OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **DAVID JAMES SMITH, M.D., Respondent.**	**Case No. 22-47823-1**

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, J.D., General Counsel and attorney for the IC, having a reasonable basis to believe that David James Smith, M.D., (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor applying for or holding an active license to practice medicine in the State of Nevada (License No. 17853). Respondent was originally licensed by the Board on April 16, 2018.

COUNT I

NRS 630.304(1) – Obtaining A License By Fraud And Misrepresentation

2. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

3. NRS 630.304(1) provides that obtaining, maintaining, or renewing or attempting to obtain, maintain or renew a license to practice medicine by bribery, fraud, or misrepresentation or

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Bret W. Frey, M.D. (Chair), Chowdhury H. Ahsan, M.D., Ph.D., FACC, and Col. Eric D. Wade, USAF (Ret.) (Public Member).

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by any false, misleading, inaccurate, or incomplete statement is grounds for initiating disciplinary action against a licensee.

4. Respondent submitted his application for initial licensure to practice medicine in the State of Nevada to the Board on or about September 18, 2017 (Initial Application). In his Initial Application, Respondent swore an Affirmation, which was executed by Respondent on or about August 17, 2017, and which reads in its entirety:

> I, David James Smith, MD, being duly sworn, depose and say: That the answers to the foregoing questions and statements made in the above application, as well as any and all further explanations contained on any separate attached pages, are true and correct, that I am the person named in the credentials to be submitted, and that the same were procured in the regular course of instruction and examination without fraud or misrepresentation. I understand that if any of my responses on this application are false, fraudulent, misleading, inaccurate, or incomplete, my application for licensure will be denied.
>
> I am responsible to keep the Board informed of any circumstance or event that would require a change to my initial responses provided to the Board in my application for licensure, and which occurs prior to my being granted licensure to practice medicine in the state of Nevada.

5. In Question #31 of his Initial Application, Respondent was asked the following question: "Have you EVER been: a) asked to respond to an investigation; b) notified that you were under investigation for; c) investigated for; d) charged with; or e) convicted of any violation of a statute, rule or regulation governing your practice as a physician by any medical licensing board, hospital, medical society, governmental entity, or agency other than the Nevada State Board of Medical Examiners?"

6. To Question #31, Respondent answered: No.

7. Contrary to his response to Question 31, Respondent had, in fact, been repeatedly investigated by the State of California, Department of Consumer Affairs, Medical Board of California, and through its Division of Investigation, Health Quality Investigation Unit and other agencies of the State of California (California Board), for alleged violations of statutes, rules and

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regulations governing his practice as a physician in the State of California prior to submitting, under oath, his Initial Application.

8. Contrary to his response to Question #31, Respondent had, in fact, been repeatedly asked to respond to investigations by the California Board for alleged violations of statutes, rules and regulations governing his practice as a physician in the State of California prior to submitting, under oath, his Initial Application.

9. Contrary to his response to Question #31, Respondent had, in fact, been repeatedly notified that he was under investigation by the California Board for alleged violations of statutes, rules and regulations governing his practice as a physician in the State of California prior to submitting, under oath, his Initial Application.

10. Contrary to his response to Question #31, Respondent was, in fact, presently under investigation by the California Board for alleged violations of statutes, rules and regulations governing his practice as a physician in the State of California prior to submitting, under oath, his Initial Application, and Respondent had actual notice and knowledge of this fact when he filed his Initial Application.

11. Respondent's answer to Question #31 was false, misleading, and inaccurate.

12. Additionally, Respondent's answer to Question #31 was materially false and Respondent knew it was materially false when he made it.

13. On April 13, 2018, Respondent's Initial Application came before the Board for review at a regularly scheduled and noticed public meeting. Respondent appeared, assisted by his counsel, identifying himself as Matt Rifat, Esq.[2] Respondent was questioned regarding the fact that he had not disclosed on his application for licensure three (3) cases of malpractice that had been filed against him. Respondent explained that he didn't think he had been named on two (2) of those cases, and the other case was one that was pending. Mr. Rifat stated the omission was his office's fault, as his office provided the initial listing of cases to the Board, explaining that those cases were included in an addendum after it was brought to their attention. Respondent then described the circumstances surrounding five cases of malpractice that had been filed against him

[2] On information and belief, upon querying the State Bar of Nevada, no attorney going by or resembling the name of "Matt Rifat" is or ever has been admitted to practice law in the State of Nevada. *See* NRS 7.285.

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that resulted in settlements. Respondent did not otherwise inform the Board that he was under investigation by the California Board at that time, nor did he change initial response to Question #31.

14. As demonstrated by, but not limited to, the above-outlined facts, Respondent's statements to the Board in his Initial Application, and his statements in his appearance before the Board on April 13, 2018, were knowing misrepresentations of the truth and made to conceal material facts that would have prevented him from obtaining licensure.

15. As demonstrated by, but not limited to, the above-outlined facts, Respondent's statements and omissions in his Initial Application and to the Board on April 13, 2018, were intentionally misleading, and made to induce the Board to act to the detriment of the public safety by issuing him a license to practice medicine.

16. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.301(3) – Disciplinary Action By Another State Medical Board

17. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

18. NRS 630.301(3) provides that any disciplinary action, including, without limitation, the revocation, suspension, modification or limitation of a license to practice any type of medicine, taken by another state, among other parties, is grounds for initiating disciplinary action against a licensee.

19. Pursuant to a final order and Decision dated August 25, 2020, in Case No. 800-2015-013651, which Decision is attached hereto as **Exhibit 1** and incorporated hereto in its entirety by this reference, the California Board found that Respondent committed acts of gross negligence, repeated negligent acts, failed to maintain adequate and accurate medical records, and unprofessional conduct in the care and treatment of multiple patients. The California Board found Respondent incompetent in the care and treatment of a patient, and that he excessively prescribed controlled substances to three (3) patients. Effective October 15, 2020, the California Board

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revoked Respondent's license to practice medicine in the State of California, with the order stayed, and was placed on probation for seven (7) years subject to numerous terms and conditions including, but not limited to the following: maintaining a record of all controlled substances ordered, prescribed, dispensed, administered, or possessed and any recommendations or approvals to possess or cultivate marijuana; completing an education course, a prescribing practices course, a medical record keeping course, and an ethics course; completing a clinical competence assessment program; prohibited from ordering, prescribing, dispensing, administering, furnishing or possessing schedule II, III, or IV drugs until completion of the clinical competence assessment program; prohibited from performing any care or treatment with patients involving the use, management or any surgical procedures related to intrathecal pumps until completion of the clinical competence assessment program; obtaining a practice monitor; notification to patients of probation status; prohibited from supervising physician assistants and advanced practice nurses; submitting proof of notification of Decision and First Amended Accusation to required parties; submitting quarterly declarations of compliance with all conditions of probation, complying with the Board's probation unit; prohibited from engaging in the practice of medicine in Respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility; and paying costs associated with probation monitoring.

20. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.306(1)(k) – Failure To Report Disciplinary Action By Another State Medical Board

21. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

22. NRS 630.306(1)(k) provides that failure by a licensee or applicant to report in writing, within 30 days, any disciplinary action taken against the licensee or applicant by another state, among other parties, is grounds for initiating disciplinary action against a licensee.

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23. Respondent failed to report the California Board's disciplinary action in Case No. 800-2015-013651 against him to the Board within thirty (30) days in violation of NRS 630.306(1)(k).

24. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(3) – Disciplinary Action By Another State Medical Board

25. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

26. In a subsequent matter, pursuant to a final order and Decision dated December 22, 2021, in Case No. 800-2018-042234, which Decision is attached hereto as **Exhibit 2** and incorporated hereto in its entirety by this reference, the California Board found that Respondent committed acts of gross negligence in the care and treatment of three (3) patients, repeated negligent acts, excessively prescribed controlled substances, and failed to maintain adequate and accurate medical records in the care and treatment of two (2) patients, and unprofessional conduct. Effective January 21, 2022, the California Board again revoked Respondent's license to practice medicine in the State of California, with that order stayed, and was placed on probation for the duration of Respondent's probation in the prior matter, Case No. 800-2015-013651, until the anticipated end date of October 14, 2027, subject to the following additional terms: 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 Respondent's probation in case No. 800-2015-013651.

27. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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COUNT V

NRS 630.306(1)(k) – Failure To Report Disciplinary Action By Another State Medical Board

28. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

29. NRS 630.306(1)(k) provides that failure by a licensee or applicant to report in writing, within 30 days, any disciplinary action taken against the licensee or applicant by another state, among other parties, is grounds for initiating disciplinary action against a licensee.

30. Respondent failed to report the California Medical Board's disciplinary action in Case No. 800-2018-042234 to the Board within thirty (30) days in violation of NRS 630.306(1)(k).

31. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 9th day of June, 2022.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AARON BART FRICKE, J.D.
General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: africke@medboard.nv.gov
Attorney for the Investigative Committee

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VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF WASHOE)

Bret W. Frey, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 9 day of June, 2022.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
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CERTIFICATE OF SERVICE

I hereby certify that I am employed by the Nevada State Board of Medical Examiners and that on the 9th day of June, 2022, I served a file-stamped copy of the foregoing **COMPLAINT**, via USPS Certified Mail to the following parties:

David James Smith, M.D.
[redacted]
Tracking No.: 9171 9690 0935 0254 7604 05

With courtesy copy by email to:

Matthew D. Rifat, Esq., at matthew.rifat@lomdr.com

DATED this 9th day of June, 2022.

MERCEDES FUENTES
Legal Assistant
Nevada State Board of Medical Examiners

EXHIBIT 1

EXHIBIT 1

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

In the Matter of the First Amended Accusation Against: David James Smith, M.D. Physician's & Surgeon's Certificate No G 66777 Respondent.	Case No.: 800-2015-013651

DENIAL BY OPERATION OF LAW
PETITION FOR RECONSIDERATION

No action having been taken on the petition for reconsideration, filed by September 15, 2020, and the time for action having expired at 5:00 p.m. on October 15, 2020, the petition is deemed denied by operation of law.

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

In the Matter of the First Amended Accusation Against: David James Smith, M.D. Physician's & Surgeon's Certificate No G 66777 Respondent.	Case No. 800-2015-013651 **ORDER GRANTING STAY** (Government Code Section 11521)

The Medical Board of California (Board) has filed a Request for Stay of Execution of the Decision in this matter with an effective date of October 5, 2020, at 5:00 p.m.

Execution is stayed until October 15, 2020, at 5:00 p.m.

This stay is granted solely for the purpose of allowing the Board time to review and consider the Petition for Reconsideration.

DATED: October 1, 2020

William Prasifka
Executive Director
Medical Board of California

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

In the Matter of the First Amended Accusation Against: David James Smith, M.D. Physician's & Surgeon's Certificate No G 66777 Respondent.	Case No. 800-2015-013651 **ORDER GRANTING STAY** (Government Code Section 11521)

Matthew D. Rifat, on behalf of Respondent, David James Smith, has filed a Request for Stay of execution of the Decision in this matter with an effective date of September 24, 2020, at 5:00 p.m.

Execution is stayed until October 5, 2020, at 5:00 p.m.

This stay is granted solely for the purpose of allowing the Respondent to file a Petition for Reconsideration.

DATED: September 22, 2020

William Prasifka
Executive Director
Medical Board of California

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

In the Matter of the First Amended Accusation Against: **David James Smith, M.D.** **Physician's and Surgeons Certificate No. G 66777** **Respondent.**	**Case No. 800-2015-013651**

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 September 24, 2020.

IT IS SO ORDERED: August 25, 2020.

MEDICAL BOARD OF CALIFORNIA

Kristina D. Lawson, J.D., Chair
Panel B

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

In the Matter of the First Amended Accusation against:

DAVID JAMES SMITH, Respondent

Case No. 800-2015-013651

OAH No. 2018080617

PROPOSED DECISION

Vallera J. Johnson, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on September 16, 17, 18, 23, 24, 25, 26, 27, and October 2, and 3, 2019, and January 3, and 30, 2020.

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

From commencement of the hearing, Fenton Law Group, LLP, Henry R. Fenton and Summer A. Main, and Matthew D. Riffat, Attorney at Law, of the Law Offices of Matthew D. Riffat represented David James Smith, M.D.[1]

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[1] On January 3, 2020, Fenton Law Group, LLP, Henry R. Fenton and Summer A. Fenton Main filed a Withdrawal of Counsel in this matter. Michael D. Rifat, Attorney at

Oral and documentary evidence was received.[2] The record was closed, and the matter was submitted on April 15, 2020.

Law, of the Law Offices of Matthew D. Riffat, continued to represent David J. Smith, M.D.

[2] On January 30, 2020, the taking of testimony concluded.

On February 19, 2020, a hearing occurred to address remaining issues, including exhibits and scheduling written closing argument. Respondent offered exhibits J (CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016); O (Treatment of Chronic Pain Conditions – a Comprehensive Handbook, Jason E. Pope and Timothy R. Deer, Editors); and W (Report of Lawrence R. Poree, M.D., M.P.H., Ph.D., dated April 23, 2018). During the hearing, respondent offered exhibits J and O to impeach the testimony of Dr. Pope. In addition, there were references to exhibit J by Dr. Pope and respondent during the hearing. There was no reference to exhibit O or W during the hearing. The motion to admit exhibits O and W is denied. The motion to admit exhibit J is granted.

In addition, on February 19, 2020, the administrative law judge set the schedule for filing closing arguments. Thereafter, each of the parties filed motions to extend the time to file closing argument. Without objection by the other party, the motions were granted.

On March 12, 2020, complainant filed his closing argument, it was marked exhibit 96. On April 3, 2020, respondent filed his closing brief, and it was marked

FACTUAL FINDINGS

Jurisdictional Matters

1. Complainant filed Accusation and First Amended Accusation, Case No. 800-2015-013651 regarding respondent's care and treatment of five patients.[3] Respondent filed a timely Notice of Defense.

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

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exhibit X. On April 15, 2020, complainant filed his closing rebuttal argument, and it was marked Exhibit 97.

On April 15, 2020, the record was closed, and the matter was submitted.

[3] The Accusation was filed on April 27, 2018, and the First Amended Accusation was filed on February 13, 2019. Pursuant to Business and Professions Code section 2203.5, the board must file the Accusation within three years after the board discovers the act or omission alleged as a ground for disciplinary action, or within seven years of the actual act or omission, whichever occurs first. Any facts alleged beyond the foregoing statute of limitations is for informational purpose only, not for disciplinary action.

substantial doubt." (*In re Angelia P.* (1981) 28 Cal.3d 908, 919; *In re David C.* (1984) 152 Cal.App.3d 1189, 1208.) If the totality of the evidence serves only to raise concern, suspicion, conjecture or speculation, the standard is not met.

License History

3. On August 21, 1989, the board issued Physician's and Surgeon's Certificate Number G66777 to respondent. The certificate is current, with no history of discipline, and will expire on January 31, 2021, unless disciplined or renewed.

Respondent's Education, Training and Experience

4. Respondent provided evidence of his education, training and experience.

He obtained his Bachelor of Science degree in zoology from San Diego State University in 1983. He graduated from Northwestern University School of Medicine in 1988. Respondent completed an internship in internal medicine at the University of California Los Angeles (UCLA) Wadsworth Veterans Administration, and thereafter, 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.

For more than 25 years, he has been a pain management practitioner, focused on interventional pain medicine, which he described as "the application of current outpatient surgical" and "minimal invasive techniques to ameliorate, reduce or eliminate chronic neuropathic pain."

Respondent is board certified in physical medicine and rehabilitation and in pain medicine.

Between 1993 and 2000, respondent trained under David Rutberg, M.D., a board certified neurosurgeon, "where [he] first cut his teeth, so to speak," on neuromodulation, which involves epidural stimulation with electricity and intrathecal drug therapy. Also, respondent learned to do stem implants and pulp implants under Dr. Rutberg; in 1994, Dr. Rutberg and respondent did a pump trial implant. Over the past 25 years, respondent has implanted 600 to 700 intrathecal pumps[4]. With the exception of the foregoing, respondent offered no evidence to establish what the training involved and minimal evidence of Dr. Rutberg's qualifications to train him.

Respondent described the steps he has taken to keep current in his specialty. He has taken Medtronic (produces, among other things, intrathecal pain pumps)

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[4] 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 delivers medicine directly into the cerebrospinal fluid and requires a significantly smaller amount of medication compared to systematically taken (orally) medication due to bypassing 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. 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.

training courses, and attended conferences and continuing medical education courses; in addition, he attended cadaver teaching/training courses where he learned new techniques. Also, he is a member of the societies in his specialty; he is a member of the American Pain Society, the American Society of Interventional Pain Physicians, and the American Academy of Pain Medicine. Until five years or so ago, he was a member of the American Association of Neuromuscular and Electrodiagnostic Medicine. He is on staff at Scripps Mercy Hospital and Kindred Hospital and has served on medical executive committees of these hospitals.

Respondent has been active as a specialist in pain management. Until about 2008, he has lectured a number of times and co-presented with others, including Drug Enforcement Administration officers. During this same time frame, he has collaborated with intrathecal pump manufacturers.

Complainant's Expert Witness

5. Jason Pope, M.D. (Dr. Pope) served as complainant's expert witness. He evaluated the care and treatment that respondent provided the five patients identified in the First Amended Accusation. In order to do so, among other things, he reviewed the complaint filed by Timothy Furnish, M.D. (Dr. Furnish), a physician who provided medical care for Patient A while she was a patient at University of California San Diego (UC San Diego Health), the medical records of each patient, and issued a report for each patient.

6. Dr. Pope provided evidence of his education, training and experience. He obtained a Bachelor of Science degree in chemistry in 2000 and graduated from Indiana University School of Medicine in 2004. He completed an internship and a

residency in anesthesiology at Vanderbilt University Medical Center in 2008. Dr. Pope completed a one-year pain management fellowship at Cleveland Clinic in 2010.

Dr. Pope has been licensed to practice medicine in California since 2010. In addition, he is licensed to practice medicine in West Virginia, Arizona, Virginia, Ohio, and Tennessee.

