this issue is found more persuasive than Dr. Berger's opinion that the doses were not excessive for these reasons: Dr. Wallace has had extensive experience as a practitioner of IT therapy over many years. At UCSD Dr. Wallace works on intrathecal pumps as the primary doctor at the clinic for intrathecal pumps and deals with IT pumps daily. Dr. Wallace oversees clinicians at UCSD in the use of IT therapy and teaches residents. Dr. Wallace also is also a leading researcher in the field and has a commanding knowledge of the research in the area of IT therapy. He is familiar with the current state of research in the use of IT therapy.

258. In contrast to Dr. Wallace's experience with IT therapy, nothing in Dr. Berger's CV indicates that he performs IT therapy or has published on this therapy. Moreover, his experience with IT therapy has been limited.

259. Dr. Wallace found that respondent used extreme and excessive doses of fentanyl for Patients A and B and his dosing of fentanyl departed from the standard of care and the departures were extreme. This standard requires the doctor to use small doses of the drug in IT therapy because the drug is targeted for delivery in the spinal cord and not for systemic use throughout the body. Fentanyl it is worth repeating is a hundred times more potent than morphine, and a small amount outside the pump can be dangerous to the patient. Patient A's overdose is evidence of this danger. As a matter of putting the dosing levels of fentanyl in perspective, Dr. Wallace testified he has never seen the amount of fentanyl administered to any patient in an intrathecal pump as the amount of fentanyl respondent administered to Patient A. Respondent's dosing levels of fentanyl to Patient B were similar. He likened the doses of fentanyl respondent used to that used in cardiac anesthesia.

260. In his analysis of respondent's dosing of fentanyl, Dr. Wallace found his clinical judgment lacking. Respondent did not explain why he started Patients A and B on the doses of fentanyl he started them on or why he increased the doses in the increments he did, even where the patient showed good improvement and functioning. At times, it appears respondent increased the doses when the patients asked for increases.

261. Dr. Berger agreed with Dr. Wallace concerning the importance of clinical judgment in setting dosing levels. He also recognized the importance of documenting the reasons why dosing decisions are made. He testified "as long as they [pain management doctors] document the appropriateness of that [dosing levels] in their

thought process, no one can judge them." Because respondent did not document his thought processes in his dosing of fentanyl for Patients A and B, his clinical judgment is questionable.

262. The accusation in addition alleges that respondent used ketamine for Patients A and B which is an unsafe and toxic drug in intrathecal therapy.

Dr. Wallace testified persuasively that respondent breached the standard of care requiring only safe drugs be used in IT therapy because ketamine has been found to be neurotoxic in dog and sheep studies. Dr. Wallace found the level of departures in prescribing ketamine to both patients extreme.

263. Dr. Wallace based his opinion on his extensive and up to date knowledge of studies and case reports in this area, including studies regarding the potential toxicity of ketamine Dr. Berger cited and respondent cited.

264. The accusation further alleges that respondent committed gross negligence when he failed to correctly program drug concentrations in Patient A's and B's pumps. Drs. Wallace and Berger agreed this conduct represented a departure from the standard of care, which requires accurate pump programming. Dr. Berger felt that the departures were not extreme because it did not result in patient harm. Dr. Wallace concluded that the departures were extreme.

265. Dr. Wallace's testimony on this issue is found more persuasive than Dr. Berger's. It is accepted that respondent breached the standard of care by incorrectly programing both patients' pumps. This incorrect programming placed these patients at risk of harm and injury because if they went to the hospital for treatment, a physician interrogating the pump would not have had accurate drug concentration levels. This could have resulted in either an overdose or underdose of narcotic

medications. Contrary to Dr. Berger's testimony regarding the degree of departure, actual patient harm is not a prerequisite for a departure from the standard of care to be an extreme departure.

THIRD CAUSE FOR DISCIPLINE

266. Under the Third Cause for Discipline respondent is alleged to have committed repeated acts of clearly excessive prescribing drugs or treatment to Patients A and B.

Dr. Wallace testified that respondent excessively prescribed fentanyl to Patients A and B during the course of their treatment with him during the time at issue in this matter. Dr. Berger disagreed that the dosing of fentanyl was excessive. As a leading expert and researcher in the area of intrathecal drug therapy, Dr. Wallace's opinion that respondent's dosing of fentanyl was extreme and excessive is found persuasive and fully credited. Respondent's failure to document his dosing rationale of fentanyl for Patients A and B supports this conclusion. Considering the potency of fentanyl and its use in IT therapy, respondent should have explained in Patient A and B's records why he made the dosing decisions he made.

FOURTH CAUSE FOR DISCIPLINE

267. Under the Fourth Cause for Discipline respondent is alleged to have failed to maintain adequate and accurate records for Patients A and B pursuant to Business and Professions Code section 2266. Respondent failed to maintain adequate and accurate records for both patients in these respects: He failed to document his rational for dosing decisions of fentanyl; he did not explain why he prescribed ketamine to both patients; he did not document why he added ketamine to Patient B's IT therapy; he did not document his reason for reducing by 50 percent Patient B's daily

dose rate of fentanyl on August 30 2017; and his documented programming of Patient A's and B's pumps were inaccurate. Respondent also inaccurately stated in Patient A's May 2, 2017, operative report that Patient A underwent psychological testing before the procedure when he said he spoke to the psychiatrist after the procedure.

FIFTH CAUSE FOR DISCIPLINE

268. The Fifth Cause for Discipline alleges that respondent engaged in unprofessional conduct because he breached the rules or code of the medical profession and engaged in conduct unbecoming to a member of the profession. Based on the finding in the First through Fourth Causes of discipline and for the reasons detailed later in this decision respondent engaged in unprofessional conduct in his care and treatment of Patients A, B, and C.

LEGAL CONCLUSIONS

Purpose of Discipline

1. The purpose of the Medical Practice Act (Chapter I, Division 2, of the Business and Professions Code) is to assure the high quality of medical practice; in other words, to keep unqualified and undesirable persons and those guilty of unprofessional conduct out of the medical profession. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 574.)

The purpose of administrative discipline is not to punish, but to protect the public by eliminating those practitioners who are dishonest, immoral, disreputable or incompetent. (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.)

Burden and Standard of Proof

2. Complainant bears the burden of proving the charges by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) This requires that he present evidence "of such convincing force that it demonstrates, in contrast to the opposing evidence, a high probability of the truth" of the charges (BAJI 2.62), and be "so clear as to leave no substantial doubt." (*In re Angelia P.* (1981) 28 Cal.3d 908, 919; *In re David C.* (1984) 152 Cal.App.3d 1189, 1208.)

Relevant Statutes

3. Section 2234 of the Code states in part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts. . . .

4. Section 2266 of the Code states:

The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

5. Section 725 of the Code states:

(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, optometrist, speech-language pathologist or audiologist.

(b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both that fine and imprisonment.

(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or

prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.

(d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5.

Case Law Regarding Gross Negligence

6. Medical providers must exercise that degree of skill, knowledge, and care ordinarily possessed and exercised by members of their profession under similar circumstances. (*Powell v. Kleinman* (2007) 151 Cal.App.4th 112, 122.) Because the standard of care is a matter peculiarly within the knowledge of experts, expert testimony is required to prove or disprove that a medical practitioner acted within the standard of care unless negligence is obvious to a layperson. (*Johnson v. Superior Court* (2006) 143 Cal.App.4th 297, 305.)

7. Courts have defined gross negligence as "the want of even scant care or an extreme departure from the ordinary standard of care." (*Kearl v. Board of Medical Quality Assurance* (1986) 189 Cal.App.3rd 1040, 1052.) Simple negligence is merely a departure from the standard of care.

