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

In the Matter of the Second Amended Accusation Against: Kenneth Naoyuki Matsumura, M.D. Physician's and Surgeon's Certificate No. G 20670 Respondent.	Case No. 800-2019-059098

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 December 8, 2023.

IT IS SO ORDERED November 8, 2023.

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 Second Amended Accusation Against:

KENNETH NAOYUKI MATSUMURA, M.D.,

Physician's and Surgeon's Certificate No. G 20670

Respondent.

Agency Case No. 800-2019-059098

OAH No. 2022100485

PROPOSED DECISION

Administrative Law Judge Juliet E. Cox, State of California, Office of Administrative Hearings, heard this matter on August 21 through 23, 2023, by videoconference.

Supervising Deputy Attorney General Greg W. Chambers represented complainant Reji Varghese, Executive Director of the Medical Board of California.

Attorneys Marvin Firestone and Jeff Lewis represented respondent Kenneth Naoyuki Matsumura, who was present throughout the hearing.

The record was held open for respondent to submit a certificate after completing a course in medical record-keeping. A certificate was submitted; it was

marked as Exhibit M and admitted into evidence. The record closed and the matter was submitted for decision on September 6, 2023.

FACTUAL FINDINGS

1. Since July 1, 1971, respondent Kenneth Naoyuki Matsumura, M.D., has held Physician's and Surgeon's Certificate No. G 20670. At the time of the hearing, this certificate was active and was scheduled to expire on May 31, 2025.

2. Acting in his official capacity, the former Executive Director of the Medical Board of California filed an accusation against respondent on August 17, 2022. Respondent requested a hearing. Complainant Reji Varghese then became the Board's Interim Executive Director, and later its Executive Director. Acting in his official capacity, complainant filed a first amended accusation against respondent on February 23, 2023, and a second amended accusation on April 21, 2023.

3. Complainant alleges that the Board should revoke respondent's physician's and surgeon's certificate because of his unprofessional conduct and incompetence in treating three patients for metastatic cancer using inappropriate therapies. Respondent alleges that his therapies were not inappropriate, and also that his care qualified as "alternative or complementary medicine" for which Business and Professions Code section 2234.1 precludes discipline.

Education and Professional Experience

4. According to respondent, he was "one of those boy geniuses" who established a scientific research laboratory before graduating from high school. His

curriculum vitae describes significant laboratory research before 1970, but no peer-reviewed publications resulting from any such work.

5. Respondent graduated from medical school in 1970. He completed one year of postgraduate medical training. Respondent is not board-certified in any medical specialty recognized by the American Board of Medical Specialties, and has not participated in any postgraduate medical training that would make him eligible for any such certification.

6. Between 1971 and 2011, respondent provided primary medical care on a volunteer basis at a clinic in Oakland. The evidence does not establish how frequently or regularly respondent worked in this clinic, or precisely what care he offered.

7. Respondent testified vaguely that he also has engaged in medical "research" since receiving his medical license. He described a laboratory at his home, in which he has at times maintained tissue culture facilities and laboratory animals. No other evidence corroborated this testimony.

8. Respondent also gave vague and conflicting testimony about his private oncology practice. He is in solo practice in Berkeley, without hospital admitting privileges. In an interview with Board investigative staff, respondent said that he established his practice in 1971 and has administered intravenous drug therapy against cancer using a protocol he developed (described in greater detail below in Findings 9 through 11) since 2015. At the hearing, he stated that he used this protocol first in 1992 and has used it consistently since about 2002, on approximately 1,000 patients. In a journal article respondent offered into evidence, he described providing cancer treatment in Ensenada, Mexico (in a "relaxing atmosphere that benefits the patient as they focus on conquering cancer"), since 2001.

"Side-Effect Free Chemotherapy" Protocol

9. Respondent testified, and advertises, that he has developed a novel, highly effective protocol for treating many kinds of cancer. He describes this protocol as "side-effect free chemotherapy," and boasts that it can achieve complete remission even in patients whose cancers have metastasized extensively, without the typical unpleasant or harmful effects of many cancer-treating medications, such as nausea, hair loss, or bone marrow damage.