Dr. Pope has been board certified in anesthesiology since 2008 and in pain management since 2010.

Dr. Pope has presented at meetings of professional associations and societies made up of neurosurgeons, orthopedic surgeons, spine surgeons, psychiatrists, neurologists, anesthesiologists and urologists. He is a member of and held a variety of positions in his field, including California Society of Interventional Pain Physicians, American Academy of Pain and Neuro Science, International Neuromodulation Society, and North American Neuromodulation Society.

Dr. Pope's background in intrathecal therapy has been extensive. In summary, he testified about the papers/articles, leading journal publications and book editor contributions that he authored and which content was germane to the allegations in this case. Significantly, Dr. Pope has written extensively about and participated in the drafting of practice guides and "best practices" in the field of neuromodulation and intrathecal therapy to promote safety and long-term improvements in pain. He testified about his work as a clinical researcher for Food and Drug Administration regulated studies, including his current role as the national primary investigator for research dealing with intrathecal pump therapy.

For a year prior to completing his fellowship, Dr. Pope practiced as a pain management physician. After he finished his fellowship, Dr. Pope Practiced for six

months and then returned to California. He left in 2012 and returned to California in 2015. He described his current medical practice as a pain management specialist. For the past two and one-half years, he has been in a standalone practice in northern California. Depending on the week, his day-to-day practice consists of: (1) evaluating and consulting with new and existing patients, three to five half-days per week; (2) performing regional interventions, which include injections around different generators two to three half days a week; and (3) performing minimally invasive surgery two to three one-half days a week. He has hospital privileges at Healdsburg District Hospital, Sonoma Valley Hospital, Santa Rosa Memorial Hospital and Santa Rosa Sutter Hospital.

Credibility of Expert Witness and Respondent

7. In determining the facts of this case, in addition to the burden of proof, the credibility of the expert witness and of respondent, who gave testimony as a percipient expert witness, have been considered.

Dr. Pope has practiced in California for less than three years. However, his academic training and involvement in pain management and interventional medicine is extensive. Notably, when provided with additional medical records, he changed some criticisms of respondent's practice. No evidence was offered to establish that he was not qualified to provide the opinions in this case. Dr. Pope was honest, candid and unbiased when he testified in this case.

Respondent obtained his training as an interventional pain management specialist from a neurosurgeon more than 25 years ago. Though he attended training, attended continuing education, participated in some organizations and made some presentations: respondent's formal academic training was minimal; his most recent

presentation was in 2008; his responses in this case were based on his experience with and knowledge of the patient, not the standard of care. He seemed to have no awareness that the standard of care changed over the years relevant in this preceding. In other words, in his opinion, his conduct was within the standard of care because there had been no complaint from other physicians who provided care and treatment for his patients, before Dr. Furnish; his medical records were sufficient because his records were better than some he had seen. He did not respond to the concerns for the patient posed by Dr. Pope. There is no evidence that respondent was anything but candid, but he cannot be considered unbiased.

For the foregoing reasons, despite his limited experience in California, Dr. Pope was more credible than respondent.

PREHEARING MOTIONS

Prior to hearing, respondent filed a motion to exclude the opinion and testimony of complainant's expert witness because complainant failed to comply with requirements of Business and Professions Code section 2334. After considering documentary and oral arguments, the administrative law judge determined that complainant complied with Business and Professions Code section 2334; specifically, complainant filed the expert report in a timely manner and, therefore, respondent's motion was denied.

Prior to hearing, complainant filed a motion to exclude the opinion and testimony of respondent's expert witness because respondent failed to comply with the requirements of Business and Professions Code section 2334. After considering documentary and oral arguments, the administrative law judge determined that

respondent failed to comply with Business and Professions Code section 2334, subdivision (a)(2); the report of respondent's expert witness was deficient; it did not include: (1) a complete statement of each opinion the expert would express and the bases and reasons for each opinion; (2) the facts or data considered by the expert in forming the opinions; and (3) any exhibit used to summarize or support the opinions; and therefore granted the motion. Accordingly, respondent's expert was precluded from testifying in this hearing.

Patient A[5]

8. On August 30, 2015, Dr. Furnish filed a complaint with the board regarding respondent's care and management of Patient A's implanted intrathecal pump.

The complaint filed by Dr. Furnish is discussed herein because Dr. Furnish testified; as the complainant's witness, and not as an expert, Dr. Furnish testified regarding what occurred during his care and treatment of Patient A in 2013 and 2015; in making determinations regarding technical issues described in the complaint, Dr. Pope's testimony and opinions were relied upon.

9. Since 2006, Dr. Furnish has been licensed by the board as a physician and surgeon. He is board certified in pain medicine and anesthesia. For the past nine years, he has been a physician on staff at the University of California – San Diego Medical Center (UC San Diego Medical Center); his practice is primarily outpatient chronic pain with a subset of inpatient complex acute pain. He sees patients with a variety of chronic pain conditions. He sees patients for whom he has been consulted; these

[5] The letter is used to maintain patient confidentiality.

patients are in the hospital for some acute issue and also have difficult pain control issues. In his practice, he prescribes opioids for chronic pain. Since 2013 Dr. Furnish has had administrative responsibility for UC San Diego Medical Center's pain management fellowship program which includes recruitment, interviewing, and putting the educational program together.

10. During the summer of 2013, Patient A had a prolonged admission to UC San Diego Medical Center. She had an intrathecal pump that had been managed by respondent. During the hospital stay, she needed to have her pump refilled twice. Respondent could not fill Patient's A's pump because he did not have privileges to provide care at UC San Diego Medical Center.

Therefore, UC San Diego Medical Center's "pain service" did the pump refill. In 2013, Dr. Furnish had filled intrathecal pumps on a weekly basis for the prior six years. The first time that Patient A required a pump refill, Dr. Furnish interrogated the pump to determine the concentrations and doses that respondent programmed into the pump.[6] The pump's internal computer (similar to a medical record) listed the concentration of drugs, and the daily infusion dose of those drugs in milligrams, not

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[6] There is an external device that radio communicates with the pump. The pump records the information about when the pump was implanted, how long the battery has left to live, the concentration of various drugs inside the pump, the dose the pump is delivering on a daily basis, and when the pump gets close to empty. In order to refill the pump, the practitioner requires the foregoing information; the information is printed on a report or telemetry sheet and is similar to a prescription. As such, there is no need to contact the physician to get this information.

micrograms (mcg),[7] even though mcg is the standard measurement of concentration of medication used in the intrathecal pump.

Due to what Dr. Furnish characterized as, "extremely high doses", he called and spoke with respondent who verified the listed concentrations and infusion doses. Based on respondent's verification, the pharmacy prepared the refill drug, and Dr. Furnish refilled Patient A's intrathecal pump.

11. Again, in June 2015, Patient A was admitted to UC San Diego Medical Center and needed to have her intrathecal pump refilled during her stay.

During the June 2015 hospital stay, prior to refilling the pump, Dr. Furnish interrogated the pump. Because the concentrations and doses were "substantially higher than what was considered usual," he called respondent's office to verify the pump concentration and doses. He did not receive a response and left a message. A woman returned the call and identified herself as one of respondent's nurses. Dr. Furnish read the information that he obtained when he interrogated the pump – 25

[7] There are 1,000 micrograms in one milligram.

mg/mL of Fentanyl[8], 25 mg/mL of Hydromorphone (also known as Dilaudid[9]), and 5 mg/mL of Bupivacaine, and delivering 18.49 mg/mL of Fentanyl/day. Initially the nurse in respondent's office verified the drug concentrations and doses and explained how the drugs were prepared, mixing different amounts of Fentanyl and Hydromorphone in the pump, which did not make sense to Dr. Furnish. After he asked a few questions, she offered to fax the "formula sheet."[10] After receiving the "formula sheet" from respondent's office, Dr. Furnish performed some calculations. He determined that the "formula sheet" indicated major discrepancies between its listed concentrations and dosages and the final concentrations in Patient A's pump. Dr. Pope and respondent confirmed the foregoing. The concentrations respondent listed in the intrathecal pump were concentrations of the ingredients before they were mixed together and not the

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[8] Pursuant to Health and Safety Code section 11055, subdivision (c), Fentanyl is a Schedule II controlled substance. Pursuant to Business and Professions Code section 4022, Fentanyl is a dangerous drug. 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, Drug Enforcement Administration (DEA) Resource Guide (2017 Edition), at p. 40.)

[9] Pursuant to Health and Safety Code section 11055, Dilaudid, a brand name for Hydromorphone, is a Schedule II controlled substance. Pursuant to Business and Professions Code section 4022, Dilaudid is a dangerous drug.

[10] The "formula sheet" is also known as the "excel sheet". Respondent explained that a former nurse who worked in his office and a "math teacher from San Diego State University or UCSD developed the excel sheet" in order "to reconcile the absolute rate per day of individual solutes in the pump."

final concentrations in the pump; the final concentrations of the drugs were actually lower.

Based on the "formula sheet" and his calculation, Dr. Furnish determined that the actual concentration of medications in the pump were 15 mg/mL Fentanyl, 7.5, mg/mL Hydromorphone, and .5 mg/mL Bupivacaine. Patient A was actually receiving 11.1 mg/day of Fentanyl, 5.55 mg/day of Hydromorphone, and .37 mg/day of Marcaine. Dr. Furnish refilled and reprogramed Patient A's pump based on the "formula sheet" and his calculation.

Towards the end of Patient A's hospital stay, Dr. Furnish faxed a note to respondent's office indicating that he had reprogramed the pump with the actual concentrations.

12. In 2013 when he refilled Patient A's pump, Dr. Furnish did not have the "formula sheet," and therefore, after personally confirming with respondent, Dr. Furnish refilled the pump based on the information respondent recorded in the pump's computer. Therefore Dr. Furnish filled the wrong concentrations

Dr. Furnish explained that the national standard of care for pumps is to list the actual concentrations and daily infusion doses being delivered by the pump, not the ingredient concentrations, as respondent did. Based on the foregoing, in 2013, Dr. Furnish was concerned about the care he provided Patient A because Dr. Furnish believed that respondent led Dr. Furnish to overdose Patient A's daily Fentanyl dose by 66 percent and the Hydromorphone dose by 233 percent.

13. Dr. Pope identified the records he reviewed and upon which he relied in rendering his opinions regarding respondent's care and treatment of Patient A, including the following:

- Online complaint,
- Medical records from UC San Diego Medical Center,
- Medical records from respondent's office and clinic for Patient A, dated January 6, 2010 through July 25, 2016,
- Respondent's curriculum vitae, continuing medical education, and opioid maintenance contract,
- Respondent's retention of medical records policy,
- Medtronic drug calculations and progress notes for Patient A, and
- Transcript of respondent's interview regarding Patient A.

14. Commencing 2006, respondent provided treatment for Patient A's chronic pain. Relevant to this proceeding was the treatment that he provided between May 2011 and 2017.[11] She had a variety of co-morbidities, including morbid obesity, lumbar spondylosis, lumbar radiculopathy, sleep apnea, knee osteoarthritis, chronic obstructive pulmonary disorder (COPD) and open wounds.

As early as 2006, respondent treated Patient A's pain with intrathecal pump therapy. In or around 2012 and 2013, respondent implanted new intrathecal pumps in Patient A due to various medical issues.

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[11] Conduct occurring more than seven years from the filing date of the Accusation (April 27, 2018) involving Patient A is for informational purposes only and is not alleged as a basis for disciplinary action.

15. Complainant alleged that, from October 2012 until 2017, respondent managed Patient A's pain through intrathecal drug therapy and "high dose" systemic (oral) opioid drug therapy.

Dr. Pope described "high doses of opioid drug therapy" as doses that exceed certain morphine equivalency (MME)[12] doses. He explained that to standardize or qualify how one opioid compares to another, morphine is designated as the base value of potency. Everything is compared to morphine. The conversion tables that have been created have been based on a clinical experience of one medicine versus the other. Because there are a lot of different opioids and because morphine is one of the most studied opiates, the purpose of MME calculations is to communicate the dose the patient in receiving in relationship to morphine. In the pain management practice, the MME allows the physician to appreciate how much opioid the patient is getting over a 24-hour period.

In 2013, the Center for Disease Control (CDC) recommended no more than 90 MME for non-cancer related pain; by 2017, though, the CDC recommendations are controversial, there was clear evidence that the higher the morphine dose equivalent per day is the higher the likelihood of overdose and death. "So [Patient A's oral] opioid regimen by itself, looking at the peer-reviewed literature that we have would suggest that this patient has a high likelihood of potentially overdosing and death as compared to someone on less oral opioid-based medicine." Also, Dr. Pope stated that,

[12] Morphine equivalency is also known as modified morphine equivalent. The acronyms are MME, MED and MEq.

in 2016, "there was a clear understanding that if you were over 200 MME, the likelihood of overdose and death is markedly higher."

16. Though he acknowledged that he regularly prescribed opioids in excess of 300 MME for Patient A, respondent believed that he acted within the standard of care. However, he disputed that the dose was excessive. In his opinion, "he does not treat charts;" he treats patients on an individualized basis; he assesses his patients and customizes the treatment plan to the patient, his experience with the patient, his familiarity with the patient and the pharmacogenetics that the patient has displayed over many years. "This is how patients should be treated, not based upon a guideline that is pulled from a chart or a table and meant to be across the board." He utilized the foregoing criteria in justifying the opioids to Patient A.

Dr. Pope carefully evaluated the allegations in this case. More significantly, respondent did not address Dr. Pope's concern about potential overdose and death. As such, respondent's argument that he could prescribe opioids in excess of 300 MME is rejected.

17. Notwithstanding the intrathecal pump therapy, respondent routinely prescribed oral opioid medication that often exceeded 300 MME in a day. By 2017, for several years, respondent had not changed the prescribing of high dose opioids and intrathecal opioid therapy. Between October 2012 and 2017, respondent did not wean the systemic opioid medication after the intrathecal pump was placed nor during management of the pump. Patient A's co-morbidities, which included COPD, morbid obesity and sleep apnea, increased her risk of overdose and death.

18. It was established that, from October 2012 until 2017, respondent managed Patient A's pain through intrathecal drug therapy and "high dose" systemic (oral) opioid drug therapy.

19. During this same time frame, [when she was not hospitalized at UC San Diego Medical Center], respondent routinely filled Patient A's intrathecal pump with "massive doses" of controlled pain medication and routinely prescribed "excessive doses of systemic opioids" and other controlled substances. Respondent prescribed potent medications from the combined drug therapies (intrathecal and systemic) to Patient A at the same time.

20. On October 2, 2012, respondent implanted another intrathecal pump in Patient A. Seven days later, he filled and interrogated the pump. Respondent recorded the initiating dose of Fentanyl as 2.499 mg/day in Patient A's pump.

21. Expert testimony established that, even though Patient A had previously received intrathecal therapy with Fentanyl, on October 9, 2012, this was an "initiation" because it had been more than four weeks since Patient A had received intrathecal therapy; in fact, it had been 33 weeks. Because of the time between the ending of pump infusion to the beginning of the next, her body restored itself, to some degree, back to being opioid naïve.

22. On October 9, 2012, respondent documented the initiating Fentanyl dose at a concentration of 25 mg/mL, and Marcaine 5 mg/mL, with a starting dose of 2.499 mg/mL of Fentanyl per day.

In Dr. Pope's opinion, this was an extremely high dose of Fentanyl. He explained that Fentanyl is 100 to 150 times more potent than Morphine. Fentanyl is recorded in micrograms, not milligrams; there are 1000 micrograms in one milligram. "The

recommendations from the Polyanalgesic Consensus Conference (PACC) of 2012 was 25 to 75 mcg per day [of Fentanyl] in an inpatient setting." As such, respondent intended that Patient A receive 2,499 mcg/day of Fentanyl. However, after accounting for dilution, Dr. Pope found that Patient A "received 2.241 mg/day, which equals 2,241 mcg as a starting dose as an outpatient." Dr. Pope also stated that the PACC of 2012 did not set a dose limit of the amount of Fentanyl that could be prescribed, "but most authors described that the maximal dose that you would get to after titration would be anywhere from 2,000 to 5,000 mcg per day." So, that was after titration over a length of time, not an initiating dose. Dr. Pope stated that he had never seen Fentanyl initiated over 2,000 mcg at an inpatient or outpatient setting.

Significantly, Dr. Pope found that respondent's intended initiating dose of intrathecal Fentanyl on October 9, 2012, was "the largest initiating dosing . . . of Fentanyl into a patient" that he had seen.

23. Respondent did not dispute the facts in the foregoing paragraph. However, in respondent's opinion, the dose of Fentanyl was not excessive. He stated that, along with other variables (tolerance, body habitus, pharmacogenetics, amount of oral pills Patient A had taken) and Patient A's positive response at 2.4 or 2.5 mg/mL of Fentanyl caused respondent to "be secure and safe in initiating this as a starting dose." However, no evidence was offered to establish that Patient A had a pump trial during the 33 months prior to implantation and fill of the intrathecal pump in October 2012. Therefore, respondent's argument was rejected.

24. The evidence established respondent initiated Patient A's intrathecal pump with an extremely high dose of Fentanyl.

25. Between October 2012 and 2017, respondent routinely filled Patient A's intrathecal pump with "massive doses", as Dr. Pope put it, of controlled pain medication and routinely prescribed "excessive doses of systemic opioids" and other controlled substances. Respondent prescribed potent medications from the combined drug therapies (intrathecal and systemic) to Patient A at the same time.

26. Complainant alleged that respondent did not clearly and accurately document the concentration of initial medication that was used.

According to the chart note for October 9, 2012, respondent initiating Fentanyl dose was documented at a concentration of 25 milligrams (mg) per millimeter (mL), Marcaine 5 mg/mL, with a starting dose of 2.4999 mg of Fentanyl per day.

Expert testimony established that the standard of care is to accurately program the pump with concentrations within the solution. When respondent programmed the pump, he inputted the initial concentrations of Fentanyl 25 mg/mL, Marcaine 5 mg/mL, and the daily dose as 2.499 mg/mL. However, the actual concentrations of the drugs in the pump were Fentanyl 22.6 mg/mL, Marcaine 0.4997 mg/mL with a daily dose of 2.241 mg/mL of Fentanyl.