Case Law Regarding Unprofessional Conduct

8. In *Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 575, the appellate court noted that "unprofessional conduct" as that term was used in Business and Professions Code section 2361 (now section 2234), included certain enumerated conduct. (Id. at p. 575.) The court further stated (*Ibid.*):

> This does not mean, however, that an overly broad connotation is to be given the term "unprofessional conduct;" it must relate to conduct which indicates an unfitness to practice medicine. [Citations.] Unprofessional conduct is that conduct which breaches the rules or ethical code of a profession, or conduct which is unbecoming a member in good standing of a profession. [Citation.]

Cause Exists to Discipline Respondent's Certificate

9. Pursuant to Business and Professions Code section 2234, subdivision (b), under the First Cause for Discipline, complainant proved by clear and convincing evidence that respondent committed gross negligence in his care and treatment of Patients A, B, and C, as found in this decision.

10 Pursuant to Business and Professions Code section 2234, subdivision (c), under the Second Cause for Discipline, complainant proved by clear and convincing evidence that respondent engaged in repeated negligent acts in his care and treatment of Patients A, and B, as found in this decision.

11. Pursuant to Business and Professions Code sections 725 and 2234, under the Third Cause for Discipline, complainant proved by clear and convincing evidence that respondent clearly excessively prescribed drugs or treatments to Patients A and B, as found in this decision.

12. Pursuant to Business and Professions Code section 2266, under the Fourth Cause for Discipline, complainant proved by clear and convincing evidence that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patients A, and B, as found in this decision.

13. Pursuant to Business and Professions Code section 2234, under the Fifth Cause for Discipline, complainant proved by clear and convincing evidence that respondent engaged in unprofessional conduct in his care and treatment of Patients A, B, and C, as found in this decision. His conduct constituted violations of the Medical Practice Act.

The Board's Disciplinary Guidelines and Evaluation Regarding the Degree of Discipline

14. With causes for discipline having been found, the determination now must be made regarding the degree of discipline and the terms and conditions to impose. In this regard, the board's Manual of Model Disciplinary Orders and Disciplinary Guidelines (12th Edition 2016) states:

> The Board expects that, absent mitigating or other appropriate circumstances such as early acceptance of responsibility, demonstrated willingness to undertake Board-ordered rehabilitation, the age of the case, and evidentiary problems, Administrative Law Judges hearing cases on behalf of the Board and proposed settlements submitted to the Board will follow the guidelines, including those imposing suspensions. Any proposed decision or settlement that departs from the disciplinary guidelines shall identify the departures and the facts supporting the departure.

15. For the causes of discipline that have been found the board's disciplinary guidelines provide that revocation is the maximum discipline and the minimum recommended terms and conditions are as follows:

- For gross negligence and repeated negligent acts under Business and Professions Code section 2234, subdivisions (b) and (d), or failure to maintain adequate records under Business and Professions Code section 2266, revocation, stayed, and five years' probation, with conditions including an education course, prescribing practices course, medical record keeping course, professionalism program (ethics course), clinical competence assessment program, monitoring, solo practice prohibition, and prohibited practices. The guidelines recognize that under appropriate circumstances, for repeated acts of negligence, a public reprimand may be ordered.

- For excessive prescribing and treatments under Business and Professions Code section 725 revocation, stayed, and five years' probation, a suspension of 60 days or more, with conditions including an education course, prescribing practices course, medical record keeping course, professionalism program (ethics course), clinical competence assessment program, monitoring, solo practice prohibition, and prohibited practices.

Disciplinary Considerations and Disposition Regarding the Degree of Discipline

16. As noted, the purpose of an administrative proceeding seeking the revocation or suspension of a professional license is not to punish the individual, the purpose is to protect the public from dishonest, immoral, disreputable or incompetent

practitioners. (*Fahmy, supra*, 38 Cal.App.4th at p. 817.) Rehabilitation is a state of mind and the law looks with favor upon rewarding with the opportunity to serve one who has achieved "reformation and regeneration." (*Pacheco v. State Bar* (1987) 43 Cal.3d 1041, 1058.)

17. The determination whether respondent's license should be revoked or suspended includes an evaluation of the nature and severity of the conduct and rehabilitation and mitigation factors as set forth under California Code of Regulations, title 16, section 1360.1, which provides as follows:

> When considering the suspension or revocation of a license, certificate or permit on the ground that a person holding a license, certificate or permit under the Medical Practice Act has been convicted of a crime, the division, in evaluating the rehabilitation of such person and his or her eligibility for a license, certificate or permit shall consider the following criteria:
>
> (a) The nature and severity of the act(s) or offense(s).
>
> (b) The total criminal record.
>
> (c) The time that has elapsed since commission of the act(s) or offense(s).
>
> (d) Whether the licensee, certificate or permit holder has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against such person.

(e) If applicable, evidence of expungement proceedings pursuant to Section 1203.4 of the Penal Code.

(f) Evidence, if any, of rehabilitation submitted by the licensee, certificate or permit holder.

18. After considering the board's guidelines, and the factors under California Code of Regulations, title 16, section 1360.1, the evidence of rehabilitation, and mitigation, and the evidence of record as a whole, it is determined that revocation is not necessary to ensure public protection and would amount to impermissible punishment. A period of probation to run concurrently with the probation imposed under Case No. 800-2015-013651 with the added restriction that respondent not practice intrathecal therapy would ensure public protection. This conclusion is reached for these reasons:

The nature of respondent's misconduct was serious and exposed Patients A and B to actual harm. Patient A in fact suffered harm when a small amount of fentanyl was released subcutaneously when her pump was refilled at respondent's clinic. Between 2015 to 2018 he excessively administered Patients A and B with fentanyl, a drug 100 times more potent than morphine. During his treatments of both patients he increased the dosing of this drug, even where both patients reported their pain levels and functioning improved. The increases of fentanyl can fairly be described as haphazard. In addition, respondent administered ketamine, a drug that is not deemed safe due to its potential neurotoxicity. Without documenting his reason for using this drug, respondent used it in treating both patients. In addition, despite evidence all three patients suffered from mental health issues that called into question their psychosocial stability, respondent did not obtain psychological evaluations of them. Psychological evaluations are a recognized and important part of the decision whether or to proceed

with IT therapy. By themselves respondent's programming errors regarding the drug concentrations in the pumps of both patients, and his inadequate and inaccurate record keeping, would warrant the imposition of serious discipline considering their scope and pervasiveness.

Against this serious misconduct there are a number of factors in his favor that have been considered: Respondent has complied fully with the terms of his probation, he completed a clinical competency course, and has been subject to monitoring. He credibly stated he has made changes to his practice to ensure that the programming errors don't reoccur and based on what he learned from the medical keeping course he took he is committed to improving his record keeping. In his treatment of all three patients, respondent was attentive and closely followed them. In general, he appears to be a compassionate and caring physician.

Considering these factors and the evidence of record as a whole, as a matter of public protection, it is not necessary to revoke his license. Public protection would be served if during the duration of his probation under Case No. 800-2015-013651 respondent is prohibited from performing intrathecal therapy or consulting with other providers regarding intrathecal therapy.

ORDER

Physician and Surgeon's Certificate No. G 66777 issued to David James Smith, M.D., is revoked. However, the revocation is stayed, and respondent is placed on probation for the duration of his probation in Case No. 800-2015-013651, with the following additional term:

Respondent is prohibited from performing any care or treatment with patients involving the use, management, or any surgical procedure related to intrathecal pumps, or advising any medical provider on the care or treatment of patients involving the use, management, or any surgical procedure related to intrathecal pumps, for the duration of his probation in Case No. 800-2015-013651.