10. As it relates to the three patients whose care is at issue in this matter, the "side-effect free chemotherapy" protocol involves two drugs. Respondent's records represent[1] that these patients received these drugs intravenously in four-day cycles, roughly every other week.

a. One drug, mesna, is a compound that physicians commonly administer to patients who are receiving either cyclophosphamide or ifosfamide as cancer therapy. These drugs can cause severe bladder irritation, but mesna protects patients' bladders against such irritation.

b. Respondent characterizes mesna's role in his chemotherapy protocol as protecting neutrophil[2]-producing stem cells in patients' bone marrow. He describes mesna as an "antidote" to anti-cancer medication, and attributes the "side-effect free" nature of his protocol to it. Respondent's protocol is to administer mesna on each of

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[1] In light of all evidence in this matter, respondent's medical records are not credible documentation of either his observations or his actions.

[2] A neutrophil is a type of white blood cell that is part of the immune system.

the treatment cycle's four days. Patients receive varying mesna doses, but respondent did not explain either in testimony or in his records how he chooses each dose.

c. The other drug, carboplatin, is a drug that came into use as treatment for some cancers in the late 1980s.[3] Carboplatin impairs cell division in rapidly dividing cells. Its most significant effects, aside from slowing or stopping some cancer cells' replication, are nausea (because of damage to rapidly dividing cells lining the gastrointestinal tract) and thrombocytopenia (low platelet count, because of damage to platelet-producing cells in bone marrow).

d. Respondent administers carboplatin on the treatment cycle's second day. He testified that he calculates a patient's carboplatin dose by referring to laboratory measurements of the patient's kidney function, but not to the patient's body size.

e. Respondent told the three patients whose care is at issue in this matter that he tests the carboplatin he administers, before administering it, to ensure its "potency." He represented to them that this testing was one of many ways in which his chemotherapy protocol would be superior to the protocols that other oncologists had proposed or might propose to them. Respondent also stated in testimony that he performs such testing, describing it as involving tissue culture cells in a laboratory setting. No detailed test protocol or results are in evidence.

11. Respondent offers his patients ondansetron, an anti-nausea medication that became available in the early 1990s and that is commonly used to counter nausea

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[3] Respondent testified that he uses carboplatin not because of its particular efficacy against his patients' cancers, but because its patent has expired, making inexpensive generic versions available.

in cancer patients receiving cytotoxic chemotherapy. Respondent also prescribes either Neupogen or Zarxio, which are drugs that stimulate white blood cell production and that are commonly used to counter bone marrow damage in cancer patients receiving cytotoxic chemotherapy or radiation therapy. Respondent testified, however, that many of his patients do not need either medication because mesna is so effective.

12. Respondent presented no evidence other than his own testimony to support his contention that his "side-effect free chemotherapy" protocol is safe or effective. No formal clinical trials of this protocol ever have occurred, and no reputable peer-reviewed medical journal ever has published an article describing it.[4] As described below in greater detail, all of the patients whose care is at issue in this matter suffered significant pain, as well as nausea and bone marrow damage, during treatment with respondent; and all of them died at about the time that treating physicians other than respondent had predicted they would die.

13. Each of the three patients whose care is at issue in this matter signed a document respondent had prepared, purporting to memorialize the patient's informed consent to "side-effect free chemotherapy."