Between October 2012 and 2017, during the time that respondent managed Patient A's intrathecal pump refills, there was inaccurate documentation in the pump interrogation report.

Significantly, Dr. Pope noted that, based on the review of Patient A's medical records, respondent made the same error consistently throughout the tenure of his care of Patient A; after the refill at UC San Diego Medical Center in July 2015 respondent reverted back to the "formula sheet" when he programmed Patient A's pump.

27. Respondent admitted that he did not clearly and accurately document the medication that was used in the pump. He described the protocol used to determine whether a pump might be beneficial for his patient, described the pump trial and stated that about 20 percent of his patients did not receive the intrathecal pump.

Respondent explained that, over the previous 25 years, he had implanted at least 600 pumps. He described the protocol that he used to determine whether an intrathecal pump might be beneficial for pain control for a patient; if the pump was the consideration, there was a pump trial; thereafter, about 20 percent of patients did not receive a pump; the intrathecal pump was implanted in an outpatient setting; he identified the medicines that he typically selected to be infused in the pump; he described the "formula sheet/excel sheet" that he developed to calculate the final concentration of medicines, the daily infusion rate and the pump telemetry sheet.

Unlike Dr. Pope (who got his medication from the compounding pharmacy already in a syringe), respondent ordered individual vials from the compounding pharmacy and mixed it at the time of the fill; this allowed him to be patient-specific, to talk to the patient at the time of the pump fill to determine if he needed to "implement any formula changes." Respondent stated that, over 20 years, this had morphed into how he had done it in order to provide the greatest amount of flexibility to the patients at the time of their presentation for fills.

Respondent has had patients in hospitals, skilled nursing facilities or moved from San Diego County who required pump refills, and he described the procedure he followed in such circumstances. When notified he had a patient in the hospital, respondent stated, typically, it was easier if he refilled the pump himself and was granted temporary hospital privileges to do so. If he was unable to fill the pump,

respondent or his staff forwarded the "excel sheet", telemetry sheet, also known as a "telesheet", (data from the pump) and the most recent chart note to the hospital, skilled nursing facility or accepting physician; at times, he received and responded to calls about pump refills from physicians. Prior to the complaint by Dr. Furnish, he had received no complaints about his pumps or pump refills.

Respondent had no memory of speaking with Dr. Furnish but believed that he "must have." Further, he acknowledged that he understood how his method of programming the pump could be confusing for a physician like Dr. Furnish looking at the telesheet and not understanding the method that he had developed and used to determine the final concentration and daily rate of infusion. In order for a subsequent physician to fill a patient pump, the subsequent physician must have his excel sheet in order to fill the pump with the intended amount of prescribed medicines; the subsequent physician could not rely on the information that respondent recorded the pump, found on the telemetry sheet. However, prior to the complaint by Dr. Furnish, regarding his pumps and pump fills, he had no problem with doctors in the community or receiving physicians.

At the time of the hearing, respondent had approximately 100 patients with implanted pumps. After the board filed the Accusation in 2018, respondent began reprogramming the pumps as patients came into the office for pump refills.

28. The evidence established that respondent failed to clearly and accurately document the concentration of initial medication that was used to fill the pump.

29. Further, respondent documented that Patient A was continuing to orally take Methadone[13] and Roxicodone[14] for pain. Notwithstanding the amount of controlled pain medications Patient A was getting through combined intrathecal and systemic drug therapies, respondent gave verbal orders for an intramuscular injection of Dilaudid 4 mg for Patient A at this visit. Dr. Pope explained that, considering the pharmacokinetics of the intramuscular rout of delivery (of Dilaudid) and the significant dose of medicine that Patient A received intrathecally, there was a need for a period of observation because of concern about respiratory depression; and this was not indicated in the chart note. Dr. Pope did not identify what the period of observation should have been.

30. Respondent acknowledged that he ordered the intramuscular injection of Dilaudid because Patient A was experiencing significant pain after the pump fill; however, he disputed that there was no period of observation. Normally, there is a period of observation of 20 minutes or more to handle issues related to the pump fill, such as the telemetry, re-programming the pump, writing out prescriptions, doing a wound check and allowing a patient to get dressed. Though respondent did not

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[13] Pursuant to Health and Safety Code section 11055, Methadone is a Schedule II controlled substance. Pursuant to Business and Professions Code section 4022, Methadone is a dangerous drug.

[14] Pursuant to Health and Safety Code section 11055, Roxicodone is a Schedule II controlled substance. Pursuant to Business and Professions Code section 4022, Roxicodone is a dangerous drug.

document in Patient A's chart that there was an observation period or what that was, his statements regarding what occurred was logical.

31. Based on the facts, on October 9, 2012, after the pump fill, respondent ordered the intramuscular injection of 4 mg of Dilaudid. Respondent established that there was a period of observation after the pump fill.

32. Complainant alleged that, on October 2, 2017, following a pump pocket fill of Patient A's intrathecal pump, respondent sent her home and failed to observe Patient A after the single dose of Naloxone and evaluate potential side-effects, including, but not limited to, opioid over-dosage.

The issue is whether a pump pocket fill occurred, and if it did, whether there was a sufficient period of observation by respondent thereafter.

In support of the allegation, complainant offered the testimony of Dr. Pope. Dr. Pope explained what a pump pocket fill[15] is, how a clinician knows when a pump pocket fill has occurred, the dangers associated with a pump pocket fill and what steps are taken in the event a pump pocket fill occurs. Thereafter, he evaluated the October 2, 2017 chart note.

Dr. Pope explained that, when the intrathecal pump is refilled, the goal is to place the needle in the reservoir, remove the medicine left in the pump and then refill the pump with new medicine to the volume that the pump accommodates. Often, the

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[15] When the pump is implanted, there is a process called epithelialization that occurs; which essentially creates a connective tissue holding device for these spots. This is the pocket.

needle is placed in the reservoir and then a sequential aspiration is done; that is, the clinician injects 5 cc, pulls back 3 cc repeatedly; the clinician confirms that the needle is where he wants it to be before he deposits large volumes of medicine with high concentrations around the pump. If a pump pocket fill occurs with an opioid-based medicine, within five to 10 minutes, the patient exhibits signs of an opioid overdose; the patient becomes somnolent, confused, and potentially unresponsive. This is a life threatening event, a medical emergency.

If a pump pocket fill occurs, the standard of care requires the clinician to identify that the event occurred; put the needle in and suck out the medicine from the pocket and then administer a reversal agent – Naloxone[16]. Depending on the clinical scenario, frequently, the patient is dosed every 30 to 45 minutes. If the pump pocket fill occurs in an outpatient setting, the standard of care requires that, after the reversal agent is administered, the patient is taken to the hospital, by ambulance for overnight observation.

33. In Dr. Pope's opinion, according to the chart note for October 10, 2017, after respondent attempted to refill the pump, there was a clinical scenario that suggested that some of the medicine may have gone around the pocket instead of into the pump; five minutes after they completed the procedure, Patient A experienced "euphoria" and became sedated. Further, the chart note stated:

> At 12:20 p.m., Patient A's vital signs were obtained; at 12:25 p.m., respondent injected an intramuscular dose of 0.4 mg Narcan (diluted over 10 cc) into her right deltoid; at 12:30

[16] Naloxone is a medication designed to rapidly reverse opioid overdose.

> p.m., Patient A's vital signs were reassessed; at 12:34 p.m., a (0.01 mg) dose of Narcan was administered; at 12:35 p.m., Patient A's vital signs were reassessed, and she reported that the feeling of euphoria had resolved; at 12:40 p.m., her vital signs were reassessed. Twenty-five minutes after Patient A reported feeling "euphoria," she was discharged from respondent's clinic. According to the chart note, "[Patient A's] caregiver was given remaining amount of Narcan in syringe with atomizer attachments and given instructions for use should the patient again display symptoms of opioid overdose.

In Dr. Pope's opinion, respondent's clinical decisions, made during this emergent event, showed that he responded as if Patient A had suffered an "opioid overdose" due to a pump pocket fill; despite the immediate onset of Patient A's "euphoria" within minutes of injecting significant concentrations of Fentanyl, Dilaudid, Marcaine and Ketamine into her body, there is no evidence in the chart note that respondent attempted to remove the medicine that may have leaked in and around the pump. In Dr. Pope's opinion, given that the pump pocket fill occurred, the period of observation by respondent and/or his staff was inadequate.

34. Respondent adamantly denied that the pump pocket fill occurred when he filled Patient A's pump on October 10, 2017. He explained he used ultrasound, then he put the needle down and hit the bottom of the reservoir; in addition, he aspirated "one mL of residual drug sitting down here," it was clear, and had no biological material in it; so, he knew he was in the pump; then he put the medication into the pump (stopping every three to four mL and pulling back one or two mL); he did that

four or five times during the fill; this confirmed that he was in the pump and nowhere else; after he filled the pump, he pulled the needle out quickly. Respondent stated that, as he pulled the needle out, it had medication in the tubing and in the needle; occasionally, when the needle is pulled out, a small drop of medication is expressed; that drop gets absorbed quickly and causes a brief period of sedation. In respondent's opinion, this is what occurred to Patient A; as the needle came out, a small drop of medication caused a "very transient period of sedation;" therefore, he acted properly.

35. In order to ascertain whether a pump pocket fill occurred, Dr. Pope's and respondent's testimony and the bases of their testimony were considered. As stated previously, Dr. Pope's education, training and involvement in the pain management community exceeds that of respondent but respondent has more experience. In this case, Dr. Pope relied on the medical chart to render his opinions. However, respondent was present on October 2, 2017; his explanation for the reasons that he was in the pump were reasonable and logical and consistent with the medical record. For the foregoing reasons, respondent's testimony that there was not a pump pocket fill and that he acted appropriately are more credible and reliable.

36. Insufficient evidence was offered to establish that, on October 2, 2017, a pump pocket fill occurred; therefore, it was not established that the period of observation of Patient A was inadequate or that respondent established that respondent otherwise acted inappropriately.

37. Respondent routinely issued prescriptions to Patient A for concomitant use of controlled substances including, but not limited to, MS Contin[17], Roxicodone, and Phentermine[18]. Respondent did not prescribe the benzodiazepines[19].

In 2017 respondent routinely prescribed a combination of systemic (oral) opioids, intrathecal opioids and other controlled medications (including MS Contin, Roxicodone, Soma[20] and Phentermine. Expert testimony established that the risks

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[17] MS Contin is a brand name for morphine. Pursuant to Health and Safety Code section 11055, subdivision (b), MS Contin is a Schedule II controlled substance; pursuant to Business and Professions Code section 4022, MS Contin is a dangerous drug. The DEA has identified Phentermine as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 50.)

[18] Pursuant to Health and Safety Code section 11057, subdivision (f), Phentermine is a controlled substance; pursuant to Business and Professions Code section 4022, it is a dangerous drug. The DEA has identified Phentermine as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 50.)

[19] Pursuant to Health and Safety Code section 11057, subdivision (d), benzodiazepines are Schedule IV controlled substances; pursuant to Business and Professions Code section 4022, it is a dangerous drug.

[20] Soma is a brand name for Carisoprodol; pursuant to Health and Safety Code section 11057, subdivision (d), Soma is a Schedule IV controlled substance; pursuant to Business and Professions Code section 4022, Soma is a dangerous drug. The DEA has identified Soma as a drug of abuse. (Drugs of Abuse, Resource Guide (2017 Edition), at P.50.)

involved were respiratory depression, overdose, and death. Dr. Pope defined respondent's prescribing pattern as "[p]olypharmacy . . . using more than one medicine to treat a patient." Prescriptions for these dangerous drug combinations were issued to Patient A on multiple dates including, but not limited to, January 23, 2017; February 21, 2017; March 6, 2017; April 28, 2017; June 1, 2017; August 7, 2017; and October 2, 2017, which demonstrated a pattern of polypharmacy.

38. Respondent did not document in the medical records justification for prescribing a complex and concurrent regimen to Patient A.

39. Complainant alleged that the medical records that respondent maintained for Patient A demonstrated that he had knowledge of her drug seeking behavior and did not address her drug seeking behavior. In support of the foregoing, complainant offered the testimony of Dr. Pope. He described the criteria that the pain management physician uses to monitor aberrant drug behavior, the standard of care applied when a physician identifies such behavior and identified the aberrant behavior in Patient A's chart and action/inaction taken by respondent.

40. One method to monitor aberrant drug behavior/drug seeking behavior is pulling the Controlled Substances Utilization Review and Evaluation System (CURES) report[21].

[21] A CURES report is an online database that allows for inspection of controlled substances that are prescribed to patients, the physician who is prescribing the medication and the pharmacy that is filling the prescription.

The October 29, 2013 chart note states, in part, that, based on the CURES report, Patient A was inconsistent[22] because there were multiple prescriptions for Promethazine and Soma; respondent called (or instructed his staff to do so) the pharmacy to inform that there were multiple prescriptions for Promethazine and Soma. Further, respondent stated that, at the next office visit, he would go over the opioid contract.

Following the October 29, 2013 office visit, there were three more office visits through 2013. According to Patient A's medical record, on October 29, 2013, and at the following office visits, Patient A continued to receive Promethazine, Soma, Roxicodone, MS Contin and intrathecal therapy with a daily dose of Fentanyl of 7.5 mg/day. There is no evidence in Patient A's medical records that respondent obtained a subsequent CURES report, urine drug sample (UDS) or discussed the (aberrant behavior/drug seeking behavior) issue or discussed the opioid contract with Patient A.

41. Besides evaluating CURES reports, in order to evaluate potential aberrant drug behavior, clinicians may obtain a UDS to monitor what medicines the patient is taking and/or is not taking; the clinician looks at what the patient is being prescribed

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[22] Dr. Pope explained that the clinician considers what the patient is being prescribed, confirms that with a CURES report and then looks to see what is in the patient through a urinary drug screen (UDS); those things have to line up in order for the patient to be consistent with prescribing or with taking the medicines. For example, if the patient is prescribed Hydrocodone, then the UDS report should be positive for Hydrocodone; however, if it is negative for Hydrocodone, it is inconsistent.

and looks for its presence in the urine sample and the absence of medicines that are not prescribed to the patient.

42. Patient A's chart note for April 27, 2016 states, in part: LCMS[23] from April 1, 2016, consistent/inconsistent; Patient A was taking MS Contin orally, and she had Dilaudid in her intrathecal pump; she reported taking her medicines as directed and did not know why the MS Contin was not detected; respondent notified the laboratory to re-run and re-test LCMS as Dilaudid runs through the intrathecal pump and review at next office visit.

Dr. Pope explained that there are clinical scenarios where a prescription is given to a patient that is not detected in a urine compliance test. Respondent prescribed Morphine orally and should have been detected in the urine sample; Dilaudid "is running intrathecally through the pump; because the doses are relatively low systemically," sometimes they are not detected. However, the Dilaudid may be detected in the sample under certain circumstances; it depends on the sensitivity of the test, if the testing is at a really low threshold or if a high complexity test is performing the test.

43. Dr. Pope also explained that, when there is an inconsistent UDS, the standard of care is to repeat the UDS.

Between April 27, 2016 and December 22, 2016, with the exception of June 2016, Patient A had office visits on a monthly basis. From the inconsistent test in April

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[23] LCMS is a urine drug screen that "dequantifies the sensitivity or specificity of the tests. There are different types of urine drug screenings;" "that would highlight the type of urine drug screen."

2016 until December 2016, there was nothing in Patient A's medical records that she was testing consistently; there is no indication that a UDS was performed following the consistent/inconsistent test in April 2016.

Patient A's chart note for May 25, 2017, stated "LCMS from May 19, 2017 was inconsistent, negative for MS Contin." Since respondent was being prescribed MS Contin, the expectation is that it would be present in her urine sample. Dr. Pope explained the reasons that, though the patient is prescribed MS Contin, it did not appear in the urine sample. If the patient is prescribed a medicine, and it does not appear in the urine sample, there are a couple of things that could be responsible. One of them is the test; the test may be flawed because the detection limit for the medicine is not low enough to detect the medicine. It could be a patient metabolism issue; some patients metabolize medicines faster than others; so, that would be an issue. The other is that the testing is accurate and metabolism is relatively normal, so the medicine is not actively in the patient. That could mean that the patient did not take the medicine for a few days, or it could mean the patient never took the medicine. That could indicate diversion and misuse. The other scenario is that the patient is taking the medicine but the patient overtook it earlier in the month; the patient comes in for the 30-day refill, and the patient has been out of the medicine for a handful of days; but, that is not taking the medicine as prescribed. That is of concern as well.

44. There is insufficient documented evidence in the record to establish that respondent documented discussion with Patient A about her aberrant drug behavior (in 2016 and 2017) about the reasons and/or explanations for the inconsistencies.

45. It was established that, between 2011 and 2017, notwithstanding his knowledge of Patient A's documented history of "drug seeking" behavior respondent continued to prescribe "massive" amounts of controlled pain medicines. The chart

notes for Patient A do not adequately document any discussion with Patient A about the reasons and or explanations for the consistencies.

PATIENT A – GROSS NEGLIGENCE

46. Expert testimony established that, after initiation of intrathecal therapy, the standard of care is to reduce or eliminate systemic opioid drug therapy, and Dr. Pope explained; in doing so, he described the difference between systemic therapy and intrathecal therapy and the purpose of both.

Systemic drug therapy is delivered transdermally or orally. So, the whole body is exposed to it, to a much larger degree than a targeted strategy, commonly referred to as intrathecal therapy. Intrathecal therapy is provided through an implanted pump that delivers medicine to the spinal space through a catheter. The purpose of intrathecal therapy is to improve pain by directly targeting the opioid neuroreceptors on the dorsal horn of the spinal cord to allow overall systemic dosing by delivering the medicine where it works in the body. The intrathecal pump is implanted only after a successful trial; the trial is done either through a catheter that is placed temporarily with infusion of medicine into the intrathecal or epidural space; An alternative temporary method is by a single injection into the intrathecal space. In both circumstances, the patient has to demonstrate success prior to implantation of the pump, which typically is qualified as a 50 percent improvement in the pain numerical score.