DATE: November 9, 2021

Abraham M. Levy (Nov 9, 2021 08:30 PST)

ABRAHAM M. LEVY

Administrative Law Judge

Office of Administrative Hearings

XAVIER BECERRA
Attorney General of California
ALEXANDRA M. ALVAREZ
Supervising Deputy Attorney General
JOSEPH F. MCKENNA III
Deputy Attorney General
State Bar No. 231195
600 West Broadway, Suite 1800
San Diego, California 92101
P.O. Box 85266
San Diego, California 92186-5266
Telephone: (619) 738-9417
Facsimile: (619) 645-2061

Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DAVID JAMES SMITH, M.D.** **3703 Camino Del Rio South, #210** **San Diego, California 92108** **Physician's and Surgeon's Certificate No. G 66777,** Respondent.	Case No. 800-2018-042234 **ACCUSATION**

Complainant alleges:

PARTIES

1. William Prasifka (Complainant) brings this Accusation solely in his official capacity as the Executive Director of the Medical Board of California (Board), Department of Consumer Affairs.

2. On or about August 21, 1989, the Board issued Physician's and Surgeon's Certificate No. G 66777 to David James Smith, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2023, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

STATUTORY PROVISIONS

4. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, be publicly reprimanded which may include a requirement that the licensee complete relevant educational courses, or have such other action taken in relation to discipline as the Board deems proper.

5. Section 2234 of the Code states, in pertinent part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
>
> (1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.
>
> (2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.
>
> ...

6. Unprofessional conduct under section 2234 of the Code is conduct which breaches the rules or ethical code of the medical profession, or conduct which is unbecoming to a member in good standing of the medical profession, and which demonstrates an unfitness to practice medicine. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 575.).

7. Section 2228 of the Code states, in pertinent part:

The authority of the board or the California Board of Podiatric Medicine to discipline a licensee by placing him or her on probation includes, but is not limited to, the following:

(a) Requiring the licensee to obtain additional professional training and to pass an examination upon the completion of the training. The examination may be written or oral, or both, and may be a practical or clinical examination, or both, at the option of the board or the administrative law judge.

(b) Requiring the licensee to submit to a complete diagnostic examination by one or more physicians and surgeons appointed by the board. If an examination is ordered, the board shall receive and consider any other report of a complete diagnostic examination given by one or more physicians and surgeons of the licensee's choice.

(c) Restricting or limiting the extent, scope, or type of practice of the licensee, including requiring notice to applicable patients that the licensee is unable to perform the indicated treatment, where appropriate.

...

8. Section 2228.1 of the Code states, in pertinent part:

(a) On and after July 1, 2019, except as otherwise provided in subdivision (c), the board shall require a licensee to provide a separate disclosure that includes the licensee's probation status, the length of the probation, the probation end date, all practice restrictions placed on the licensee by the board, the board's telephone number, and an explanation of how the patient can find further information on the licensee's probation on the licensee's profile page on the board's online license information Internet Web site, to a patient or the patient's guardian or health care surrogate before the patient's first visit following the probationary order while the licensee is on probation pursuant to a probationary order made on and after July 1, 2019, in any of the following circumstances:

(1) A final adjudication by the board following an administrative hearing or admitted findings or prima facie showing in a stipulated settlement establishing any of the following:

...

(D) Inappropriate prescribing resulting in harm to patients and a probationary period of five years or more.

(2) An accusation or statement of issues alleged that the licensee committed any of the acts described in subparagraphs (A) to (D), inclusive, of paragraph (1), and a stipulated settlement based upon a nolo contendre or other similar compromise that does not include any prima facie showing or admission of guilt or fact but does include an express acknowledgment that the disclosure requirements of this section would serve to protect the public interest.

(b) A licensee required to provide a disclosure pursuant to subdivision (a) shall obtain from the patient, or the patient's guardian or health care surrogate, a separate, signed copy of that disclosure.

(c) A licensee shall not be required to provide a disclosure pursuant to subdivision (a) if any of the following applies:

(1) The patient is unconscious or otherwise unable to comprehend the disclosure and sign the copy of the disclosure pursuant to subdivision (b) and a guardian or health care surrogate is unavailable to comprehend the disclosure and sign the copy.

(2) The visit occurs in an emergency room or an urgent care facility or the visit is unscheduled, including consultations in inpatient facilities.

(3) The licensee who will be treating the patient during the visit is not known to the patient until immediately prior to the start of the visit.

(4) The licensee does not have a direct treatment relationship with the patient.

(d) On and after July 1, 2019, the board shall provide the following information, with respect to licensees on probation and licensees practicing under probationary licenses, in plain view on the licensee's profile page on the board's online license information Internet Web site.

(1) For probation imposed pursuant to a stipulated settlement, the causes alleged in the operative accusation along with a designation identifying those causes by which the licensee has expressly admitted guilt and a statement that acceptance of the settlement is not an admission of guilt.

(2) For probation imposed by an adjudicated decision of the board, the causes for probation stated in the final probationary order.

(3) For a licensee granted a probationary license, the causes by which the probationary license was imposed.

(4) The length of the probation and end date.

(5) All practice restrictions placed on the license by the board.

(e) Section 2314 shall not apply to this section.

GENERAL STATUTES

9. Section 725 of the Code states, in pertinent part:

(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, optometrist, speech-language pathologist, or audiologist.

...

(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.

(d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5.

PERTINENT DRUG INFORMATION

10. Antidepressants:

(a) Cymbalta is an antidepressant used to treat different medical conditions including depression and anxiety. Cymbalta requires a prescription from a medical doctor and is a dangerous drug pursuant to Business and Professions Code section 4022. Cymbalta is a brand name for duloxetine.

(b) Prozac is an antidepressant used to treat different medical conditions including depression and panic attacks. Prozac requires a prescription from a medical doctor and is a dangerous drug pursuant to Business and Professions Code section 4022. Prozac is a brand name for fluoxetine.

(c) Trazodone is an antidepressant used to treat major depressive disorder. Trazodone requires a prescription from a medical doctor and is a dangerous drug pursuant to Business and Professions Code section 4022.

11. Benzodiazepines are Schedule IV controlled substances pursuant to Health and Safety Code section 11057, and are a dangerous drug pursuant to Business and Professions Code section 4022. The risk of respiratory depression, drug overdose, and death is increased with the concomitant use of benzodiazepines and opioids. The Drug Enforcement Administration (DEA) has identified benzodiazepines as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 59.)

(a) Xanax is a benzodiazepine used for the short term treatment (4-6 weeks) of severe anxiety, panic attacks, or muscle spasms when other modalities have failed. Xanax is a brand name for alprazolam.

12. Opioids are Schedule II controlled substances pursuant to Health and Safety Code section 11055, and are a dangerous drug pursuant to Business and Professions Code section 4022. The DEA has identified opioids as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at pp. 38-39.)

(a) Fentanyl is a potent synthetic opioid drug used as an analgesic and anesthetic. Fentanyl is "approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic." (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 40.)

(b) Fentanyl patches are applied to the skin and used to relieve severe pain. The fentanyl patch is usually applied to the skin once every 72 hours. Duragesic is a brand name for fentanyl patches.

(c) Methadone is a synthetic opiate primarily used in the detoxification and maintenance of patients who are dependent on opiates, and the treatment of patients with chronic, severe pain.

(d) Morphine Sulfate Immediate Release (MS-IR) is an opioid used to treat moderate to severe pain. MS-IR is a brand name for morphine.