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[4] Respondent offered an article into evidence that he authored, describing several case studies of patients who had used his protocol with near-miraculous results. Despite the article's anecdotal and promotional nature (and rampant typographical errors), he characterized it as having been published in a reputable peer-reviewed medical journal. This testimony is not credible.

a. The document states that the patient will receive "one or more cytotoxic chemotherapy drugs . . . which will be combined with mesna to protect my body's healthy cells from the chemotherapy, to prevent or reduce side effects."

b. The document identifies respondent as "a physician-scientist who also has developed the world's first bio-artificial liver."[5]

c. The document describes "side-effect free chemotherapy" falsely as having "been studied in a phase 2 trial" that showed "substantial reduction of side effects of chemo agent carboplatin" including protection of "blood circulating levels of platelets and white blood cell neutrophils." It also states that the protocol is "substantially" more likely than "conventional chemotherapy" to cause cancer remission, "and with less side effects."

d. The document states that by signing it, the patient endorses one or both of two statements: "A. I am not currently being offered medical treatment for my cancer, either because all standard medical treatments have failed, or because my oncologist (or other specialist) has determined that there are no proven treatment options for me"; or "B. I have been offered generally accepted medical treatments for my cancer. After reviewing the risks and benefits of those treatments with my doctor(s), I voluntarily chose not to receive them."

e. The document states that no part of respondent's treatment is "yet covered by insurance or Medicare," and that the patient will be fully responsible for

[5] No evidence aside from respondent's statements supports this assertion.

paying respondent as well as for "any tests that may be necessary but are not covered under my health insurance."

14. Complainant presented expert testimony about drug therapies for cancer from three board-certified oncologists. Before reviewing respondent's records in this matter, none of these witnesses had ever heard of respondent's "side-effect free chemotherapy" protocol, or of any similar drug protocol combining strong effectiveness against a wide variety of cancers with a comfortable patient experience.

a. Sara Hurvitz, M.D., is board-certified in internal medicine and medical oncology. Until recently, she served as a professor of medicine and as director of the breast oncology program at the University of California, Los Angeles, medical center. She now is the Senior Vice President of Clinical Research and a professor of medicine at the Fred Hutchinson Cancer Center at the University of Washington.

b. Michael Benjamin, M.D., is board-certified in hematology and medical oncology. He is in private practice as a medical oncologist in Southern California, and also serves as an adjunct clinical instructor of medicine at the University of California, Los Angeles.

c. John Shin, M.D., is board-certified in internal medicine, hematology, and medical oncology. He is an assistant professor of medicine at Loma Linda University, where he provides clinical care and trains medical students and residents in oncology.

15. Drs. Hurvitz, Benjamin, and Shin testified that mesna's only value in cancer treatment is to protect against bladder irritation from cyclophosphamide or ifosfamide. Mesna has no effect on the gastrointestinal tract or bone marrow, no drug interaction with carboplatin, and no independent anti-cancer effect. It is not an "antidote" to anything. This testimony is credible and persuasive.

16. Drs. Hurvitz, Benjamin, and Shin also testified that carboplatin is effective against some cancers but ineffective against others. To calculate an appropriate carboplatin dose for a patient who may benefit from carboplatin, a physician must consider not only the patient's kidney function as measured by laboratory testing but also the patient's age, body mass and surface area, and sex. This testimony also is credible and persuasive.

17. Finally, Drs. Hurvitz, Benjamin, and Shin emphasized that carboplatin is a very dangerous drug that has significant risks for every patient despite its potential benefits for some patients. For this reason, the standard of care among all physicians is that only physicians with postgraduate training in medical oncology should prescribe or administer this drug. A physician without such training who prescribes or administers carboplatin commits an extreme departure from the standard of care. This testimony also is credible and persuasive.

Unprofessional Treatment of Patients 1, 2, and 3

18. The evidence does not establish that respondent's medical practice involves any treatment other than "side-effect free chemotherapy." Detailed records are in evidence regarding three patients respondent treated between 2018 and 2020.

PATIENT 1

19. Patient 1 and her husband lived in Arizona, but traveled to Berkeley approximately twice a month for about a year for respondent to treat Patient 1. They paid respondent more than $100,000, and also incurred travel and lodging costs, for futile care. This experience significantly diminished Patient 1's quality of life during her final year, and continues through traumatic memory to diminish her husband's quality of life.