The purpose of instituting intrathecal therapy for patients who have systemic therapy is to minimize the systemic therapy because medicine is being placed in an area where the body responds to opioids more robustly. So the medicine is bypassing some of the common challenges associated with systemic therapy by instituting an

intrathecal targeted route. Because it is a different route of drug delivery, there is a higher likelihood of respiratory demise in using an intrathecal opioid and a systemic opioid.

In respondent's opinion, the dose of Fentanyl was not excessive. Further, respondent stated that, at all times during treatment of this patient, the therapy he initiated or continued was based on the patient's presentation, the circumstances at the time, with the goal to decrease pain, maintain function through using both the intrathecal drug delivery system and oral medications, knowing when he could decrease oral medications; it was his goal but not always an achievable goal; it was patient specific; however, Patient A was one of his most complicated patients. Nevertheless, considering the facts in the foregoing paragraphs, it was not sufficient to justify the potential for respiratory demise.

47. After introduction of intrathecal therapy on October 9, 2012, respondent continued Patient A on high doses of systemic opioids. By 2017, respondent had not changed his prescribing practices and continued to maintain Patient A on a dangerous combination of high dose oral opioids and intrathecal opioid therapy.

48. Expert testimony established that respondent's concurrent administration of dual opioid drug therapies to Patient A constituted an extreme departure from the standard of care.

49. Expert testimony established that the standard of care is to initiate intrathecal therapy as an inpatient for opioid based therapies or at doses where there is a safe response as an outpatient. Respondent's initiating a very high dose (2,499 mcg/day) of (Fentanyl) on October 9, 2012, in an outpatient setting with no observation period constituted an extreme departure from the standard of care.

50. On October 9, 2012, considering the intrathecal opioid therapy initiated on that date, respondent's verbal order for an intramuscular shot of 4 mg of Dilaudid constituted an extreme departure from the standard of care.

51. Insufficient evidence was offered to establish that a pump pocket fill occurred when respondent performed a pump fill on October 2, 2017.

52. Expert testimony established that respondent's failure to accurately program drug information into Patient A's intrathecal pump and accurately record drug concentration information in Patient A's medical record constituted an extreme departure from the standard of care.

53. Expert testimony established that respondent repeatedly and clearly excessively prescribed, furnished, and/or administered opioids to Patient A; he routinely prescribed dangerous drug combinations and doses to Patient A including, but not limited to, MS Contin, Roxicodone, Soma and Phentermine; his prescribing patterns constituted an extreme departure from the standard of care.

54. Expert testimony established that respondent's failure to document his clinical judgment behind prescribing the controlled medication combination for concomitant use by Patient A with potentially lethal consequences constituted an extreme departure from the standard of care.

55. With knowledge of Patient A's drug seeking behavior, respondent continued to repeatedly prescribe excessive amounts of controlled medications without responding to the objective signs of her aberrant drug behavior. This conduct constituted an extreme departure from the standard of care.

PATIENT A – REPEATED NEGLIGENT ACTS

56. In his care and treatment of Patient A, respondent engaged in repeated negligent acts as found above.

PATIENT A – INCOMPETENCE

57. Expert testimony established that respondent's care and treatment of Patient A demonstrated incompetence.

PATIENT A – REPEATED ACTS OF CLEARLY EXCESSIVELY PRESCRIBING

58. Expert testimony established that respondent committed repeated acts of clearly excessive prescribing drugs or treatment to Patient A.

PATIENT A – FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS

59. Expert testimony established that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patient A.

Patient B[24]

60. Dr. Pope identified the records that he reviewed and upon which he relied in rendering his opinions regarding respondent's care and treatment of Patient B, including the following:

- Complaint to CCU,

[24] The letter is used to maintain patient confidentiality.

- Death Certificate for Patient B,
- Certified copy of the examiner's report,
- Certified copy of death investigation report,
- Signed Release of Medical Information for San Diego Comprehensive Pain,
- Signed Release of Medical Information for Veterans Affairs Hospital,
- Certified copy of Patient B's medical records for San Diego Comprehensive Pain,
- Respondent's curriculum vitae, CMEs, and opioid maintenance contract,
- Respondent's retention of medical records policy, and
- Transcript of respondent's interview.

61. Between 2004 and November 2013 respondent provided care for Patient B. The period relevant to this proceeding was May 2011 until November 2013.[25]

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[25] Conduct occurring more than seven years from the filing of the initial Accusation (April 27, 2018) involving Patient B is for informational purposes only and not alleged as a basis for disciplinary action.

Among other things, Patient B had diagnoses of lumbar radiculopathy, spinal stenosis, lumbar spondylosis and failed back surgery syndrome. He had a history of post-traumatic stress disorder (PTSD), obstructive sleep apnea, hyperlipidemia, hypertension, and obesity; in May 2011, respondent added the diagnosis of opioid dependence; in 2013, respondent added diagnoses of anxiety and depression.

On April 19, 2015, Patient B died of a drug overdose. The medical examiner's autopsy report determined his cause of death was from "mixed medication intoxication (Fentanyl, Oxycodone, Oxymorphone, and Diazepam)."

62. A review of Patient B's medical record, between January 2011 and November 2013, provided insight into respondent's care and treatment of this patient.

> Between January 2011 through May 2011, respondent prescribed Vicodin 5/325 mg, two to four times a day, and Valium 10 mg, one pill by mouth before noon.
>
> On March 10, 2011, under diagnosis, respondent first identified Opioid Dependence.
>
> On the April 5, 2011 chart note, under Medications, among other things, he included Vicodin and Valium; under Treatment Provided, respondent stated that he reviewed the urine screen that was collected on March 10, 2011; it

was positive for Percocet and Benzoylecgonine[26]; also he stated that he would not prescribe controlled substances until Patient B had a clean UDS; during this office visit, Patient B provided a UDS. It is unclear whether respondent issued the prescription.

On the May 3, 2011 chart note, under Medications, among other things, respondent identified Vicodin, Valium and Toradol; under Treatment Provided, respondent stated the UDS will be discussed at the next office visit (not available); further, respondent stated: "Cont all other meds as prev . . ." From the chart note, it is unclear whether respondent issued a prescription for the Vicodin and Valium; based on the foregoing language, presumably he issued the prescriptions.

On the June 23, 2011 chart note, under Subjective Complaints, among other things, respondent stated, at the time, Patient B reported that he was not taking pain medications or muscle relaxants; under Medicines, among other things, respondent stated Vicodin and Valium; under Treatment Provided, among other things, respondent

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[26] Benzoylecgonine is a metabolite for cocaine. Dr. Pope explained that cocaine does not last very long in the body; if Patient B had been tested the day before, he would have been positive for cocaine.

reported: "D/C Vicodin and Valium – due to inconsistent UDS; Pt provided own medication supply."

Regarding the UDS collected on April 5, 2011, the LCMS qualitative report was issued on May 2, 2011, and the quantitative report was issued on May 5, 2011; it was positive for Benzoylecgonine, a metabolite of cocaine, an illicit drug. There was no mention in this May 3, 2011 chart note or the June 23, 2011 chart note.

On the September 8, 2011 chart note, under Subjective Findings, Patient B reported: "At this point in time he continues to use Vicodin on a very PRN basis states that it is from an old rx that he has and states that it is very effective in terms of pain control. Therefore, would like to discuss w/MD about possibly restarting the medication. Pt. is req . . . req refills on: Valium, Vicodin, Abilify and Zoloft." Under Treatment Provided, respondent stated that he "obtained a routine UDS" "using LCMS and quantitative confirmation of positives/negatives;" and he "restarted Norco[27] 5/325 1 PO QID #56, 2 week supply and Valium 10 mg QAM #14;" and ordered "testosterone 300 mg given im."

[27] Norco, an opioid, is a hydromorphone preparation.

On the October 6, 2011 chart note, under Subjective Findings, Patient B reported that he continued to use Vicodin on an as needed basis for pain control, and it was very effective in terms of pain control when needed. Under Medications, respondent identified medicines that he had previously prescribed for Patient B. Under Treatment Provided, he stated, among other things, "testosterone 400 mg given im;" "Continue other meds as prev;" "Toradol 60 mg given im;" "Pt provided own med supply;" "Refilled Norco 5/325 1 PO QID #120 and Valium 10 mg 1 PO QAM;" "Refilled testosterone 200 mg/mL multidose vial."

Patient B had no office visits between October 6, 2011 and May 1, 2012.

On the May 1, 2012 chart note, Patient B reported that he was not taking medications because he wanted to know how bad the pain was; Patient B wanted to discuss "rf int of his medication." Under Medications, respondent listed, among other things, Norco, Toradol, and Testosterone. Under Treatment Provided: "Cont other meds as prev;" "Using LCMS and quantitative confirmation of positives and negatives; a random UDS obtained today;"

On the May 15, 2012 chart note, under Subjective Findings, respondent documented that Patient B reported that he continued to use Norco which he stated was effective but would like to discuss possible medication increase to

further decrease levels of pain. Under Medicines, respondent identified, among other things, "Norco 5/325 1 PO QID-PRN/Valium 10 mg QAM." Under Treatment Provided, respondent stated: Increase "Norco 5/325 2 PO QID #112 (2 week supply);" Also, "MD to review UDS from 5/1/12 – Pt consistent."

On the June 26, 2012 chart note, under Subjective Findings, respondent reported that Patient B continued to use Norco which was effective in decreasing levels of pain and increasing function and quality. Under Medications, he identified Norco and Valium, consistent with the prescription issued on May 15, 2012; there is no indication in the chart note that respondent refilled these prescriptions.

On July 25, 2012, respondent continued and refilled Norco and Valium. Under Subjective Findings, respondent repeated the statement "that Patient B continued to use Norco which was effective in decreasing levels of pain and increasing function and quality." Under Medications, he identified Norco, Toradol and Testosterone. Under Treatment Provided, respondent reported: "Continue other meds as prev."

On the August 24, 2012 chart note, under Subjective Findings, again respondent repeated "Patient B continued to use Norco which was effective in decreasing levels of

pain and increasing function and quality." Under Medications, he identified "Norco5/325 1 PO QID-PRN/Valium 10 mg QAM, Toradol and Testosterone." However, respondent reported "Faxed rx refill for Norco 5/325, 2 PO QID #240; Valium 10 mg, 1 PO QAM #30."

On September 24, 2012 chart note, under Subjective Findings, again respondent stated: "That W/C denied refill of Norco from last ov and hasn't had any since Friday 9/21/12;" and then repeated "Patient B continued to use Norco which was effective in decreasing levels of pain and increasing function and quality. However was denied last rx." Under Medications, respondent identified Norco 5/325 1 PO QID-PRN/Valium 10 mg QAM and testosterone. Under Treatment Requested, respondent stated: "Please cont to authorize Norco 5/325 1 PO QID every month."

It is noted that the medications are consistent in this chart note but inconsistent with the prior month.

Patient B had no office visit in October. However, according to the CURES report, Patient B picked up Hydrocodone 5/325 mg from a pharmacy; the prescription was written by respondent.

On the November 29, 2012 chart note, under Medications, it stated Norco, 5/325, "2 PO QID-PRN/Valium 10 mg QAM;" under Treatment Provided, respondent stated:

"Norco 5/325 2 PO QID;" under Treatment Requested, respondent stated: "Please continue to authorize "Norco 5/325 1 PO QID every month."

There was an inconsistency between the medications identified under Medications in the chart note and the medications that he identified under Treatment Requested.

On January 15, 2013, Patient B reported medications working well. Respondent continued the Norco #240 and obtained a UDS using LCMS; the test results (issued on the same date) were inconsistent for Hydrocodone; the note on the report stated: "repeat 4/16/13."

On February 14, 2013, Patient B reported that the medication was working well; respondent issued prescription for Norco #240. Respondent did not discuss the inconsistent UDS report from the January office visit.

On the March 14, 2013 chart note, under Subjective Findings, respondent documented that Patient B self-increased Norco to 11 per day due to increased pain; Patient B reported that he did not notify respondent's practice that he had increased the medication. Patient B reported that he was out of medication. Under Treatment Provided, respondent reviewed the opioid maintenance contract with Patient B, reminding him that he could not increase medication without respondent's consent; Patient

B verbalized he understood; no further questions or concerns were addressed; respondent recorded "Inc Schedule II Norco 5/325 2 PO Q4-6Hrs NTE, 9/day #270."

Respondent did not obtain a UDS.

On April 16, 2013 chart note, under Subjective Findings, respondent stated that Patient B self-increased Norco to 12 per day approximately; he stated that he went the weekend without medication and borrowed Percocet from a friend which was still ineffective in decreasing the pain level. Respondent reviewed the opioid maintenance contract with Patient B, reminded him that he could not increase medicine without contacting respondent and waiting for direction from respondent and advised of the side effects of him increasing his own medication; respondent increased the Norco to 10/day #300.

On May 16, 2013 chart note, under Subjective Findings, respondent reported "cont to use Norco, Duexis and Valium, which Pt reports is somewhat effective in dec his pain. However would like to discuss with MD about having a medication change. Pt states that with his inc activity level his pain inc and he has been needing to inc his meds." Under Treatment Provided, respondent stated "d/c Norco - not effective; init and p/u Roxicodone 5 mg 1 – 2 PO QID NTE 10/day #300 to start 05/16/13; refilled Valium 10 mg 1 PO QD #30;" "Collect LCMS at next ov."

On June 14, 2013 chart note, under Subjective Findings, respondent reported "pt was init on Roxicodone at last ov which pt reports was effective in dec his pain better than Norco; refilled Valium 10 mg 1 PO QD #30;" "Collect LCMS at next ov; pt cont to use Duexis and Valium which pt reports is effective in dec his pain." Under Treatment Provided, respondent stated "d/c Norco – not effective; p/u Sched II Roxicodone 5 mg 1 – 2 PO QID NTE 10/day #300 to start 6/15/13; refilled Valium 10 mg 1 PO QD #30; per MD collect LCMS at next ov (requested today)." Under Treatment Requested, respondent stated "MD req a routine urine screen using LCMS and using quantitative confirmation of pos/neg to be obtained at next ov."

In the Workers' Compensation (WC) Progress Report, dated July 15, 2013, under Present Complaint, respondent stated "Pt reports that the Roxicodone in conj with the Valium, which pt reports is effective in dec his pain." Respondent added "Anxiety State, Unspecified, Depressive Disorder Not Elsewhere Classified" to Patient B's diagnoses and requested psychotherapy for treatment with Dr. Cathy Hammond twice a week for eight weeks for industrial related depression; requested refills for Roxicodone 5 mg 1 PO Q4HRS NTE 10/D #300 and Valium 10 mg 1 PO QAM #30. There was no reference to obtaining an UDS.

In the WC Progress Report, dated August 1, 2013, under Medication, respondent stated "Roxicodone 30 mg tablet 1 – 2 tablet every 4 hours PRN for 14 days, prescribe 140 tablets, and Valium 10 mg tablet 1 tablet every for 14 days, prescribe 14 tablet."

It is noted that there was a significant increase in the Roxicodone from July 15, 2013. Under Work Status, respondent reiterated the need for a referral to Dr. Hammond.

In the WC Progress Report, dated August 14, 2013, Under History of Present Illness, respondent reported, among other things, that Patient B reported for medication refill with an "agitated effect, states that dates of the Abilify were messed up by the pharmacy and did not have his daily dose for the first few weeks on the month. States that the pain in his back had been so unbearable that he had to increase the dose of his [*sic*] and Roxicodone and even doubling the dose of Valium was insufficient to allow him a restful night's sleep;" Patient B stated that he was "totally out of medication." "States that he went to the V.A. Hospital on the 9th and 11th for bouts of Tonsillitis and treated there with intravenous Dilaudid; still taking antibiotics though he cannot recall what the name of the antibiotic. Pt became fractious when asked to provide a routine urine sample." Under Medication, respondent stated, among other things,

"Roxicodone 30 mg tablet 1 – 2 tablets every 4 hours PRN for 14 days, dispense 140 tablets, and Valium 10 mg tablet 1 tablet once a day for 14 days, dispense 14 tablets." Under Diagnosis, respondent stated, among other things, "Opioid Type Dependence Unspecified Pattern of Use." Under Treatment Plan, respondent stated "Pt given 14 day [*sic*] supply only of pain maedication [*sic*] allowing for closer observation from MD;" "MD reoriented Pat to terms of opioid contract, pt verbalized understanding regarding ER visits and committed to continued adherence to contract. MD requesting pt use Dr. Thompsons outpatient pain management program to equip pt with non-drug pain coping tools. In compliance with DOJ/DEA, a routine urine screen using LCMS and using quantitative confirmation of pos/neg obtained today to help prevent diversion and abuse."

Under Medications, Treatment Plan and Treatment Requested sections of the document, respondent referred to the amount and dosage of the Valium and Roxicodone; in addition, he issued written prescriptions for these medications. The Valium was consistent with the prescription and in the sections of this document. However, the Roxicodone was inconsistent. Under Medication, respondent stated "Roxicodone 30 mg tablet 1 – 2 tablets every 4 hours PRN for 14 days, dispense 140 tablets; the prescription issued for Roxicodone on this date was

consistent with the foregoing dosage and amount; under Treatment Plan, respondent stated "P/U Schedule II Roxicodone 5 mg 1-2 QID NTE 10/day #140 to start today." Under Treatment Requested, respondent stated, "please authorize refills" for "Roxicodone 5 mg 1 PO Q4hrs NTE 10/D #300."

The LCMS test report (collected on August 14, 2013) was issued on August 15, 2012 and was inconsistent for Hydromorphone, Oxycodone [expected to be on Hydromorphone and Oxycodone], and NorFentanyl (a metabolite of Fentanyl)[not expected to be in Fentanyl), and positive for cocaine and Benzoylecgonine (the metabolite of cocaine), an illicit drug.