(e) MS-Contin is an opioid used to treat the symptoms of acute pain and chronic severe pain. MS-Contin is a brand name for morphine sulfate controlled-release.

(f) Norco is an opioid used for the management of moderate to severe pain. Norco is a brand name for hydrocodone-acetaminophen.

(g) Roxicodone is an opioid used for the management of moderate to severe pain. Roxicodone is a brand name for oxycodone HCL.

(h) Percocet is an opioid used for the management of moderate to severe pain. Percocet is a brand name for oxycodone-acetaminophen.

13. Ketamine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, and a dangerous drug pursuant to Business and Professions Code section 4022. Ketamine is a dissociative anesthetic used in veterinary medicine and human anesthesia.

14. Marcaine is an anesthetic medication generally given in a medical setting for local or regional anesthesia or analgesia for surgery. Marcaine is a prescription medication and is a dangerous drug pursuant to Business and Professions Code section 4022. Marcaine is a brand name for bupivacaine.

15. Narcan is a medication designed to rapidly reverse opioid overdose.

PERTINENT CASE INFORMATION

16. Respondent, at all times relevant to the charges and allegations brought in Accusation No. 800-2018-042234, owned San Diego Comprehensive Pain Management Center (SDCPMC), where he also employed and supervised a number of different physician assistants (PA), nurse practitioners (NP), and registered nurses (RN). Respondent electronically signed SDCPMC's progress notes relevant to the charges and allegations in this case, as the "supervising physician."

17. On August 21, 2019, Respondent, with his attorneys present, was interviewed by a Division of Investigation investigator and a district medical consultant working on behalf of the Board. During the interview, Respondent answered a number of general background questions, including questions asked about SDCPMC's pain management practices. Respondent also answered questions about specific patients seen by him and other providers whom he supervised, which are relevant to the charges and allegations brought in Accusation No. 800-2018-042234.

18. An intrathecal pump is a medical device used to deliver medication directly into the space between the spinal cord and the protective sheath surrounding the spinal cord for targeted drug delivery. An intrathecal pump has a reservoir that delivers medicine directly into the cerebrospinal fluid and requires a significantly smaller amount of medication compared to systemically (orally) taken medication due to bypassing the systemic path that oral medication must travel in the body. An intrathecal pump is programmable and it stores information about the medication in its memory. An intrathecal pump is programmed to slowly release medication over a period of time and can be programmed to release different amounts of medication at different times of the day. When the intrathecal pump's reservoir is empty, the medication is refilled by insertion of a needle through the skin and into the fill port on top of the pump's reservoir. Microgram (mcg) is the standard measurement of concentration of medication used in an intrathecal pump. One thousand (1,000) micrograms equal 1 milligram (mg).

19. For a comparison of opioid doses, morphine equivalent dose was developed to equate the many different opioids into one standard value. This standard value is based on morphine and its potency. A morphine equivalency is commonly referred to as MED, MME, or MEq.

20. The Controlled Substance Utilization Review and Evaluation System (CURES) is a program operated by the California Department of Justice (DOJ) to assist health care practitioners in their efforts to ensure appropriate prescribing of controlled substances, and law enforcement and regulatory agencies in their efforts to control diversion and abuse of controlled substances. (Health & Saf. Code, § 11165.) California law requires dispensing pharmacies to report to the DOJ the dispensing of Schedule II, III, and IV controlled substances as soon as reasonably possible after the prescriptions are filled. (Health & Saf. Code, § 11165, subd. (d).) It is important to note that the history of controlled substances dispensed to a specific patient based on the data contained in CURES is available to a health care practitioner who is treating that patient. (Health & Saf. Code, § 11165.1, subd. (a).)

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FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

21. Respondent has subjected his Physician's and Surgeon's Certificate No. G 66777 to disciplinary action under sections 2227 and 2234, as defined in section 2234, subdivision (b), of the Code, in that Respondent committed gross negligence in his care and treatment of Patients A, B, and C,[1] as more particularly alleged hereinafter:

22. **Patient A**

(a) On or about December 12, 2016, Patient A, a then-54-year-old female, presented for her first visit at SDCPMC. Patient A had been referred to Respondent for a consultation to discuss the implantation of an intrathecal pump.[2] The progress note for this initial visit recorded Patient A's history of chronic neck, back, and hip pain, and her history of failed drug treatments and other therapies. Patient A's then current pain was "7/10" on a pain scale of 0-10, according to the progress note.

(b) The progress note also documented a number of medical issues including, but not limited to, that Patient A had been diagnosed with depression and that she had a direct family history of "mental illness" and "nervous breakdown" involving her mother. Patient A was being prescribed a variety of antidepressant and antianxiety medications including, Cymbalta, Prozac, trazadone, and Xanax, at the time of her initial visit at SDCPMC, according to Patient A's medical record.

(c) The progress note further documented that CURES was reviewed at this initial visit and that Patient A was receiving Percocet and fentanyl patches from Dr. D.D.

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[1] To protect the privacy of the patients involved in this matter, patient names have not been included in this pleading. Respondent is aware of the identities of Patients A, B, and C.

[2] Dr. D.D., the physician who referred Patient A to Respondent, had been treating Patient A for her pain management since in or around 2015. Patient A's progress notes and other medical records from Dr. D.D.'s clinic were faxed to Respondent prior to Patient A's first visit at SDCPMC.

(d) On or about December 12, 2016, Patient A completed and signed a number of intake documents at SDCPMC including, informed consent forms and a patient authorization form permitting Respondent to obtain "psychotherapy notes" from Patient A's treating clinical psychologist.

(e) On or about April 25, 2017, Patient A returned to SDCPMC to ask Respondent questions before moving forward with implantation of an intrathecal pump. According to the progress note for the visit, Respondent and Patient A discussed the "risks and benefits" of an intrathecal pump trial. Significantly, however, Respondent did not discuss or document discussing with Patient A the types of medications that would be used in the intrathecal pump for the trial.

(f) On or about April 25, 2017, during the same office visit, Patient A continued to report depression and that she was taking a number of antidepressant and antianxiety drugs, according to the progress note. Significantly, however, Respondent did not discuss or document discussing with Patient A having a psychological evaluation performed before beginning the pump trial.

(g) On or about May 2, 2017, Respondent surgically implanted a percutaneous catheter in Patient A. An external pump used for the trial was filled with the following intrathecal medication: fentanyl 25 mg/ml (1 ml), ketamine 20 mg/ml (1 ml), and Marcaine 5 mg/ml (1 ml).

(h) The operative procedure note from May 2, 2017, documented that Patient A had undergone "psychological testing" and that she had been "cleared to proceed with the pump trial." The operative procedure note further documented that Patient A had "no contraindications of depression, substance abuse or other psychological preclusions" that would preclude her from the trial.

(i) Significantly, however, on the same date of the procedure, Patient A continued to report suffering from depression and that she was still taking a number of antidepressant and antianxiety drugs, according to the progress note signed by Respondent on or about May 2, 2017. Notably, the progress note does

not include any reference to, or information about, the alleged "psychological testing" referred to in the operative procedure note. Furthermore, Patient A's medical records from SDCPMC do not contain any evidence that she had ever undergone "psychological testing" for the purposes of being cleared to proceed with the intrathecal pump trial ordered by Respondent.

(j) On or about May 3, 2017, and on or about May 5, 2017, Patient A returned to SDCPMC to have the medication rate increased during the pump trial. On each date, Patient A also signed an "Informed Consent For Intraspinal Drug Therapy Via The Intrathecal Infusion Device." Significantly, however, the informed consent documentation that Patient A signed did not contain any reference or information about the use of intrathecal ketamine during the trial.

(k) On or about May 9, 2017, the pump trial ended and Respondent explanted the percutaneous catheter from Patient A. Later that same day, Patient A had to go to an emergency department due to experiencing "withdrawals" after the catheter and pump were removed.

(l) On or about May 19, 2017, Patient A returned to SDCPMC for a pre-op evaluation for implantation of a permanent intrathecal pump. The progress note for this visit documented Patient A's visit to the emergency department due to "withdrawals" and sickness after the seven day pump trial ended. However, Respondent did not discuss or document discussing with Patient A whether the "withdrawals" were related to the two medication rate increases given in a short span of time. Also, Respondent did not discuss or document discussing with Patient A any concern about her continuing depression and/or whether she was a suitable candidate for a permanent pump due to potential psychosocial barriers.

(m) On or about June 13, 2017, Respondent surgically implanted a Medtronic 20-ml Synchromed II infusion pump in Patient A under general anesthesia. The surgical procedure was performed at Pacific Surgical Institute.

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The pump was programmed by a Medtronic representative and then placed inside Patient A, according to the operative procedure note.

(n) Later that same day, Patient A reported to SDCPMC to have the new pump reprogrammed and filled with intrathecal medication, according to the progress note for the visit. The initial formula of intrathecal medication appears to have been fentanyl, ketamine, and Marcaine. However, there are discrepancies between medication amounts that were documented in the progress note, telemetry report, and the Medtronic drug calculation spreadsheet. Finally, the initial daily dose of fentanyl was 2.402 mg per day.

(o) On or about June 16, 2017, Patient A returned to SDCPMC for a follow up visit. Patient A reported discomfort at the incision site and described her pain as "8/10" on a pain scale of 0-10, according to the progress note for the visit. Respondent reprogrammed the pump and increased the daily dose of fentanyl to 3.752 mg per day.[3] At this visit, Patient A also completed an intrathecal pump questionnaire and signed an informed consent. However, this documentation did not contain any reference to Respondent's use of intrathecal ketamine in Patient A's pump.

(p) On or about June 21, 2017, Patient A returned to SDCPMC for a follow up visit. Patient A reported a reduction in pain and described her pain level as "5/10." However, despite reporting reduced pain, Patient A requested another increase of fentanyl. Per her request, Patient A's daily dose of fentanyl was again increased to 4.750 mg per day. Notably, Patient A signed an informed consent at this visit that included reference to the use of intrathecal ketamine for the first time in her medical records.

(q) On or about June 28, 2017, Patient A returned to SDCPMC for a follow up visit. Patient A reported that the last increase of fentanyl was effective and that

[3] The Medtronic drug calculation spreadsheet documenting this particular medication rate change is actually dated "6/17/2017," one day after the progress note.

she had begun walking further without noticing any increased pain, according to the progress note for the visit. Again, however, despite reporting reduced pain, Patient A requested another increase of fentanyl. Per her request, Patient A's daily dose of fentanyl was again increased to 7.757 mg per day at this visit. Significantly, after this visit, Patient A's daily dose of intrathecal fentanyl had more than tripled in only fifteen (15) days since implantation of the pump.

(r) On or about August 11, 2017, Patient A returned to SDCPMC on a walk-in basis and requested another increase in fentanyl. Notably, Patient A described her pain as "4/10" and reported "more than 50% relief ... [and she] feels like a new woman," according to the progress note for the visit. Notwithstanding the significant reduction in Patient A's reported pain, Respondent inexplicably increased the daily dose of intrathecal fentanyl to 13.748 mg per day at this visit.[4] Significantly, 13.748 mg of fentanyl, per day, amounted to an approximate four hundred and seventy percent (470%) increase of the initial starting dose of intrathecal fentanyl, which Patient A had begun receiving only two months earlier.

(s) On or about August 30, 2017, Patient A returned to SDCPMC for a pump refill. Patient A's daily dose of fentanyl was reduced by fifty percent (50%) at this visit, from 13.748 mg to 6.874 mg per day. Notably, to "prevent abrupt med withdrawal" was one of the reasons listed in the progress note for Patient A's pump refill and regular maintenance. Significantly, however, the medical judgment and rationale for the sudden and extreme reduction in fentanyl dosing was not documented in the progress note for this visit; nor did the note address Patient A's prior negative experience of "withdrawals" following the initial pump trial only a few months earlier, which involved much lower fentanyl dosing.

(t) On or about October 16, 2017, Patient A returned to SDCPMC for a pump refill. Patient A described her pain level as "5/10" and reported "about 50%

[4] The Medtronic drug calculation spreadsheet documenting this particular medication rate change is missing from Patient A's medical record.

relief," according to the progress note for the visit. Notwithstanding significant reduction in her reported pain, Patient A's fentanyl dosing was again increased to 11.853 mg per day.[5]

(u) In 2017, Patient A consistently reported that she was suffering from depression, according to the progress notes from SDCPMC. In addition, it was well documented in the progress notes that Respondent had diagnosed Patient A with opioid dependence. Despite these significant "red flags," no documentation was found in the medical records that Respondent ever obtained a psychological evaluation of Patient A in 2017.

(v) By the end of 2017, Patient A's daily dose of intrathecal fentanyl remained at an excessively high level; Patient A's intrathecal fentanyl dose had been increased approximately fourteen (14) times despite sustained improvement in reported pain levels; the use of intrathecal ketamine in the pump remained constant; and Respondent had begun prescribing systemic (oral) opioids to Patient A, in addition to intrathecal pain medicine.

(w) On or about January 24, 2018, and on or about March 2, 2018, Patient A returned to SDCPMC for pump refills. At both visits, the intrathecal medication formula and daily dosing rate remained unchanged, where Respondent continued to prescribe 11.853 mg of fentanyl per day. Patient A also continued to fill prescriptions for systemic (oral) opioids for concurrent use with the intrathecal medication.

(x) On or about March 30, 2018, Patient A returned to SDCPMC for a pump refill. The refill was done by a nurse practitioner "under Dr. David J Smith's supervision," according to the progress note for the visit.[6] The pump was refilled with fentanyl, ketamine, and Marcaine. The daily rate of intrathecal

[5] The Medtronic drug calculation spreadsheet documenting this particular medication rate change is missing from Patient A's medical record.

[6] The progress note was electronically signed by Respondent on the same day of the clinical visit/refill at SDCPMC.

fentanyl remained the same at 11.853 mg per day. Notably, the progress note does not document whether an observation of Patient A occurred after the pump refill and before she left SDCPMC that day.

(y) That same day, approximately thirty to forty-five (30-45) minutes after her pump was refilled at SDCPMC, Patient A suffered an acute drug overdose. After leaving SDCPMC, Patient A became acutely sedated and had to be revived with Narcan given by EMTs, who had responded to her husband's emergency 911 call. Patient A was then transported to UCSD Medical Center's Emergency Department due to an acute drug overdose. Patient A was later admitted overnight to UCSD Medical Center for observation.

(z) On or about May 4, 2018, Patient A returned to SDCPMC for a pump refill. The intrathecal medication formula and daily dose rates remained unchanged. However, unlike all of the prior progress notes from SDCPMC for Patient A, the May 4, 2018 progress note contained a specific reference to a forty-five (45) minute observation period of Patient A following the pump refill performed at that visit. Finally, the progress note indicated that Patient A was scheduled to return in the following month for a pump refill, on June 8, 2018.