In the WC Progress Report, dated August 29, 2013, under Treatment Plan, respondent stated "P/U and int scheduled II Butrans Patch 20 mcg/hour apply 1 patch top change qweek #4;" and "MD reviewed LCMS patient inconsistent positive for Cocaine and fentanyl negative for dilaudid and oxycodone." Under Treatment Requested, respondent requested psychotherapy twice a week for eight weeks for the industrial related depression; also, he requested that Patient B be authorized to "use Dr. Blake Thompsons [*sic*] pain management program to equip pt with non drug pain coping tools."

Under Medication, respondent noted, among other things, "Butrans 20 mcg/hour transderm patch 1 transdermal patch every week for 30 days, dispense 4 unspecified;" and, "Roxicodone 30 mg tablet 1 – 2 tablet every 4 hours PRN for 14 days, dispense 140 tablet." Under Treatment Requested, respondent requested authorization for refills for, among other things, "Roxicodone 5 mg 1 PO Q4HRS NTE 10/Day #300"; however, respondent requested "Lidoderm patches apply 1 patch to painful area 12 hours on 12 hours off." Though there is no mention of it in the WC Progress Report, apparently respondent collected a UDS during this office visit. The LCMS report was issued on September 6, 2013.

Patient B's WC Insurance Company authorized him to be evaluated by Multidisciplinary Pain Rehabilitation Program (MDPRP); on September 9, 2013, Patient B was evaluated by a multidisciplinary team "for purposes of conducting an MTUS[28] guideline-compliant multidisciplinary chronic pain evaluation." Thereafter, on the same date, a report was issued. During the evaluation, among other things, Patient B reported his illicit drug use. In order to participate in the program, Patient B was required to be and remain sober. The MDRP "requested 20 full sessions of the intensive

[28] MTUS is an acronym for Medical Treatment Utilization Schedule.

multidisciplinary pain rehabilitation program. These sessions will consist of physical treatment, medical care and supervision, psychological and behavioral care, psychosocial care, vocational rehabilitation training and education." Among other things, the report stated "One of the primary goals of the MDPRP is to teach patients to take responsibility for managing their own rehabilitation and recovery. To this end, MDPRP teaches the patient chronic pain self-management skills that include cognitive and behavioral strategies and other behavioral medicine interventions designed to decrease pain rumination and catastrophizing." MDPRP provided respondent with a copy of the report.

On September 12, 2013, a UDS was collected, and the quantitative laboratory report was issued on September 17, 2013. The report was inconsistent; he was positive for Hydrocodone[29]. Respondent received a copy of the report from the laboratory.

In the chart note for October 1, 2013, under Present Complaint, respondent stated "Pt would like to go over UDS

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[29] Hydrocodone and Nor-Hydrocodone, which was not supposed to be in the patient's body, was discovered in the patient's body. Norco is a combination of Hydrocodone plus Tylenol. So this is the opioid component of the Norco that the patient was prescribed. Nor-Hydrocodone is a metabolite of Hydrocodone.

results to discuss with MD starting pain medication Roxicodone again to help dec pain. Pt states at last ov was initiated on Butrans patch which pt found to be eff in dec pain level but had trouble with patches coming off when he inc activity and started sweating." Under Medication, among other things, respondent stated "Roxicodone 30 mg tablet 1-2 tablet every 4 hours PRN for 14 days, dispense 140 tablet." Under Treatment Plan, respondent stated "Pt to continue with medication as prev; MD discussed with pt the importance of being compliante [*sic*] with UDS and contract signed with office at initial ov; MD also informed pt the importance of taking medication as prescribe." "Per MD will not be able to rx prev medication until pt is compliant;" "per MD will continue to rx Butrans patch to help keep pt in compliant until UDS is consistent and as well as DEA CURES."

In the chart note for November 12, 2013, under Present Complaint, respondent stated "Patient reports to clinic stating that he is unable to get and [*sic*] appointment with his new Dr and would like Dr. Smith to carry his refills for another month, stating that his adjuster advised him to return to the clinic. States that the Butrans Patch is not effective, it will adhere to his skin only sometimes;" "Patient expresses desire to return to opioid therapy and would like to discuss prescription options with MD." "Patient states that he has been without medications for the past two

weeks and as a result can only leave the house with great difficulty and has been out of his home only once due to anxiety attacks causing him to be fearful of leaving." Under Medications, respondent listed, among other things, "Roxicodone 30 mg tablet 1-2 tablet every [the number is illegible] hours PRN for 14 days, dispense 140 tabs." Under Treatment Plan, respondent stated, among other things, "Patient advised that due to inconsistent urine and planned start to another MDs practice no Schedule II substances will be prescribed, should he require medication he is to go to VA Hospital for 13 day [*sic*] supply to carry him until appointment on 11/25/2013 with Dr. Thompson."

63. Between May 2011 and November 2013, respondent prescribed escalating doses of opioids in combination with other controlled substances, including benzodiazepines, antidepressants, muscle relaxants and testosterone.

64. In May, 2011, respondent prescribed Vicodin 5/325 two to four times a day. In September 2011 he prescribed Vicodin four times a day. According to the chart note, on October 6, 2011, respondent discontinued Vicodin because of the inconsistent UDS; without explanation in the chart note, there were no office visits by Patient B between October 2011 and May 2012. On May 1, 2012, respondent prescribed Norco 5/325, one pill, four times a day. On May 15, 2012, the next office visit, respondent increased the Norco from one to two pills, four times a day which continued until February 2013. It is noted that, according to the medical record, there was no office visit in October 2012, and on this date Patient B obtained a prescription of Norco #240. Respondent continued prescribing the same dose and amount of

Norco on a monthly basis until May 2013, when he discontinued the Norco and commenced Roxicodone 5 mg one to two tablets a day; in August, 2013, respondent increased the Roxicodone 30 mg one to two times a day.

65. Dr. Pope explained that, as early as 2009, there was guidance describing that, if a patient received more than 200 MME the likelihood of overdose and death is higher statistically; the standard of care was to avoid prescribing above 200 MME per day. In 2013, the CDC recommendation was to prescribe no more than 90 MME.

Over the course of treatment, respondent's opioid prescribing increased; Dr. Pope explained that tolerance occurs with repeated exposure to these medications which can lead to the need to increase the dose to obtain the same analgesic effect; he said "this is predictable." During the relevant period, the opioid doses on the CURES report (August 14, 2012, through August 14, 2013) reflected the following:

- March 14, 2013 – Norco 5-325 #270 (9/day) 45 MME
- May 16, 2013 – Oxycodone 5 mg (10/day) #300 75 MME
- June 14, 2013 – Oxycodone 5 mg (10/day) #300 75 MME
- July 15, 2013 – Oxycodone 5 mg (10/day) #300 75 MME
- August 14, 2013 – Roxicodone 30 mg every four to six hours as needed for pain (10/day) #140 450 MME

66. Between May 2011 and November 2013, respondent had knowledge of Patient B's documented history of opioid dependence, drug abuse, depression and other aberrant drug behaviors. During the course of treatment, respondent had repeated inconsistent drug test results. On more than one occasion, he had a urine

sample test positive for the metabolite of cocaine and/or cocaine. There were inconsistencies in Patient B's UDSs and CURES report, including but not limited to, Patient B's UDS was inconsistent for Vicodin and Valium on June 23, 2011; Patient B admitted that he misused his prescription on March 14, 2013 and April 16, 2013; and Patient B's urine sample, collected on August 14, 2013, was positive again for cocaine. Patient B admitted on several occasions that he self-increased the amount of opioids he was taking; and finally, on one occasion, he admitted that he took Percocet without prescription.

Despite the facts in the foregoing paragraph, respondent continued to prescribe large amounts of controlled substances, including opioids, to Patient B.

67. Respondent, in the chart notes for Patient B during this time frame, did not adequately document discussion with Patient B about the reasons and/or explanations for the inconsistencies.

68. Despite multiple "red flags" involving drug abuse and depression, respondent did not document any discussion with Patient B regarding a referral to addictionology or rehabilitation facility. However, respondent sought authorization from Patient B's WC insurance company for him to obtain therapy for his depression. No evidence was offered to establish whether Patient B was authorized to obtain psychotherapy for his depression or whether Patient B, in fact, obtained the psychotherapy.

In August 2013 respondent sought authorization for Patient B to attend MDPRP. Respondent explained that, in his opinion, this program is more effective than a recovery or addiction program. On September 9, 2013, a multidisciplinary team performed an evaluation of Patient B and thereafter issued a report with the same

date. According to the report, the program would teach Patient B responsibility for managing his chronic pain and focus on decreasing symptoms of depression and anxiety. In order to participate in the program, Patient B was required to remain sober, and MDPRP had the expectation that respondent would work with Patient B to stabilize Patient B's pain medications. According to the report, it was recommended that Patient B be authorized to attend 20 sessions. Presumably, the WC insurance company authorized Patient B to attend and he agreed to do so because the November 2013 chart note discusses Patient B's scheduled appointment with Dr. Thompson later in November 2013.

Based on the foregoing, respondent referred Patient B to an appropriate program for his drug abuse and drug seeking behavior.

69. In a chart note, dated November 29, 2012, respondent documented that Patient B requested a different dosage of medication in order to help with his depression. On January 15, 2013, the next charted visit, there was no documentation of a follow up on Patient B's request for a different dosage. However, it was documented that Patient B had been experiencing increased anxiety but with no further comment or follow up charted in the note.

70. There are multiple inaccurate chart notes documenting conflicting information regarding what medication was being prescribed and taken.

PATIENT B – GROSS NEGLIGENCE

71. Expert testimony established that, respondent prescribed excessive amounts of opioids, including, but not limited to, on October 1, 2013, when he issued a prescription for Roxicodone (30 mg) (#140) amounting to ten tablets daily.

72. In respondent's opinion, regarding his care and treatment of Patient B, he acted within the standard of care and explained.

Respondent was familiar with the board's guidelines as well as the CDC guidelines regarding opioid prescribing. In respondent's opinion, the board guidelines placed "no ceiling on the prescribing dose of opioid agonist; the board recognizes that, in certain clinical cases, large doses may be needed in the treatment of chronic pain patients; however, the board recommended using caution." Regarding the foregoing, respondent did not clarify the time frame to which he was referring. Regarding the CDC guidelines, respondent stated that, in 2016, "in response to the opioid epidemic," the CDC "put forth guidelines for primary care physicians," which recommended "80 or 90 MME;" but, "it was meant to be a guideline for primary care physicians and opioid naïve patients, not a guideline for specialists in pain medicine or for patients who were already opioid tolerant."

Respondent explained that, in recent years, there has been criticism in the literature about relying on MME "daily dosage;" "this is causing significant restriction on access to analgesics, particularly patients" in his practice; "it has a chilling effect on our ability to prescribe; the problem is patients who present to a practice who are on a dosage of 90 MME or greater. Do we have to wean them down? How do we document the justification for continuation?" So the issues revolved around these "arbitrary guidelines" put forth by the CDC, and the CDC recognized that these were only supposed to be guidelines for primary care physicians or opioid naïve patients. "But, because of the environment today, with the amount of opioid overdoses, they have become adopted more as not guidelines but mandates, and that is leading to a fair amount of disruption in patient care and in the prescribing of opioids." It's important to remember that, from 1990 through 2010, when "we [meaning my specialty] would

go to our symposiums, they beat into our heads that there was no ceiling on opioids." That was the philosophy. Around 2015/2016, "things changed because of the significant amount of opioid deaths, accidental opioid deaths, and then the Fentanyl coming in from Mexico that was manufactured in China. There's been a paradigm shift in the community, which put a very big chill on prescribers so that we were afraid to prescribe in many cases more than the 90 MME doses. In so doing, we have to really document why we're doing it, which I understand. But a lot of patients are suffering." So, instead of a guideline, "as we're seeing with me here today, this is being somewhat utilized to criticize my prescribing techniques and my past prescribing practices."

Finally, respondent stated that the CDC has since written articles "walking back their initial guidelines as they recognized that it was causing harm to patients and limiting access to appropriate patients such that they were unable to get their opioid analgesic pain medication. They walked it back and provided further clarification." Respondent did not explain or offer evidence to establish what he meant by the foregoing testimony.

73. Respondent's arguments, set forth in the foregoing paragraph (Finding 72) are not persuasive. From respondent's testimony, it is clear that he understood the standard of care and believed that he was not required to comply because he was a pain management specialist exercising his judgment regarding Patient B. More specifically, he understood the potential for overdose and death by prescribing MME doses that were more than twice the recommended MME dose (of 200 MME). Finally, as stated previously, based on Dr. Pope's education, training and experience, Dr. Pope's testimony is more persuasive.

74. Expert testimony established that respondent did not properly monitor and manage Patient B's drug use.

Dr. Pope explained that when a patient tests positive for an illicit drug, "it's very common for people to be discontinued on opioid-based therapy and either discharged from the practice with referral to an addictionologist or, typically, a continuation in the practice, just without the use of controlled substances to maintain their discomfort." Dr. Pope stated, this is true, "even after only one dirty test," because "illicit substances, like methamphetamine and cocaine, typically carry a greater weight because of the drug abuse behavior that typically correlates with it." Further, Dr. Pope explained that, if there is a pattern of inconsistency in drug tests, that is "provider dependent." "Clearly a change that needs to occur." The purpose of sampling is to determine compliance. "If there's no compliance in the sample," "the patient's not a candidate to continue opioid based therapy."

Based on noncompliance and inconsistent urine tests, including testing positive for morphine when respondent had not prescribed this. As such, he should have discharged Patient B from his practice or, at minimum, modified or reduced his prescription of Schedule II controlled substances. He did not.

In Dr. Pope's opinion, respondent's management of Patient B's pain medications was "lax". He did not do enough to make sure this patient was with or without Schedule II medicines with the presence of an illicit substance.

Expert testimony established that respondent's care and treatment of Patient B constituted an extreme departure from the standard of care, specifically:

- For continuing to prescribe despite urine confirmation results that indicated positive for cocaine; and

- For continuing to prescribe controlled substances while respondent was using illicit drugs (cocaine) and his UDS test screen results were inconsistent both for expected medications he prescribed and unexpected prescription medications he did not prescribe;

75. Based on the medical records, there were chart notes documenting conflicting information regarding what medications were being prescribed and Patient B was taking. This constitutes an extreme departure from the standard of care.

PATIENT B – REPEATED NEGLIGENT ACTS

76. In his care and treatment of Patient B, respondent engaged in repeated negligent acts.

PATIENT B – REPEATED ACTS OF CLEARLY EXCESSIVELY PRESCRIBING

77. Expert testimony established that respondent committed repeated acts of clearly excessive prescribing drugs or treatment to Patient B.

PATIENT B – FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS

78. Expert testimony established that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patient B.

Patient C[30]

79. Dr. Pope identified the records that he reviewed and upon which he relied in rendering his opinions regarding respondent's care and treatment of Patient C, including the following:

- Complaint from CCU,
- Certified copy of Patient C's medical examiner's investigative report, autopsy report and toxicology report,
- Certified copy of Patient C's death certificate,
- Certified copy of death investigation report from San Diego County Sheriff's Department,
- Signed information releases for records maintained at Sharp Hospital, Alvarado Hospital, respondent's office and the Spine Institute of San Diego,
- Certification of no records from Sharp Hospital,
- Certified copy of medical records from Alvarado Hospital,
- Certified copy of medical records from respondent's office,

[30] The letter is used to maintain patient confidentiality.

- Certified copy of Patient C's medical records from the Spine Institute of San Diego,
- Respondent's Curriculum Vitae and CME, and
- Transcript of respondent's interview.

80. Between May 1, 2008 and July 5, 2012, respondent treated Patient C for chronic pain from a work related injury.[31] The period relevant to this proceeding is May 12, 2011 through July 5, 2012.[32] Patient C was diagnosed with "L4 to S1 spondylosis, L4 through S1 facet sclerosis, bilateral lumbar radiculitis, L4-L5 spinal stenosis, facet hypertrophy at L4 through S1and disk annular fissure L4-L5."

On July 22, 2012, Patient C died of a drug overdose while he was under respondent's care. The medical examiner's autopsy report determined her cause of death was from "acute Oxycodone, Carisoprodol, and Diazepam intoxication."

81. In his report and during the hearing, Dr. Pope reviewed Patient C's medical records, stated each medicine and identified the classification of the medicine. In Dr. Pope's opinion, respondent excessively prescribed controlled substances to Patient C; he managed Patient C on many medication classes including, but not limited

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[31] Conduct occurring more than seven years from the filing date of the initially filed Accusation (April 27, 2018) involving Patient C is for informational purposes only and is not as a basis for disciplinary action.

[32] Conduct occurring more than seven years from the filing date of the initially filed Accusation (April 27, 2018) involving Patient C is for informational purposes only and is not alleged as a basis for disciplinary action.

to, opioids (long-acting and short-acting)[33], multiple benzodiazepines, neuropathic pain medication, multiple muscle relaxants at the same time, and an antiemetic. Dr. Pope characterized this as "overabundance of layering" of medications and explained that this occurs when "a pharmacologic agent with the same mechanism or reaction or a similar mechanism of action, with potentially similar benefits and side effects, are given to the patient simultaneously." When Dr. Pope reviewed Patient C's medical records, he highlighted multiple chart notes from 2011 and 2012, where, in Dr. Pope's opinion, respondent prescribed an excessive number of controlled substances that performed the same or similar mechanisms of action.

82. In respondent's opinion, he acted within the standard of care when he provided care and treatment for Patient C, that he appropriately prescribed for this patient, that he did not excessively prescribe because she "was alert and oriented," and he was able to provide pain relief for her such that she had a better quality of life.

Respondent described the treatment Patient C had received since her injury in 2006. In his opinion, the doses he prescribed were not excessive because they were

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[33] Dr. Pope described the difference between long-acting opioids and short-acting opioids; exclusive of Morphine, all opioid-based therapies are short-acting. It is the packaging around the medicine that crease a long-acting slow release.

Long-acting analgesics are typically employed when the dosing frequency of short-acting agents is frequent, and the pain experience is more continuous than intermittent or with incident pain. To avoid peaks and valleys of dosing with short-acting analgesics throughout the day, a long-acting medication is employed to deliver a more continuous dose.

within the Food and Drug Administration guidelines, and he had not received complaints about his prescribing practices from other physicians who were treating the patient. Respondent did not dispute that he prescribed two benzodiazepines for Patient C and explained the purpose that he prescribed the medicines.