(aa) On or about June 8, 2018, Patient A had her pump refilled, according to documents found in Patient A's medical record from SDCPMC. Specifically, a telemetry report, a Medtronic drug calculation spreadsheet, and a handwritten prescription appear to show that Patient A's pump was refilled on or about June 8, 2018. Significantly, however, Patient A's medical record from SDCPMC does not document that a physical examination of Patient A occurred prior to dispensing intrathecal medication to her.[7]

(bb) Between in or around January 2018, through in or around June 2018, Patient A's daily dose of intrathecal fentanyl remained at an excessively high level; the use of intrathecal ketamine in the pump remained constant; Patient A

[7] There is no progress note in Patient A's medical records from SDCPMC for this visit.

was maintained on systemic (oral) opioids in addition to intrathecal pain medicine; and Respondent never obtained a psychological evaluation of Patient A during this timeframe.

(cc) Between in or around June 2017, through in or around June 2018, the exact drug concentrations programmed into Patient A's pump were inaccurate. During this timeframe, the actual drug concentration contained in the pump was lower than the pump's programmed amount of drug concentration.

(dd) During Respondent's subject interview held on August 21, 2019, Respondent was asked questions about the intrathecal fentanyl dosing he had prescribed to Patient A, and whether he considered the dosing as low, medium, or high. Respondent stated that he had patients who ranged from 2.4 mg per day, up to 25 mg per day. He then explained that "[e]verybody is different ... I suppose it depends on their pharmacokinetics and their metabolism." Respondent was also asked questions about Patient A's overdose on March 30, 2018. Respondent speculated that "little drops" could have come out of the tip of the needle when it was pulled out, which then got into the patient's subcutaneous tissue. He then added, "[i]t's rare, but it can happen." Respondent stated that it was "customary" at SDCPMC to observe patients for twenty (20) minutes after their pump was filled. Respondent was asked whether observations are documented, to which he replied, "[w]e don't necessarily document that."

23. Respondent committed gross negligence in his care and treatment of Patient A including, but not limited to, the following:

(a) Respondent failed to obtain a psychological evaluation prior to implantation of an intrathecal pump in Patient A;

(b) Between in or around May 2017 through in or around June 2018, Respondent routinely used excessively high doses of intrathecal fentanyl in Patient A's pump;

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(c) Between in or around May 2017 through in or around June 2018, Respondent routinely used ketamine in Patient A's pump, which is unsafe and toxic as an intrathecal medication; and

(d) Between in or around June 2017 through in or around June 2018, Respondent routinely failed to accurately program drug concentrations in Patient A's intrathecal pump.

24. **Patient B**

(a) On or about May 13, 2015, Patient B, a then-60-year-old female was first seen by Respondent at a skilled nursing home. Patient B had been under the care of a psychiatrist for many years, and she had recently been transferred to the nursing home following a recent hospital admission due to an overdose of methadone. Respondent documented Patient B's medical complaints included chronic pain in her spine, legs, knees, and hands; and that her past pain medications included fentanyl patches and Roxicodone. Patient B took methadone for pain but told Respondent that it was ineffective.

(b) Respondent also documented a past medical history and family/social history taken during this first visit with Patient B, which included a history of opioid abuse; anxiety; depression; schizophrenia; and spinal cord injury with traumatic brain injury secondary to domestic abuse. Respondent found that Patient B had "most likely" engaged in opioid abuse, and that an overdose had occurred because of her response to Narcan given by paramedics. Respondent then concluded that "[Patient B] is an excellent candidate for an infusion pump," and that when she was discharged from the nursing home he would "attempt to get her in for an intrathecal pump trial which should prevent any future abuses or accidental or intentional overdoses." Significantly, notwithstanding multiple "red flags" involving opioid misuse and abuse, Respondent did not discuss or document discussing with Patient B the need to undergo a psychological evaluation before considering her for an intrathecal pump trial.

(c) On or about May 26, 2015, and on or about August 6, 2015, Patient B reported to SDCPMC for follow up visits and pain medication refills of fentanyl patches and Roxicodone. Patient B admitted to a history of prescription opioid abuse, according to the progress notes. The progress notes also documented that Patient B was suffering from depression, anxiety, mood swings, and nervousness, and that she was "not acting in appropriate manner. She is in mild distress ... Her recent memory is not intact. Her mood and affect exhibits paranoia and shows anxiety." Again, Respondent did not discuss or document discussing with Patient B the need to undergo a psychological evaluation before considering her for an intrathecal pump trial.

(d) On or about August 18, 2015, Respondent surgically implanted a percutaneous catheter in Patient B and a pump trial was begun. An external pump used for the trial was filled with the following intrathecal medication: fentanyl 25 mg/ml (1 ml), and Marcaine 5 mg/ml (1 ml).

(e) The operative procedure note from August 18, 2015, noted that the pump trial was being used "to determine the appropriateness of a Medtronic Synchromed II infusion pump as [Patient B] has failed all conservative methods." However, the note did not document any information about any other "failed" conservative therapies, or what further evaluation for cause of Patient B's pain was performed by Respondent. The note also did not document any information about whether Patient B had undergone a psychological evaluation prior to the start of pump trial. In fact, Patient B's medical records from SDCPMC do not contain any evidence that she had ever undergone "psychological testing" for the purposes of being cleared to proceed with the intrathecal pump trial performed by Respondent.

(f) On or about August 20, 2015, a progress note indicated that nursing staff located at Patient B's facility had contacted SDCPMC about the worsening of Patient B's schizoaffective behaviors since the pump trial had begun two days earlier.

(g) On or about August 21, 2015, a short progress note indicated that Patient B had reported to SDCPMC for "pump trial EXPLANT." Notably, Patient B's pump trial ended abruptly and with no scheduled follow up, nor any documentation of a plan for her ongoing pain management care and treatment.

(h) On or about November 3, 2015, Respondent surgically implanted a percutaneous catheter in Patient B and a second pump trial was begun. An external pump used for the trial was filled with the following intrathecal medication: fentanyl 25 mg/ml (1 ml), and Marcaine 5 mg/ml (1 ml).

(i) Significantly, however, Patient B's progress notes and medical records from SDCPMC do not contain any evidence that she had undergone "psychological testing" for the purposes of being cleared to proceed with a second pump trial; nor is there any information about what had happened to her since August 21, 2015, after termination of the first pump trial.

(j) On or about November 6, 2015, Patient B returned to SDCPMC for a follow up, and to have the medication rate increased. Respondent increased the pump trial rate from 0.2 mg to 0.3 mg per day, according to the progress note for the visit.

(k) On or about November 10, 2015, the pump trial ended and Respondent explanted the percutaneous catheter from Patient B. Patient B stated that she wanted to proceed with the implantation of a permanent intrathecal pump, according to the progress note for the visit.

(l) On or about December 17, 2015, Respondent surgically implanted a Medtronic 20-ml Synchromed II infusion pump in Patient B under general anesthesia. The surgical procedure was performed at Pacific Surgical Institute. The pump was programmed by a Medtronic representative and then placed inside Patient B, according to the operative procedure note.

(m) Later that same day, Patient B reported to SDCPMC to have the new pump reprogrammed and filled with intrathecal medication, according to the

progress note for the visit. The initial formula of intrathecal medication appears to have been fentanyl 25 mg/ml (18 ml), and Marcaine 5 mg/ml (2 ml). The initial daily dose of fentanyl was 1.997 mg per day. Finally, the Medtronic drug calculation spreadsheet is missing from Patient B's medical record.

(n) On or about December 31, 2015, Patient B returned to SDCPMC for a follow up visit. Patient B requested an increase of fentanyl. Per her request, Patient B's daily dose of fentanyl was increased to 4.242 mg per day at this visit. Significantly, after this visit, Patient B's daily dose of fentanyl had more than doubled in only fourteen (14) days since implantation of the pump.

(o) In 2015, Patient B consistently reported that she was suffering from depression, anxiety, mood swings, and nervousness, according to the progress notes from SDCPMC. It was well documented in the progress notes that Patient B had memory problems; that she exhibited paranoia and had been diagnosed with schizophrenia; and that she had a history of prescription opioid abuse. Despite these significant "red flags," no documentation was found in the medical records that Respondent ever obtained a psychological evaluation of Patient B in 2015.

(p) By the end of 2015, Respondent maintained Patient B on excessively high daily doses of intrathecal fentanyl via the pump, despite continuing to prescribe her fentanyl patches and Roxicodone for pain management.

(q) On or about January 15, 2016, Patient B requested an increase of intrathecal fentanyl in her pump. Patient B reported some knee pain due to a recent fall, but she only rated her pain at approximately "2" (out of 10 on pain scale), according to the progress note for the visit. Per Patient B's request, Respondent increased her daily dose of fentanyl to 5.498 mg per day.

(r) On or about March 11, 2016, Patient B requested another increase of intrathecal fentanyl in her pump. Patient B reported pain in groin area, but she only rated her pain at approximately "1-2" (out of 10 on pain scale), according to the progress note for the visit. Per Patient B's request, Respondent increased her daily

dose of fentanyl to "7.0" mg per day, but there was no record of a telemetry report or Medtronic drug calculation spreadsheet found in the medical record for this date.

(s) On or about July 1, 2016, Patient B reported to SDCPMC for a pump refill. Patient B only rated her pain at approximately "1-3" (out of 10 on pain scale), according to the progress note for the visit. Despite significant reduction in Patient B's pain levels, and without further explanation in the progress note, her daily dose of fentanyl was increased to 7.503 mg per day.

(t) On or about October 26, 2016, Patient B reported to SDCPMC for a pump refill. The intrathecal medication formula, drug concentration, and daily rate remained unchanged, according to the progress note for the visit. However, the drug concentration values contained in the corresponding telemetry report differed from the actual concentration values reported in the corresponding Medtronic drug calculation spreadsheet.

(u) In 2016, Patient B consistently reported that she was suffering from depression, anxiety, mood swings, and nervousness, according to the progress notes from SDCPMC. It was well documented in the progress notes that Patient B had memory problems; that she exhibited paranoia and had been diagnosed with schizophrenia; and that she had a history of prescription opioid abuse and opioid dependence. Despite these significant "red flags," no documentation was found in the medical records that Respondent ever obtained a psychological evaluation of Patient B in 2016.

(v) By the end of 2016, Respondent maintained Patient B on excessively high daily doses of intrathecal fentanyl; Patient B's intrathecal fentanyl dose was increased multiple times despite sustained improvement in reported pain levels; and Respondent continued prescribing fentanyl patches and Roxicodone in addition to Patient B's intrathecal pain medication.

(w) On or about January 4, 2017, Patient B reported to SDCPMC with an empty pump. Patient B claimed to have more pain due to multiple assaults that

she allegedly sustained during a recent hospitalization. However, a physical examination did not reveal that she had sustained any physical injuries. Patient B signed an informed consent for opioid maintenance at this visit. Finally, Patient B's daily dose of fentanyl was reduced from 7.503 mg to 3.506 mg per day.

(x) On or about February 23, 2017, Patient B returned to SDCPMC reporting pain to multiple body parts, and she requested an increase in fentanyl. Patient B claimed to have suffered multiple injuries as a result of "physical altercations" she had in the past with roommates at different care facilities. Patient B's daily dose of fentanyl was increased to 3.994 mg per day at this visit.[8]

(y) On or about March 10, 2017, Patient B reported to SDCPMC for a pump refill. Significantly, Respondent added ketamine to the intrathecal medication formula filled into Patient B's pump at this visit. Also, the corresponding Medtronic drug calculation spreadsheet represented the following drug concentrations: fentanyl 25 mg/ml (16 ml), ketamine 20 mg/ml (2 ml), and Marcaine 5 mg/ml (2 ml). However, the drug concentration values contained in the corresponding telemetry report differed from the actual concentration values reported in the Medtronic drug calculation spreadsheet. Finally, Patient B's daily dose of fentanyl remained unchanged at 3.994 mg per day.

(z) Per the CURES report for Patient B, on or about May 9, 2017, and on or about June 27, 2017, fentanyl and ketamine were prescribed by Respondent and a nurse practitioner working under Respondent's supervision. Significantly, however, there are no corresponding progress notes or other documents in Patient B's medical record documenting that her pump was refilled on those dates at SDCPMC.

(aa) On or about August 10, 2017, SDCPMC mailed a letter of discharge to Patient B. Respondent signed the discharge letter informing Patient B that, effective August 10, 2017, "Please secure the care of another physician. To assist you in

[8] The Medtronic drug calculation spreadsheet documenting this particular medication rate change is missing from Patient B's medical record.

continuing to receive medical care, we will make your medical records available to your new physician that you so designate in writing." Notably, the discharge letter did not provide any information or guidance to Patient B about what to do in the event her pump ran out of intrathecal medication after receiving the letter.

(bb) Between in or around January 2017, through in or around June 2017, Patient B's daily dose of intrathecal fentanyl remained at an excessively high level, and Respondent never obtained a psychological evaluation of Patient B despite numerous "red flags" involving opioid dependence, and psychiatric and behavioral issues.

(cc) Between in or around March 2017, through in or around June 2017, Respondent ordered the use of intrathecal ketamine in Patient B's pump.

(dd) Between in or around December 2015, through in or around March 2017, the exact drug concentrations programmed into Patient B's intrathecal pump were inaccurate. During this timeframe, the actual drug concentration contained in the intrathecal pump was lower than the pump's programmed amount of drug concentration.

(ee) During Respondent's subject interview held on August 21, 2019, Respondent was asked whether a psychological evaluation had been performed prior to implantation of Patient B's pump. Respondent replied that Patient B had a "psych evaluation" at the nursing home, and that he had spoken to the psychiatrist who "cleared her for the pump."[9] Respondent was also asked if he had tried alternative treatments for Patient B prior to installing the pump. Respondent replied, "[n]o, I don't believe we did." Finally, Respondent admitted that he was not aware that Patient B had filled prescriptions for controlled substances from eight (8) different providers in 2016.

[9] No documentation exists in Patient B's medical record of the alleged conversation between Respondent and a psychiatrist involving clearing her for an intrathecal pump. In fact, there is no documentation in the medical record that she was ever "cleared" by a psychological evaluation, at any point in time between 2015 and 2017.

25. Respondent committed gross negligence in his care and treatment of Patient B including, but not limited to, the following:

(a) Respondent failed to obtain a psychological evaluation prior to implantation of an intrathecal pump in Patient B;

(b) Between in or around December 2015, through in or around March 2017, Respondent routinely used excessively high doses of intrathecal fentanyl in Patient B's pump;

(c) Between in or around March 2017, through in or around June 2017, Respondent used ketamine in Patient B's pump, which is unsafe and toxic as an intrathecal medication; and

(d) Between in or around December 2015, through in or around March 2017, Respondent routinely failed to accurately program drug concentrations in Patient B's intrathecal pump.