83. Regarding respondent's medical records for Patient C, Dr. Pope stated, in part:

> Medical documentation for satisfaction of return outpatient clinic visits are characterized by CPT codes 99212, 99213, and 99214, based on complexity of the visit and the detail of examination and treatment plan. These oftentimes include a chief complaint, history of present illness, review of systems, an accurate list of medications, physical exam, which includes vitals and a pin score, an assessment and a plan.

In describing the deficiencies in respondent's medical records for Patient C, Dr. Pope stated: "most notes lacked a well-defined chief complaint. None had a review of symptoms." Further, he stated: "The accuracy of the medical chart is uncertain. It appeared that the patient had legacy prescribed medication listed on the active list that did not correlate with those prescribed. Templates are commonly used in medical records. Accuracy between one visit and another are not always performed," and mistakes happen but "not with the regularity of this record."

PATIENT C – GROSS NEGLIGENCE

84. Dr. Pope explained that, in 2012, it was recommended to avoid co-prescribing benzodiazepines, muscle relaxants and opioids because the risk of drug related side effects and complications increase.

In respondent's opinion, he acted within the standard of care when he provided care and treatment for Patient C, and he appropriately prescribed controlled medications to this patient, that he did not excessively prescribe, and that he was able to provide pain relief for her such that she had a better quality of life.

Respondent described the treatment Patient C had received since her injury in 2006. In his opinion, the doses he prescribed were not excessive because they were within the FDA guidelines, and he had not received complaints about his prescribing practices from other physicians who were treating the patient. Despite the foregoing, respondent offered no evidence to establish that he considered the risks of drug related side effects or complications. As such, respondent's argument is rejected.

In Dr. Pope's opinion, this "overabundance of layering" was excessive and constituted an extreme departure from the standard of care.

PATIENT C – REPEATED NEGLIGENT ACTS

85. In his care and treatment of Patient C, respondent engaged in repeated negligent acts.

86. Dr. Pope opined that, during his treatment of Patient C, respondent prescribed two muscle relaxants at the same time, and this was below the standard of care.

87. The standard of care requires clearly described chief complaint, history, physical examination, diagnosis and treatment plan with accurate representation of decision making. Respondent's medical records for Patient C did not include a review of systems, failed to consistently include a well-defined complaint and to accurately record information regarding prescribed medication. In respondent's opinion, his medical records complied with the standard of care; among other things, he believed that his medical records adequately documented respondent's chief complaints. Respondent stated, as a pain management specialist, he was not required to perform a review of systems. For the reasons stated previously, Dr. Pope's opinion regarding completing medical records was more credible than respondent's. As such, respondent's medical records were below the standard of care.

PATIENT C – REPEATED ACTS OF CLEARLY EXCESSIVELY PRESCRIBING

88. Expert testimony established that respondent committed repeated acts of clearly excessive prescribing drugs or treatment to Patient C.

PATIENT C – FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS

89. Expert testimony established that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patient C.

Patient D[34]

90. Dr. Pope identified the records that he reviewed and upon which he relied in rendering his opinions regarding respondent's care and treatment of Patient D, including the following:

- Certified copy of Patient D's Medical Examiner's investigation report, autopsy report and toxicology report,
- Certified copy of Patient D's death certificate,
- Certified copy of Patient D's death investigation report from the San Diego Sheriff's Department,
- Certified copy of Patient D's medical records from Sharp Hospital,
- Certified copy of Patient D's medical records from Scripps Mercy Hospital of Chula Vista,
- Certified copy of Patient D's medical records from Sharp Grossmont Hospital,
- Certified copy of Patient D's medical records from respondent's office,
- Respondent's curriculum vitae,

[34] The letter is used to maintain patient confidentiality.

- Respondent's retention of medical records policy,
- Uncertified copy of Patient D's medical records from respondent's office,
- Certification of Patient D's medical records from respondent's office,
- Transcript of respondent's interview,
- CURES patient report,
- Compact disc with Patient D's medical records from Sharp Grossmont Hospital,
- Certified copy of Patient D's medical records maintained by respondent,[35] and
- Audio of respondent's interview.

91. Between December 2011 and July 2012, respondent provided care and treatment for Patient D's chronic pain.[36] Among other things, she had diagnoses of cervical spondylosis, multiple sclerosis, Cushing's Syndrome, Thoracic Kyphoplasty

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[35] Dr. Pope received medical records from respondent's office on different dates.

[36] Conduct occurring more than seven years from the filing date of the First Amended Accusation involving Patient D is for informational purposes only and is not alleged as a basis for disciplinary action.

(which would suggest a vertebral compression fracture), pulmonary emboli, insulin-dependent diabetes, central pain syndrome and opioid dependence.

On August 1, 2012, Patient D died of a drug overdose while under respondent's care. The medical examiner's autopsy report determined her cause of death was from "acute Tapentadol, Fentanyl and Alprazolam intoxication."

92. During the hearing, respondent admitted that, during the time that Patient D was under the care of respondent, she was morbidly obese; she had a long history of poor pulmonary function and pulmonary disease, and she had a documented history of opioid dependence. Also, respondent admitted that she was opioid dependent and explained, anyone who has been on opioids for more than six months is opioid dependent; however, opioid dependent is distinguished from opioid abuse.

During the time that he treated Patient D, respondent did not have her prior medical records. He was not aware of Patient D's medical history until after the board filed charges against him regarding Patient D. No evidence was offered to the contrary.

93. Dr. Pope reviewed Patient D's medical records for the period between January 5, 2009 and July 30, 2012. He noted that Patient D had a documented history of opioid dependence; Patient D had a long and documented history of multiple emergency department and hospital admissions for various medical conditions, including documentations due to opioid induced respiratory depression. Also, Dr. Pope noted that on November 23, 2011, Patient D visited the emergency department and what occurred during this visit.

During the time that he treated Patient D, respondent did not have her prior medical records. He was not aware of the facts in the foregoing paragraph until after the board filed charges against him regarding Patient D. No evidence was offered to the contrary.

94. On December 23, 2011, respondent had his initial assessment of Patient D. In his chart note for the visit, respondent documented that "[Patient D] had leftover Methadone from a *few years* ago and began taking due to the fact that she was out of Oxy IR . . . [Patient D] stated that she last took Methadone this morning."

95. Between December 2011 and July 2012, respondent managed Patient D on many different medication classes for her drug therapy, including but not limited to opioids, benzodiazepines and muscle relaxants at the same time. According to respondent's testimony, supported by the CURES report, Patient D's primary care physician prescribed the benzodiazepine, and he did not.

96. In a chart note for Patient D, dated July 26, 2012, respondent documented that the patient wanted to change medications, namely replace Dilaudid with Nucynta[37] because she reported that Nucynta was more effective for her pain control. Respondent prescribed transdermal Fentanyl 25 mcg patch[38] every 48 hours,

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[37] Pursuant to Health and Safety Code section 11055, subdivision (b), Nucynta is a brand name for Tapentadol, a Schedule II controlled substance; pursuant to Business and Professions Code section 4022, it is a dangerous drug.

[38] Transdermal Fentanyl (Duragesic) patches are applied to the skin; used to relieve severe pain; the patch is usually applied to the skin once every 72 hours. Fentanyl patches may cause serious life-threatening breathing.

Nucynta 100 mg #228, while on Xanax prescribed by her primary care physician. Expert testimony established that this new regimen represented a MME of 395; the transition from Hydromorphone (Dilaudid) to Tapentadol (Nucyntal) represented an MME increase of 152.[39]

97. In Dr. Pope's opinion, respondent's medical records for Patient D were deficient; as he reviewed the medical records Dr. Pope described the deficiencies. Respondent did not document that vital signs were taken at each visit; his review of systems was actually a physical examination, not a review of systems; further, he copied his "review of systems" from each office visit to the next; at times respondent identified a chief complaint but did not chart a clearly defined complaint on a regular basis; finally, the accuracy of the medical chart is uncertain. It appeared that "Patient D had prescribed medications on the active list that did not correlate with those on the prescribed."

In his expert report, Dr. Pope stated "appropriate titration requires an assessment of vital signs." There is no dispute that respondent did not take Patient D's vital signs while under respondent's care.

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[39] Dr. Pope addressed the issue of the increase in MME when respondent replaced Dilaudid with Nucynta in his report but not during his testimony. However, there was some typographical mistakes regarding this issue; for example, there was a reference to Patient A and he referred to transition from Nucynta to Dilaudid; however, he properly cited respondent's chart note for July 26, 2012; therefore, it was presumed that these were typographical mistakes.

Dr. Pope explained that "templates are commonly used in the medical space. Accuracy between one visit and another are not always performed [*sic*]and mistakes do happen, but not to the regularity of this record."

PATIENT D – GROSS NEGLIGENCE

98. Expert testimony established that when respondent issued Patient D a prescription for Nucynta (100 mg) (#228), this acceleration and increase of MME constituted an extreme departure from the standard of care.

99. Respondent's failure to accurately record information in Patient D's medical record including, vital signs at each visit, a review of systems, a well-defined chief complaint and past and then-currently prescribed controlled medications constituted an extreme departure from the standard of care.

PATIENT D – REPEATED NEGLIGENT ACTS

100. Expert testimony established that respondent committed repeated acts of clearly excessive prescribing drugs or treatment to Patient D.

101. As there was no evidence that respondent received Patient D's medical records while he provided care and treatment for Patient D, it was not established that respondent engaged in repeated negligent acts when he did not document Patient D's medical hospitalizations.

PATIENT D – FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS

102. Expert testimony established that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patient B.

Patient E[40]

103. Dr. Pope identified the records that he reviewed and upon which he relied in rendering his opinions regarding respondent's care and treatment of Patient E, including the following:

- Certified copy of Patient E's medical examiner's investigative report, autopsy report, and toxicology report,
- Certified copy of Patient E's death certificate,
- Certified copy of the death investigation report from the San Diego County Sheriff's Department,
- Certified copy of Patient E's medical records,
- Respondent's curriculum vitae,
- Respondent's retention of medical records policy,
- Transcription of respondent's interview,
- CURES patient profile report,
- Audio of respondent's interview,
- Certified copy of Patient E's medical records, and

[40] Letter E is used to maintain patient confidentiality.

- Audio of respondent's interview.

104. Between April 2013 and October 2013, respondent provided pain management for Patient E due to low back pain.[41] On December 15, 2013, Patient E died of a drug overdose. The medical examiner's autopsy report determined his cause of death was from "acute bronchopneumonia, contributing: chronic prescription medication abuse with acute oxycodone and alcohol intoxication; pulmonary emphysema, and hepatic cirrhosis."

105. In a chart note for Patient E, dated June 26, 2013, a UDS drug sample was taken. Respondent obtained the result on July 15, 2013, indicating that the test was inconsistent because Patient E was "negative" for benzodiazepines, despite being prescribed benzodiazepine by respondent.

Expert testimony established that the standard of care required that, under the circumstances, respondent would make sure the validity of the test was appropriate, and the sensitivity was appropriate and then talk to the patient and attempt to dissect out the risk-benefit profile of continuing to do that.

Respondent did not document that he required Patient E to get another UDS and/or other confirmatory screen to confirm that he was taking the controlled medication being prescribed to him. He did not document any discussion with Patient

[41] Conduct occurring more than seven years from the filing date of the Accusation involving Patient E is for informational purposes only and is not alleged as a basis for disciplinary action.

E in the medical record about any past history of illicit drug use. Instead, respondent continued to issue prescriptions for controlled pain medication.

106. Patient E had a history of illicit drug use. Respondent did not document in the medical record that he had a discussion with Patient E about his past history of illicit drug use.

PATIENT E – REPEATED NEGLIGENT ACTS

107. Expert testimony established that respondent's failure to require Patient E to get another UDS and/or other confirmatory screen to confirm that Patient E was taking the controlled medications that respondent had been prescribing was a simple departure from the standard of care.

108. Expert testimony established that respondent's failure to document any discussion with Patient E about his past history of illicit drug use was a simple departure from the standard of care.

109. Based on the foregoing (Findings 104, 105, 106, 107 and 108), respondent engaged in repeated negligent acts.

PATIENT E – FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS

110. Expert testimony established that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patient E.

Mitigation and Rehabilitation

111. The board has licensed respondent for more than 30 years. He has practiced as a pain management specialist for more than 25 years. There is no evidence that, prior to the complaints in this case, there has been any other complaint

filed against respondent. Besides a pending civil complaint, there is no evidence that any other civil action had been filed against respondent.

112. Respondent provided the following letters of support as a physician and surgeon: Patient A, two of respondent's employees, two physicians (Sharon Thompson, M.D. and Brenton Wynn, M.D.).

> Dr. Thompson described her education, training and experience. After completing her residency, Dr. Thompson participated in a pain management fellowship at Vanderbilt University but did not receive the certification because it was in the anesthesiology department, and her specialty was physical medicine and rehabilitation. She has active licenses in Georgia and California, first licensed in California in 1985.
>
> Dr. Thompson had worked with respondent as a contract physician, most of the time on a part-time basis, most recently, maybe in the last two years on a full–time basis. They are in the midst of negotiating a contract for her to provide services in his practice.
>
> Over the course of time, Dr. Thompson has provided care for the majority of patients in his practice; in her opinion, he is competent, has a good reputation in the community, and she has learned from him.
>
> Dr. Thompson learned about the charges against respondent in early 2019; she read a portion of the

Accusation immediately prior to testifying and believes that the charges are essentially "excessive prescribing."

Dr. Wynn described his education, training and experience. He did a residency in physical medicine and rehabilitation and a fellowship in interventional musculoskeletal medicine. He was first licensed in California in 2003 and has known respondent since 2005 and is familiar with his practice.

Dr. Wynn and respondent have covered for each other, and there have been patients who have gone from Dr. Wynn's practice to respondent's and vice versa, usually because of issues related to insurance. Dr. Wynn has reviewed some of respondent's medical records, the majority on a limited basis.

In Dr. Wynn's opinion, respondent is a competent, ethical and compassionate physician who provides care for complex patients.

Dr. Wynn was not aware of the charges against respondent. He had not reviewed the Accusation or First Amended Accusation. Dr. Wynn stated that, if the charge was related to over prescribing, it would not change his opinion. Further, he stated that, in his opinion, "doing something outside the standard of practice of medicine would be out of character" for respondent. Patient A testified on behalf of respondent. She described the pain relief that he provided and his compassion. As a result, she had increased ability to participate in activities of daily living.

In addition, respondent submitted an additional 17 letters from patients. They support the testimony of Patient A.

Other Matters Considered

113. Respondent did not understand the standard of care regarding the intrathecal pump, specifically the amount of Fentanyl that can be used in the pump, the programming of the pump or the use of intrathecal therapy in conjunction with systemic therapy; most significantly, respondent was treating pain without justification for potential harm to Patient A.

114. Respondent was aware of the CDC's guidelines for excessive MME but nevertheless continued to prescribe excessive doses of MME because he was a pain management specialist or his patient was opioid dependent, again, without regard to the potential dangers to patients.

115. Based on his own testimony, it appeared that respondent was relying on the standard of care between 1990 and 2010, rather than the standard of care between 2011 and 2017. Regarding the intrathecal therapy, respondent explained that he had been filling pumps in the same manner for the prior 25 years, and it had worked. Regarding MME, he explained that between 1990 and 2010, it was drummed into his head [and other pain management specialists] to provide sufficient opioids to relieve pain, and there was no ceiling on prescribing opioids. He had not changed his practice or provided justification for the deviation from the standard of care at the time.

116. Regarding his medical records, respondent admitted that he used templates to complete his medical records but they were frequently inaccurate and confusing. Most significantly, from the medical records, it was difficult to determine whether Patient A had an implanted intrathecal pump between 2010 and 2012.

Frequently, it was difficult to determine what medications had been prescribed for patients.

117. Despite Dr. Thompson's commitment to be honest, it cannot be disregarded that she might have been biased when she testified in this case.

118. No evidence was offered to establish that any of the patients who submitted letters in support of respondent were aware of the charges filed by the board in this case.

119. No evidence was offered to establish that respondent has accepted responsibility or changed his practice.

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.)

Relevant Statutes

2. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his 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.

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.
>
> [¶] . . . [¶]

(d) Incompetence . . .

4. Unprofessional conduct under section 2234 of the Code is conduct which breaches the rules of ethical conduct of the medical profession, or conduct which is unbecoming of 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.)

5. 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.

6. 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.

7. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

Relevant Case Law

8. 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.)

9. 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.

Incompetence has been defined as "an absence of qualification, ability or fitness to perform a prescribed duty or function." (Id. at 1054). Incompetence has been defined as a "general lack of present ability to perform a given duty." (See, *Pollak v. Kinder* (1978) 85 Cal.App.3d 833, 837-838, where the court distinguished negligence from incompetence when it stated, "[A] licensee may be competent or capable of performing a given duty but negligent in performing that duty.") *In James v. Bd. of Dental Examiners* (1985) 172 Cal.App.3d 1096, 1109, the court held: "Incompetence generally is defined as a lack of knowledge or ability in the discharge of professional obligations."

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.]

Violations, if any

10. Pursuant to Business and Professions Code section 2234, subdivision (b), cause exists to discipline respondent's Certificate in that he committed gross negligence in his care and treatment of Patients A, B, C and D.

11. Pursuant to Business and Professions Code section 2234, subdivision (c), cause exists to discipline respondent's Certificate in that he engaged in repeated negligent acts in his care and treatment of Patients A, B, C, D and E.

12. Pursuant to Business and Professions Code section, 2234, subdivision (d), cause exists to discipline respondent's Certificate in that he engaged in incompetence in his care and treatment of Patient A.

13. Pursuant to Business and Professions Code section 2234, as defined in Business and Profession Code section 725, cause exists to discipline respondent's Certificate in that he clearly excessively prescribed drugs to Patients A, B, and C.

14. Pursuant to Business and Professions Code section 2266, cause exists to discipline respondent's Certificate in that respondent failed to maintain adequate and accurate records in connection with his care and treatment of Patients A, B, C, D and E.

15. Pursuant to Business and Professions Code section 2234, cause exists to discipline respondent's Certificate in that respondent engaged in unprofessional conduct in his care and treatment of Patients A, B, C, D and E.

Appropriate Measure of Discipline

16. The purpose of the Medical Practice Act is to assure the high quality of medical practice. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 574.) Conduct supporting the revocation or suspension of a medical license must demonstrate unfitness to practice. The purpose of a disciplinary action is not to punish but to protect the public. In an administrative disciplinary proceeding, the inquiry must be limited to the effect of the doctor's actions upon the quality of his service to his patients. (*Watson v. Superior Court* (2009) 176 Cal.App.4th 1407, 1416.) Because the main purpose of license discipline is to protect the public, patient harm is not required before the board can impose discipline. It is far more desirable to impose discipline on a physician before there is patient harm than after harm has occurred. (*Griffiths v. Superior Court* (2002) 96 Cal.App.4th 757, 772-773).

17. Rehabilitation requires a consideration of those offenses from which one has allegedly been rehabilitated. (*Pacheco v. State Bar* (1987) 43 Cal.3d 1041, 1048.) 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. (*Id.*, at 1058.) The absence of a prior disciplinary record is a mitigating factor. (*Chefsky v. State Bar* (1984) 36 Cal.3d 116, 132, fn. 10.) Remorse and cooperation are mitigating factors. (*In re Demergian* (1989) 48 Cal.3d 284, 296.) While a candid admission of misconduct and full acknowledgment of wrongdoing may be a necessary step in the rehabilitation process, it is only a first step. A truer indication of rehabilitation is presented if an individual demonstrates by sustained conduct over an extended period of time that he is once again fit to practice. (*In re Trebilcock* (1981) 30 Cal.3d 312, 315-316.)

18. In making a determination about the appropriate level of discipline the highest priority is protection of the public from harm.

Respondent had been licensed by the board more than 30 years, with no prior disciplinary action, no prior complaints and one pending civil action. The testimony and letters in support of respondent were considered. However, this case involved numerous violations of the Medical Practice Act in respondent's care and treatment of five patients.

With the exception of acknowledging that the information that he included on the "excel sheet" could not be programmed into the pump, at no time did respondent acknowledge that he made a mistake; though he changed his practice by reprogramming the pumps in his practice, respondent did so because of the issues associated with the board filing the pleadings in this case, not because it was wrong or below the standard of care.

Of greatest concern was respondent's failure/refusal to understand the standard of care for programming the intrathecal pump, his failure/refusal to understand the significance of excessively prescribing Fentanyl, failure/refusal to acknowledge the

danger associated with intrathecal and systemic drug therapy, failure to understand the dangers of excessively prescribing MME, not explaining his significant deviations from the standard of care in medical records and failing to maintain adequate and accurate records and attempting to justify his deficient records.

There is no evidence that respondent accepted responsibility for his mistakes or that he had taken action to change/correct his practice. Given the facts and the law, in order to adequately protect the public, the following order is made.

ORDER

Physician and Surgeon's Certificate No. G 66777 issued to David James Smith, M.D., is revoked. However, the revocation is stayed, and he is placed on probation for seven years upon the following terms and conditions.

1. **Controlled Substances – Maintain Records and Access to Records and Inventories**

Respondent shall maintain a record of all controlled substances ordered, prescribed, dispensed, administered, or possessed by respondent, and any recommendation or approval which enables a patient or patient's primary caregiver to possess or cultivate marijuana for the personal medical purposes of the patient within the meaning of Health and Safety Code section 11362.5, during probation, showing all of the following: (1) the name and address of patient; (2) the date; (3) the character and quantity of controlled substances involved; and (4) the indications and diagnosis for which the controlled substances were furnished.

Respondent shall keep these records in a separate file or ledger, in chronological order. All records and any inventories of controlled substances shall be available for immediate inspection and copying on the premises by the board or its designee at all times during business hours and shall be retained for the term of probation.

2. Education Course

Within 60 calendar days of the effective date of this Decision, and on an annual basis thereafter, respondent shall submit to the board or its designee for its prior approval educational program(s) or course(s) which shall not be less than 40 hours per year, for each year of probation. The educational program(s) or course(s) shall be aimed at correcting any areas of deficient practice or knowledge and shall be Category I certified. The educational program(s) or course(s) shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of his license. Following completion of each course, the board or its designee may administer an examination to test respondent's knowledge of the course. Respondent shall provide proof of attendance for 65 hours of CME of which 40 hours were in satisfaction of this condition.

3. Prescribing Practices Course

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in prescribing practices approved in advance by the board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six months after respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one year of

enrollment. The prescribing practices course shall be at respondent's expense and shall be in addition to the CME requirements for renewal of his license.

A prescribing practices course taken after the acts that gave rise to the charges in the First Amended Accusation, but prior to the effective date of the Decision may, in the sole discretion of the board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

4. Medical Record Keeping Course

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a medical record keeping course, approved in advance by the board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six months after respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one year of enrollment. The medical record keeping course shall be at respondent's expense and shall be in addition to the CME requirements for renewal of his license.

A medical record keeping course taken after the acts that gave rise to the charges in the First Amended Accusation, but prior to the effective date of the Decision may, in the sole discretion of the board or its designee, be accepted towards

the fulfillment of this condition if the course would have been approved by the board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

5. Professionalism Program (Ethics Course)

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California Code of Regulations (CCR) section 1358.1. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six months after respondent's initial enrollment, and the longitudinal component of the program not later than the time specified by the program, but no later than one year after attending the classroom component. The professionalism program shall be at respondent's expense and shall be in addition to the CME requirements for renewal of his license.

A professionalism program taken after the acts that gave rise to the charges in the First Amended Accusation, but prior to the effective date of the Decision may, in the sole discretion of the board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of this Decision, whichever is later.

6. Clinical Competence Assessment Program

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a clinical competence assessment program approved in advance by the board or its designee. Respondent shall successfully complete the program not later than six months after respondent's initial enrollment unless the board or its designee agrees in writing to an extension of that time.

The program shall consist of a comprehensive assessment of respondent's physical and mental health and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and American Board of Medical Specialties pertaining to respondent's current or intended area of practice. The program shall take into account data obtained from the pre-assessment, self-report forms and interview, and the Decision, First Amended Accusation, and any other information that the board or its designee deems relevant. The program shall require respondent's on-site participation for a minimum of three and no more than five days as determined by the program for the assessment and clinical education evaluation. Respondent shall pay all expenses associated with the clinical competence assessment program.

At the end of the evaluation, the program will submit a report to the board or its designee which unequivocally states whether respondent has demonstrated the ability to practice safely and independently. Based on respondent's performance on

the clinical competence assessment, the program will advise the board or its designee of its recommendation(s) for the scope and length of any additional educational or clinical training, evaluation or treatment for any medical condition or psychological condition, or anything else affecting respondent's practice of medicine. Respondent shall comply with the program's recommendations.

Determination as to whether respondent successfully completed the clinical competence assessment program is solely within the program's jurisdiction.

If respondent fails to enroll, participate in, or successfully complete the clinical competence assessment program within the designated time period, respondent shall receive a notification from the board or its designee to cease the practice of medicine within three calendar days after being so notified. Respondent shall not resume the practice of medicine until enrollment or participation in the outstanding portions of the clinical competence assessment program have been completed. If respondent does not successfully complete the clinical competence assessment program, respondent shall not resume the practice of medicine until a final decision has been rendered on the Accusation and/or a Petition to Revoke Probation. The cessation of practice shall not apply to the reduction of the probationary time period.

Respondent shall not order, prescribe, dispense, administer, furnish or possess Schedule II, III, or IV drugs until after proof of successful completion of the Clinical Competence Assessment Program has been provided to the board.

Respondent is prohibited from performing any care or treatment with patients involving the use, management or any surgical procedures related to intrathecal pumps until after successful completion of Clinical Competence Assessment Program has been provided to the board.

7. Monitoring – Practice

Within 30 calendar days of the effective date of this Decision, respondent shall submit to the board or its designee for prior approval as a practice monitor, the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the board, including but not limited to any form of bartering, shall be in respondent's field of practice, and must agree to serve as respondent's monitor. Respondent shall pay all monitoring costs.

The board or its designee shall provide the approved monitor with copies of the Decision and First Amended Accusation, and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision, First Amended Accusation, and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision and First Amended Accusation, fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement for approval by the board or its designee.

Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the term of probation.

If respondent fails to obtain approval of a monitor within 60 calendar days of the effective date of this Decision, respondent shall receive a notification from the board or its designee to cease the practice of medicine within three calendar days after being so notified. Respondent shall cease the practice of medicine until a monitor is approved to provide monitoring responsibility.

The monitor(s) shall submit a quarterly written report to the board or its designee which includes an evaluation of respondent's performance, indicating whether respondent's practices are within the standards of practice of medicine, and whether respondent is practicing medicine safely. It shall be the sole responsibility of respondent to ensure that the monitor submits the quarterly written reports to the board or its designee within 10 calendar days after the end of the preceding quarter.

If the monitor resigns or is no longer available, within 5 calendar days of such resignation or unavailability, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If respondent fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, respondent shall receive a notification from the board or its designee to cease the practice of medicine within three calendar days after being so notified. Respondent shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

In lieu of a monitor, respondent may participate in a professional enhancement program approved in advance by the board or its designee, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at respondent's expense during the term of probation.

8. Patient Disclosure Required by Business and Professions Code section 228.1

Respondent shall provide a disclosure to the patient or the patient's guardian or health care surrogate before the patient's first visit following the effective date of the board's Decision, while on probation that includes the following information: (1) his probation status, (2) the length of probation, (3) the probation end date, (4) all practice restrictions placed on respondent's license by the board, (5) an explanation of how the patient can find further information on respondent's probation on respondent's profile page on the board's online license information internet web site.

In addition, respondent shall obtain from the patient or the patient's guardian or health care surrogate, a separate, signed copy of that disclosure.

Respondent shall not be required provide the disclosure to a patient and obtain a signed copy of the disclosure (1) if the patient is unconscious or is otherwise unable to comprehend the disclosure and a guardian or health care surrogate is unavailable to comprehend the disclosure and sign the copy; or (2) if the visit occurs in an emergency room or urgent care facility or the visit is unscheduled, including consultations in inpatient facilities; or (3) if respondent is not known to the patient until immediately prior to the start of the visit.

9. Supervision of Physician Assistants and Advanced Practice Nurses

During probation, respondent is prohibited from supervising physician assistants and advanced practice nurses.

10. Notification

Within seven days of the effective date of this Decision, respondent shall provide a true and correct copy of this Decision and First Amended Accusation to the chief of staff or the chief executive officer at every hospital where privileges or membership are extended to him, at any other facility where respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the chief executive officer at every insurance carrier which extends malpractice insurance coverage to him. Respondent shall provide proof of compliance to the board or its designee within 15 calendar days of the effective date of this Decision.

11. Obey All Laws

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and shall remain in full compliance with any court ordered criminal probation, payments, and other orders.

12. Quarterly Declarations

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

13. General Probation Requirements

Respondent shall comply with the board's probation unit.

At all times, Respondent shall keep the board informed of his business and residence addresses, email address (if available), and telephone number. Changes of

such addresses shall be immediately communicated in writing to the board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

Respondent shall not engage in the practice of medicine in respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Respondent shall immediately inform the board or its designee in writing of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than 30 calendar days.

In the event respondent should leave the State of California to reside or to practice respondent shall notify the board or its designee in writing 30 calendar days prior to the dates of departure and return.

14. Interview with the Board or its Designee

Respondent shall be available in person upon request for interviews either at respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

15. Non-practice While on Probation

Respondent shall notify the board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of respondent's return to practice. Non-practice is defined as any period of time respondent is not practicing medicine, as defined in Business and Professions

Code sections 2051 and 2052, for at least 40 hours in a calendar month, in direct patient care, clinical activity or teaching, or other activity as approved by the board. If respondent resides in California and is considered to be in non-practice, respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the board or its designee shall not be considered non-practice and does not relieve respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event respondent's period of non-practice while on probation exceeds 18 calendar months, respondent shall successfully complete the Federation of State Medical Board's Special Purpose Examination, or, at the board's discretion, a clinical competence assessment program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for respondent, residing outside of California, will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws, General Probation Requirements, and Quarterly Declarations.

16. Completion of Probation

Respondent shall comply with all financial obligations (e.g., payment of educational courses, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, respondent's certificate shall be fully restored.

17. Violation of Probation

Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, after giving notice and the opportunity to be heard, the board may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

18. License Surrender

Following the effective date of this Decision, if respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, respondent may request to surrender his license. The board reserves the right to evaluate respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, within 15 calendar days, respondent shall deliver his wallet and wall certificate to the board or its designee, and respondent shall no longer practice medicine. Respondent shall no longer be subject to the terms and conditions of

probation. If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

19. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring every year of probation, as designated by the board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the board or its designee no later than January 31 of each calendar year.

DATE: June 25, 2020

DocuSigned by:
Vallera J. Johnson
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VALLERA J. JOHNSON
Administrative Law Judge
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FILED
STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO Feb. 13 2019
BY Sara Kasson ANALYST

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

In the Matter of the First Amended Accusation Against: **DAVID JAMES SMITH, M.D.** **3703 Camino Del Rio South, Suite 210** **San Diego, California 92108** **Physician's and Surgeon's License No. G66777,** Respondent.	Case No. 800-2015-013651 OAH No. 2018-080617 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs, and not otherwise.

2. On or about August 21, 1989, the Medical Board issued Physician's and Surgeon's Certificate No. G66777 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 and allegations brought herein and will expire on January 31, 2021, unless renewed.

JURISDICTION

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

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 relevant 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.

"(d) Incompetence.

" ..."

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.).

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7. 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."

8. 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 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.

"(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."

9. Section 4022 of the Code states:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

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"(b) Any device that bears the statement: 'Caution: federal law restricts this device to sale by or on the order of a _____,' 'Rx only,' or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

10. Respondent has subjected his Physician's and Surgeon's Certificate No. G66777 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, C, and D,[1] as more particularly alleged hereinafter:

11. **Patient A**

(a) Since at least 2010, Patient A treated with Respondent for pain management due to chronic pain in her back, leg, knee, and shoulder.[2] In or around that time, Patient A already had an intrathecal pump[3] implanted. In or around 2012 and 2013, Respondent implanted multiple new intrathecal pumps in Patient A due to various medical issues.

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[1] Letters A, B, C, and D are used for the purposes of maintaining patient confidentiality.

[2] Conduct occurring more than seven (7) years from the filing date of the initially filed Accusation (April 27, 2018) involving Patient A is for informational purposes only and is not alleged as a basis for disciplinary action.

[3] 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 delivers medicine directly into the Cerebrospinal fluid and requires a significantly smaller amount of medication compared to systemically taken (orally) medication due to bypassing the systemic path that oral medication must travel in the body. An intrathecal pump is programmable and it stores the information about 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.

(b) From in or around 2011 to in or around 2017, Respondent managed Patient A's pain medication through intrathecal drug therapy and high dose systemic (oral) opioid drug therapy. During this same time frame, Respondent routinely filled Patient A's intrathecal pump with massive doses of controlled pain medication and routinely prescribed excessive doses of oral opioids and other controlled substances. Significantly, the potent and highly addictive medications from the combined drug therapies (intrathecal and systemic/oral) were being taken by Patient A at the same time, as prescribed by Respondent. In fact, Respondent, notwithstanding Patient A's intrathecal drug therapy, routinely prescribed excessive amounts of oral opioid medication that often exceeded well more than three hundred (300) morphine milligram equivalents (MME) in a day. Respondent prescribed these massive oral doses of opioids to Patient A on multiple dates including, but not limited to, October 2, 2017; July 25, 2016; September 4, 2013; and November 7, 2012.

(c) On or about October 2, 2012, Respondent replaced Patient A's existing intrathecal pump with a newer model.[4]

(d) On or about October 9, 2012, Respondent filled Patient A's newly installed pump with medication but failed to clearly and accurately document the concentration of initial medication that was used to fill the pump. According to the chart note for this outpatient visit, Respondent initiated the pump's medication with an extremely high amount of fentanyl.[5] Patient A's initiating fentanyl dose was documented at a concentration of 25 milligrams (mg) per milliliter (mL), with a

[4] A pump implant operative note indicated that Respondent implanted the Medtronic Synchromed II.

[5] Fentanyl is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c), and a dangerous drug pursuant to Business and Professions Code section 4022. 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, Drug Enforcement Administration (DEA) Resource Guide (2017 Edition), at p. 40.)

starting dose of 2.499 mg of fentanyl per day. The chart note for this visit also documented filling the pump with Marcaine 5 mg/mL. The chart note further documented that Patient A was continuing to orally take Methadone[6] and Roxicodone[7] for pain. Respondent, notwithstanding the amount of controlled pain medications Patient A was getting through combined intrathecal and systemic drug therapies, also gave verbal orders for an intramuscular injection of Dilaudid[8] 4 mg for Patient A at this visit. Significantly, there was no observation period of Patient A following the pump's medication refill at this visit.

(e) Following a pump pocket fill of Patient A's intrathecal pump, Respondent sent her home after only one dose of Naloxone.[9] Significantly, Respondent failed to observe Patient A after this single dose and evaluate potential side-effects including, but not limited to, opioid over-dosage.

(f) In or around June 2015, Patient A was admitted for a prolonged admission to a hospital at the University of California San Diego (UCSD). During her admission, Patient A's intrathecal pump had to be filled with medication. A UCSD physician treating Patient A identified that the concentration of medication in her pump was "extremely high" and that the pump's internal computer listed the concentration of drugs in "milligrams," and not micrograms (mcg), even though mcg is the standard measurement of concentration of medication used in an intrathecal pump. Respondent personally verified the accuracy of the listed

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[6] Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c), and a dangerous drug pursuant to Business and Professions Code section 4022.