26. **Patient C**

(a) On or about February 17, 2018, Patient C, a then-72-year-old female was first seen by Respondent at SDCPMC. Patient C had a long history of pain, had been involved in an automobile accident in October 2017, and had not received any treatment beyond oral medication management, according to the progress note for the visit. She described her pain level as "7/10" on a pain scale of 0-10. Patient C had been taking MS Contin and Norco at the time of the initial visit. According to the progress note, Patient C stated that these medications had been "effective" in controlling her pain and improving her function. Respondent performed a physical evaluation, ordered imaging studies, issued prescriptions for MS Contin and Norco, and had the patient scheduled to return for a follow up appointment. Notably, Respondent diagnosed Patient C with opioid dependence at this visit.

(b) On or about March 20, 2018, Patient C returned to SDCPMC for her follow up appointment. Patient C reported an increase in low back pain and knee

pain, and she described her pain level as "7/10." According to the progress note for the visit, Patient C now stated that her medication regimen was "completely ineffective," and that she wanted to discuss a treatment plan that day. Respondent discontinued MS Contin and Norco due to the patient reporting the medication was ineffective, and issued a prescription for MS-IR. According to the progress note, after Respondent left the exam room, Patient C stated that the new prescription would not be effective and that her only two options were "to over take medications or to commit suicide because we give her not (sic) other options." According to the progress note, Patient C was advised to follow prescription information and to call SDCPMC for an earlier appointment if the new medication was "ineffective."

(c) At this same visit on or about March 20, 2018, Respondent recommended to Patient C that she proceed with an intrathecal pump trial the following month. According to the progress note, a pre-op packet was reviewed and signed by Patient C, she was given a list of medications that would be used in the pump trial, and the trial was scheduled for "04/24/18." Significantly, Respondent did not document discussing with Patient C the need to obtain a psychological evaluation and clearance prior to considering her for an intrathecal pump. Furthermore, Respondent did not even document whether he had any discussion with Patient C about her threats of suicide made during the visit that day.

(d) On or about April 6, 2018, Patient C returned to SDCPMC for an early refill of her medication. Patient C reported that she had "over used" her medication because the prescribed dose was "not sufficient." According to the progress note for the visit, Patient C was out of her medication thirteen days early; this was the "second time" that she had run out early; despite counseling she continued to be non-compliant; and she "needed to try other treatment modalities beyond oral medication given her repeated non-compliance." Respondent then informed Patient C "that her option was to undergo a intrathecal pump trial on 04/09/18." According to the progress note, Patient C agreed and she was given a

small prescription of MS-IR "to prevent withdrawal over the weekend." Significantly, notwithstanding multiple "red flags" of misuse and abuse of opioids, Respondent still did not consider obtaining a psychological evaluation and clearance prior to beginning (on short notice) a pump trial for a non-compliant geriatric patient.

(e) On or about April 18, 2018, Patient C returned to SDCPMC for re-evaluation and medication refill. According to the progress note for the visit, Patient C reported that she did not want to go through with the pump trial because she felt that the "possible complications" outweighed the benefits. Patient C stated that she had been on morphine (oral) for "almost 2 decades" and that no other treatment plan worked for her pain. Under "Assessment and Plan" in the progress note, it was documented that due to non-compliance "an intrathecal pump trial was recommended." It was further documented that Patient C "refused to undergo an intrathecal pump trial for compliancy," and that "no oral pain medication" was prescribed to Patient C that day due to "non-compliance with treatment plan."[10]

(f) Patient C never returned to SDCPMC after her final visit. Notably, there is no letter of discharge or referrals contained in her medical record from SDCPMC.

(g) During Respondent's subject interview held on August 21, 2019, Respondent was asked questions about Patient C's statement about committing suicide. He stated that he talked to Patient C about it and "determined that she was not suicidal, but she was just being manipulative in my opinion to try to ... lobby for more opioids. And so that raised a red flag to me." When asked about why this discussion regarding suicide was not documented in the progress note, Respondent replied, "I don't note every verbal exchange I have with my patients." When asked questions about whether he gave any consideration to referring Patient C to an addictionologist due to her more than ten-year history of opioid

[10] The progress note was electronically signed by Respondent on the same day of the clinical visit at SDCPMC.

use, Respondent replied, "no, I did not consider that." When asked questions about whether he gave any consideration to sending Patient C to psychiatry for further assessment for her chronic pain, Respondent replied, "I don't recall." When asked a follow up question if he would document that in the notes, Respondent replied, "I don't know." Respondent stated that he felt Patient C "needed to have a pump based upon her high opioid use." Respondent also stated that because Patient C was non-compliant with her oral medication use and broke her contract, that the treatment plan was to participate in a pump trial. Finally, Respondent stated that he discharged Patient C because she didn't want to participate in the pump trial.

27. Respondent committed gross negligence in his care and treatment of Patient C including, but not limited to, the following:

(a) Respondent failed to consider and/or obtain a psychological evaluation prior to scheduling implantation of an intrathecal pump in Patient C.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

28. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 66777 to disciplinary action under sections 2227 and 2234, as defined in section 2234, subdivision (c), of the Code, in that Respondent committed repeated negligent acts in his care and treatment of Patients A and B, as more particularly alleged in Paragraphs 22, 23, 24, and 25, above, and are hereby incorporated by reference and realleged as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Repeated Acts of Clearly Excessive Prescribing)

29. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 66777 to disciplinary action under sections 2227 and 2234, as defined in section 725, of the Code, in that Respondent has committed repeated acts of clearly excessive prescribing drugs or treatment to Patients A and B, as determined by the standard of the community of physicians and surgeons, as more particularly alleged hereinafter:

30. **Patient A**

(a) Paragraphs 22 and 23, above, are hereby incorporated by reference and realleged as if fully set forth herein.

31. **Patient B**

(a) Paragraphs 24 and 25, above, are hereby incorporated by reference and realleged as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Medical Records)

32. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 66777 to disciplinary action under sections 2227 and 2234, as defined in section 2266, of the Code, in that Respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patients A and B, as more particularly alleged hereinafter:

33. **Patient A**

(a) Paragraphs 22 and 23, above, are hereby incorporated by reference and realleged as if fully set forth herein.

34. **Patient B**

(a) Paragraphs 24 and 25, above, are hereby incorporated by reference and realleged as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

35. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 66777 to disciplinary action under sections 2227 and 2234 of the Code, in that Respondent has engaged in conduct which breaches the rules or ethical code of the medical profession, or conduct which is unbecoming to a member in good standing of the medical profession, and which demonstrates an unfitness to practice medicine, as more particularly alleged in paragraphs 22 through 34, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

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DISCIPLINARY CONSIDERATIONS

36. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about August 25, 2020, in a prior disciplinary action titled *In the Matter of the First Amended Accusation Against David James Smith, M.D.*, before the Medical Board of California, in Case Number 800-2015-013651, Respondent's license was disciplined and placed on probation for seven (7) years for committing gross negligence, repeated negligent acts, incompetence, excessive prescribing, failed to maintain adequate and accurate records, and unprofessional conduct in his care and treatment of five (5) patients. The Board's Decision and Order is now final and is incorporated by reference as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate No. G 66777, issued to Respondent David James Smith, M.D.;

2. Revoking, suspending or denying approval of Respondent David James Smith, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent David James Smith, M.D., to comply with the requirements of probation disclosure contained in Business & Professions Code section 2228.1, if a finding of inappropriate prescribing resulted in patient harm was made, and a probationary period of five or more years was imposed;

4. Ordering Respondent David James Smith, M.D., to pay the Medical Board the costs of probation monitoring, if placed on probation; and

5. Taking such other and further action as deemed necessary and proper.

DATED: DEC 22 2020

RETI VARGHESE
DEPUTY DIRECTOR

for: WILLIAM PRASIFKA
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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