[7] Roxicodone is a brand name for oxycodone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

[8] Dilaudid is a brand name for hydromorphone, is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

[9] Naloxone is a medication designed to rapidly reverse opioid overdose.

concentrations and infusion doses directly to the UCSD physician. A "formula sheet" containing a list of medication concentration was also faxed from Respondent's clinic to UCSD to again verify concentrations and dosages that the Respondent fills in Patient A's pump. The "formula sheet" clearly indicated that major discrepancies existed between its listed concentrations and dosages and the final concentrations actually contained in Patient A's pump.

(g) Respondent routinely issued prescriptions to Patient A for the concomitant use of addictive controlled pain medications including, but not limited to, MS Contin,[10] Roxicodone, benzodiazepines,[11] Soma,[12] and phentermine.[13] Prescriptions for this dangerous drug combination were issued to Patient A on multiple dates including, but not limited to, January 23, 2017; February 21, 2017; March 6, 2017; April 28, 2017; June 1, 2017; August 7, 2017; and October 2, 2017. Respondent failed to document his clinical judgment behind prescribing a controlled medication combination with potentially lethal consequences, which occurred every time he prescribed the concomitant use of these drugs to Patient A.

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[10] MS Contin is a brand name for morphine, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and 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, subdivision (d), and are a dangerous drug pursuant to Business and Professions Code section 4022. Concomitant use of benzodiazepines with opioids may result in profound sedation, respiratory depression, coma, and/or death. The DEA has identified benzodiazepines as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 59.)

[12] Soma is a brand name for carisoprodol, which is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022. The DEA has identified Soma as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 27.)

[13] Phentermine is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (f), and a dangerous drug pursuant to Business and Professions Code section 4022. The DEA has identified phentermine as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2017 Edition), at p. 50.)

(h) From in or around 2011 to in or around 2017, Respondent, notwithstanding his knowledge of Patient A's documented history of drug and alcohol abuse and "drug seeking" behavior, continued to prescribe massive amounts of addictive controlled pain medication even after inconsistencies were discovered in her urine drug screens and Controlled Substance Utilization Review and Evaluation System[14] (CURES) reports indicating she had received controlled prescriptions from other physicians. The chart notes during this time frame fail to adequately document any discussion with Patient A about the reasons and/or explanations for these inconsistencies.

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

(a) Respondent, after initiation of intrathecal drug therapy, failed to reduce and/or eliminate Patient A's continued use of systemic opioid drug therapy;

(b) On or about October 9, 2012, Respondent initiated an excessive dose of fentanyl at an intended concentration of 25 mg/mL and a starting dose of 2.499 mg per day, in Patient A's intrathecal pump;

(c) On or about October 9, 2012, Respondent failed to initiate intrathecal therapy in an inpatient setting to observe whether Patient A had a safe response to the medication;

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[14] 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).)

(d) On or about October 9, 2012, Respondent failed to initiate intrathecal therapy in an outpatient setting to observe whether Patient A had a safe response to the medication;

(e) On or about October 9, 2012, Respondent gave verbal orders for an intramuscular injection of Dilaudid 4 mg for Patient A despite the amount of controlled pain medications Patient A was already receiving through combined intrathecal drug therapy and systemic drug therapy;

(f) Respondent performed a pump pocket fill of Patient A's intrathecal pump, and, after administering a single dose of Naloxone, he failed to observe and evaluate the patient for potential side-effects of opioid over-dosage;

(g) Respondent failed to maintain adequate and accurate records by failing to accurately record information about medication used in Patient A's intrathecal pump, including, but not limited to, starting concentration of medication, final concentration of medication, starting and final concentration of medication after other medication was added, drug calculations, and other reported values of concentration and doses;

(h) Respondent failed to properly program medication information into Patient A's intrathecal pump, including, but not limited to, starting concentration of medication, final concentration of medication, starting and final concentration of medication after other medication was added; and other reported values of concentration and doses;

(i) Respondent repeatedly and clearly excessively prescribed, furnished, dispensed, and/or administered opioids to patient A;

(j) Respondent routinely prescribed dangerous drug combinations and doses to Patient A including, but not limited to, MS Contin, Roxicodone, benzodiazepines, Soma, and phentermine;

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(k) Respondent failed to document his clinical judgment behind prescribing a controlled medication combination for concomitant use by Patient A with potentially lethal consequences; and

(l) Respondent, with knowledge of Patient A's documented drug seeking behavior, failed to provide appropriate treatment in that he, among other things, repeatedly prescribed excessive amounts of addictive pain medication to Patient A over an extended period of time, while failing to respond to objective signs of aberrant drug behavior.

13. **Patient B**

(a) Between in or around 2004 and in or around November 2013, Patient B treated with Respondent for pain management due to a number of medical issues including, degenerative disc disease and chronic low back pain.[15] On or about April 19, 2015, Patient B died of a drug overdose. The medical examiner's autopsy report determined his cause of death was from "mixed medication intoxication (fentanyl, oxycodone, oxymorphone, and diazepam)."

(b) Between in or around 2011 and in or around 2013, Respondent prescribed Patient B escalating doses of opioids in combination with other controlled drugs, including, but not limited to, benzodiazepines, antidepressants, muscle relaxants, and testosterone. In fact, Respondent prescribed excessive amounts of opioids including, but not limited to, on or about October 1, 2013, issuing a prescription for Roxicodone (30mg) (#140) amounting to approximately ten (10) tablets daily. Significantly, this prescription alone equaled an incredibly high four hundred fifty (450) MME.

(c) From in or around 2011 to in or around 2013, Respondent, notwithstanding his knowledge of Patient B's documented history of opioid

[15] Conduct occurring more than seven (7) years from the filing date of the initially filed Accusation (April 27, 2018) involving Patient B is for informational purposes only and is not alleged as a basis for disciplinary action.

dependence, alcohol and drug abuse, depression, and other aberrant drug behaviors, continued prescribing large amounts of addictive medication even after numerous inconsistencies were discovered in Patient B's urine drug screens and CURES reports, including, but not limited to, June 23, 2011 (inconsistent for Vicodin and Valium); March 14, 2013 (misused prescription); April 16, 2013 (misused prescription); and August 14, 2013 (+cocaine). The chart notes during this time frame fail to adequately document any discussion with Patient B about the reasons and/or explanations for these inconsistencies. Although Patient B's medications were discontinued on occasion due to non-compliance, the prescriptions were later continued with similar dosing strength and frequency. Significantly, Respondent failed to document any discussion with Patient B regarding a referral to addictionology or a rehabilitation facility despite multiple "red flags" involving drug abuse and depression.

(d) In a chart note dated November 29, 2012, it was documented that Patient B requested a different dosage of medication in order to help with his depression. At the next charted visit, on or about January 15, 2013, there is no documentation of a follow up on Patient B's request for a different dosage. However, it is documented that he has been experiencing increased anxiety but with no further comment or follow up charted in the note.

(e) There are missing chart notes for July, August, and September 2013. However, Patient B filled controlled prescriptions issued by Respondent during this time frame. In addition, there are chart notes documenting conflicting information regarding what medication was being prescribed and taken.

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

(a) Respondent prescribed excessive amounts of opioids including, but not limited to, on or about October 1, 2013, issuing a prescription for Roxicodone (30mg) (#140) amounting to approximately ten (10) tablets daily;

(b) Respondent failed to effectively monitor and manage Patient B's drug use by continuing to prescribe addictive controlled medication after years of inconsistent drug tests, positive test result for cocaine, and/or repeated misuse of controlled prescriptions;

(c) Respondent failed to refer Patient B to addictionology or rehabilitation facility after repeated "red flags" of aberrant drug behavior;

(d) There are missing chart notes for July, August, and September 2013; and

(e) There are multiple inaccurate chart notes documenting conflicting information regarding what medication was being prescribed and taken.

15. **Patient C**

(a) Between in or around 2008 and in or around 2012, Patient C treated with Respondent for pain management due to chronic pain from a work related injury.[16] On or about July 22, 2012, Patient C died of a drug overdose. The medical examiner's autopsy report determined her cause of death was from "acute oxycodone, carisoprodol, and diazepam intoxication."

(b) Between in or around 2011 and in or around 2012, Respondent managed Patient C on many different medication classes for her drug therapy including, but not limited to, opioids (long acting and short acting), multiple benzodiazepines, neuropathic pain medication, multiple muscle relaxants at same time, and antiemetics. In fact, Respondent prescribed an excessive number of drugs that performed same or similar mechanisms of action to treat Patient C.

(c) Patient C's medical charts failed to include a review of systems, failed to consistently include a well-defined chief complaint, and failed to accurately record information regarding prescribed medication. In addition, there were no

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[16] Conduct occurring more than seven (7) years from the filing date of the initially filed Accusation (April 27, 2018) involving Patient C is for informational purposes only and is not alleged as a basis for disciplinary action.

CURES reports contained in Patient C's medical records nor any mention in her charts of checking CURES for patient compliance.

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

(a) Respondent prescribed an excessive number of controlled drugs, including, but not limited to, opioids (long acting and short acting), benzodiazepines, muscle relaxers, and antiemetics to treat Patient C.

17. **Patient D**

(a) Between in or around December 2011, and in or around July 2012, Patient D treated with Respondent for pain management due to chronic pain.[17] On or about August 1, 2012, Patient D died of a drug overdose. The medical examiner's autopsy report determined her cause of death was from "acute tapentadol, fentanyl, and alprazolam intoxication."

(b) During the time that Patient D was under the care of Respondent, she was morbidly obese; she had a long history of poor pulmonary function and pulmonary disease; and she had a documented history of opioid dependence. Significantly, she had a long and documented history of multiple Emergency Department and hospital admissions for various medical conditions, including hospitalizations due to opioid induced respiratory depression.[18]

(c) On or about November 23, 2011, Patient D visited an Emergency Department and had requested a medication refill because her pain management doctor was "out of town." The medical record of that visit documented that Patient D's pain management doctor at the time, Dr. A.S., was contacted and that she had contradicted the patient's account regarding lack of medication.

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[17] Conduct occurring more than seven (7) years from the filing date of the First Amended Accusation involving Patient D is for informational purposes only and is not alleged as a basis for disciplinary action.

[18] In 2011 and 2012, Patient D had multiple admissions to Emergency Departments and hospitals.

Furthermore, Dr. A.S. advised Emergency Department staff that she had been having difficulty with managing Patient D's pain due to the patient's "concomitant illicit drug use." Patient D was denied opioid medication from Emergency Department medical staff that day. Three days later, Patient D returned to the same Emergency Department and requested to be admitted for drug detoxification.

(d) On or about December 23, 2011, Respondent had his initial examination with Patient D. In the chart note for this visit, Respondent documented that "[Patient D] had leftover methadone from a *few years* ago and began taking due to the fact she was out of Oxy IR ... [Patient D] states she last took methadone this morning."

(e) Between in or around December 2011 and in or around July 2012, Respondent managed Patient D on many different medication classes for her drug therapy including, but not limited to, opioids, benzodiazepines, muscle relaxants, and anti-seizure medication at the same time.

(f) Significantly, Patient D's medical charts from Respondent's clinic do not contain any information about her vitals being taken at each clinical visit. In addition, the charts also do not include a review of systems and/or a well-defined chief complaint. Furthermore, the charts do not accurately record information regarding Patient D's past and then-currently prescribed controlled medication. Finally, Respondent prescribed Patient D large amounts of opioids without adequately documenting her past hospitalizations involving poor pulmonary function and pulmonary disease.

(g) In a chart note dated July 26, 2012, Respondent documented that Patient D had wanted to switch pain medications, namely, replace Dilaudid with Nucynta,[19] because she had reported that Nucynta was more effective for her pain

[19] Nucynta is a brand name for tapentadol, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

control. Respondent, notwithstanding Patient D's current dosages of the transdermal Fentanyl patch[20] along with other opioids, issued her a prescription for Nucynta (100mg) (#228).[21] The Nucynta prescription alone resulted in an increase of more than one hundred fifty (150) MME being taken by Patient D at that time.[22]

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

(a) On or about July 26, 2012, Respondent prescribed an excessive amount of opioids when he issued Patient D a prescription for Nucynta (100mg) (#228); and

(b) Respondent failed to accurately record critical information in Patient D's medical record, including, but not limited to, failed to have vital signs taken and/or documented at each visit; failed to accurately record information regarding Patient D's past and then-currently prescribed controlled medication; and failed to document a review of systems and/or a well-defined chief complaint.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

19. Respondent has further subjected his Physician's and Surgeon's Certificate No. G66777 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, B, C, D, and E,[23] as more particularly alleged hereinafter:

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[20] Transdermal fentanyl (Duragesic) patches are applied to the skin; used to relieve severe pain, the patch is usually applied to the skin once every 72 hours. Fentanyl patches may cause serious or life-threatening breathing problems. Taking certain medications (e.g., benzodiazepines and muscle relaxants) with fentanyl may increase the risk of serious or life-threatening breathing problems, sedation, or coma.

[21] Patient D's prescribed regimen of opioids represented a total of three hundred ninety-five (395) MME.

[22] Patient D had recently filled prescriptions for Dilaudid (Hydromorphone HCL) on July 10, 2012 (4mg) (#180), and on June 13, 2012 (4mg) (#180).

[23] Letter E is used for the purposes of maintaining patient confidentiality.

20. **Patient A**

(a) Paragraphs 11 and 12, above, are hereby incorporated by reference and realleged as if fully set forth herein.

21. **Patient B**

(a) Paragraphs 13 and 14, above, are hereby incorporated by reference and realleged as if fully set forth herein.

22. **Patient C**

(a) Paragraphs 15 and 16, above, are hereby incorporated by reference and realleged as if fully set forth herein;

(b) There are no CURES reports in Patient C's medical records nor any mention of checking CURES for patient compliance;

(c) In 2012, Respondent prescribed two (2) muscle relaxants at same time to Patient C; and

(d) Patient C's medical charts failed to include a review of systems; failed to consistently include a well-defined chief complaint; and failed to accurately record information regarding prescribed medication.

23. **Patient D**

(a) Paragraphs 17 and 18, above, are hereby incorporated by reference and realleged as if fully set forth herein; and

(b) Patient D's medical charts failed to include and/or document any information regarding Patient D's past multiple hospitalizations.

24. **Patient E**

(a) Between in or around April 2013, and in or around October 2013, Patient E treated with Respondent for pain management due to low back pain.[24] On or about December 15, 2013, Patient E died of a drug overdose. The medical

[24] Conduct occurring more than seven (7) years from the filing date of the First Amended Accusation involving Patient D is for informational purposes only and is not alleged as a basis for disciplinary action.

examiner's autopsy report determined his cause of death was from "acute bronchopneumonia; contributing: chronic prescription medication abuse with acute oxycodone and alcohol intoxication; pulmonary emphysema; hepatic cirrhosis."

(b) Between in or around April 2013, and in or around October 2013, Respondent managed Patient E on high dosages of opioids and benzodiazepines at the same time.

(c) In a chart note dated June 26, 2013, it was documented that a prescription was issued to Patient E to obtain a urine drug screen (UDS). The results of the UDS later indicated that Patient E was "negative" for benzodiazepines, despite being prescribed that drug by Respondent. However, Respondent never required Patient E to get another UDS and/or other confirmatory screen to confirm that he was taking the controlled medications being prescribed to him. Instead, Respondent continued to issue prescriptions for controlled pain medication to Patient E without documenting in the medical record any information and/or discussion with Patient E about the inconsistent UDS results.

(d) Patient E had a history of illicit drug use. However, Respondent never discussed and/or documented any discussion with Patient E in the medical record about any past history of illicit drug use.

25. Respondent committed repeated negligent acts in his care and treatment of Patient E including, but not limited to, the following:

(a) Respondent failed to require Patient E to get another UDS and/or other confirmatory screen to confirm that he was taking the controlled medications that Respondent had been prescribing to him; and

(b) Respondent failed to document in the medical record any discussion with Patient E about any past history of illicit drug use.

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THIRD CAUSE FOR DISCIPLINE

(Incompetence)

26. Respondent has further subjected his Physician's and Surgeon's Certificate No. G66777 to disciplinary action under sections 2227 and 2234, as defined in section 2234, subdivision (d), of the Code, in that Respondent demonstrated incompetence in his care and treatment of patient A, as more particularly alleged hereinafter:

27. **Patient A**

(a) Paragraphs 11 and 12, above, are hereby incorporated by reference and realleged as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Repeated Acts of Clearly Excessive Prescribing)

28. Respondent has further subjected his Physician's and Surgeon's Certificate No. G66777 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, B, and C, as determined by the standard of the community of physicians and surgeons, as more particularly alleged hereinafter:

29. **Patient A**

(a) Paragraphs 11 and 12, above, are hereby incorporated by reference and realleged as if fully set forth herein.

30. **Patient B**

(a) Paragraphs 13 and 14, above, are hereby incorporated by reference and realleged as if fully set forth herein.

31. **Patient C**

(a) Paragraphs 15 and 16, above, are hereby incorporated by reference and realleged as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Medical Records)

32. Respondent has further subjected his Physician's and Surgeon's Certificate

No. G66777 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, B, C, D, and E, as more particularly alleged hereinafter:

33. **Patient A**

(a) Paragraphs 11 and 12, above, are hereby incorporated by reference and realleged as if fully set forth herein.

34. **Patient B**

(a) Paragraphs 13 and 14, above, are hereby incorporated by reference and realleged as if fully set forth herein.

35. **Patient C**

(a) Paragraphs 15 and 22, above, are hereby incorporated by reference and realleged as if fully set forth herein.

36. **Patient D**

(a) Paragraphs 17, 18, and 23, above, are hereby incorporated by reference and realleged as if fully set forth herein.

37. **Patient E**

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

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

38. Respondent has further subjected his Physician's and Surgeon's Certificate No. G66777 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 10 through 37, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

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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 License No. G66777, 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/or advanced practice nurses;

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

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

DATED: February 13, 2019

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

SD2017802855
Doc.No.71736994

EXHIBIT 2

EXHIBIT 2

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

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., 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

[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

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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 **A C C U S A T I O N**

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

REJI VARGHESE
DEPUTY DIRECTOR

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

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