Treatment and Death

20. Patient 1 contacted respondent first in June 2018. She said that she had learned in July 2010 that she had ductal carcinoma in situ (DCIS) in her left breast, and that she had undergone no treatment for it other than "diet and supplements" and "hyperthermia treatment in Germany." When Patient 1 contacted respondent, her tumor had grown to occupy "most of my left breast and some lymph nodes."

21. In July 2018, before meeting respondent for the first time, Patient 1 underwent a radiologic scan in Arizona to determine the extent to which her cancer might have spread. The radiologist's report states that Patient 1 had "extensive" metastatic cancer in her liver, skeleton, and lymph nodes, and probable metastasis to her lungs.

22. Patient 1 brought the July 2018 radiologist's report summarized in Finding 21 to respondent at her first appointment, at the end of that month. At that appointment, Patient 1 agreed to undergo "side-effect free chemotherapy," and signed a copy of the document described above in Finding 13 purporting to memorialize her informed consent to this protocol. Patient 1's document does not indicate whether she endorsed statement A (failed all prior care), statement B (understood but did not want other care), or both.

23. Respondent referred Patient 1 to Alta Bates Hospital in Berkeley for installation of a venous access port. His referral letter states that the port's purpose would be for Patient 1 to receive "Neutrophil-potentiated Chemotherapy" to treat "Massive left breast cancer with stage 4 spread extensively to the liver and bones." Robert Y. Kim, M.D., placed the port in Patient 1 on July 30, 2018.

24. Respondent's records state that Patient 1 received 21 "side-effect free chemotherapy" treatment cycles between July 30, 2018, and May 23, 2019. Each treatment cycle followed the protocol described generally above in Finding 10.

25. Patient 1 had laboratory blood chemistry testing approximately biweekly between July 2018 and May 2019. Until February 2019, she had no further radiologic scan to evaluate whether her metastatic cancer had grown or spread. Respondent's records occasionally mention Patient 1's physical condition, but do not report that he performed regular complete physical examinations of Patient 1 during her treatment.

26. Patient 1 complained consistently about pain in her left breast or left chest during her treatment. She also reported, and respondent noted, that some of her visibly or palpably swollen lymph nodes became larger during treatment. Nevertheless, respondent's records state that he reassured Patient 1 regularly that the treatment protocol was effective: He told her that he saw "validation that her tumor is responsive," that pain was "proof therapy was affecting her cancer" and that "cancer in lymphatics takes longer to eradicate."

27. On November 19, 2018, Patient 1 had a left mastectomy at a hospital in Arizona. The surgical report states that Patient 1's tumor had invaded "deep to the skeletal muscle" under her breast. Patient 1 provided a copy of the surgical report to respondent.

28. On February 12, 2019, Patient 1 underwent an abdominal ultrasound at Alta Bates Hospital. Respondent had referred her for the ultrasound, describing Patient 1 as having "extensive stage 4 breast cancer involving bones, liver, multiple nodes" and as having been "under immuno-chemotherapy with" respondent. The radiologist who read the ultrasound (Shlomo Leibowich, M.D.) interpreted it as showing "Extensive

hepatic metastatic disease" as well as lymph node inflammation, "right lower quadrant mass[,] and periumbilical mass extending to the left."

29. Respondent knew (although Dr. Leibowich did not) that the report from Patient 1's July 2018 radiological scan did not mention a "right lower quadrant mass" or a "periumbilical mass," but instead stated that the previous radiologist did "not identify nodal metastases within the abdomen or pelvis." Nevertheless, respondent continued after the February 2019 scan to tell Patient 1 that her cancer had not progressed. He wrote in his records that a radiologist he did not name had assured him despite Dr. Leibowich's "non-descript report" that the liver lesions visible on the February 2019 scan were "cysts—benign ones," not malignant metastatic cancer; he testified similarly. This testimony is not credible; moreover, if respondent actually believes for any reason that Patient 1's February 2019 radiologic scan showed her cancer to have regressed rather than progressed, this belief is delusional.

30. During June 2019, Patient 1 did not come to Berkeley for treatment. In early July 2019, however, she was admitted to a hospital in Arizona because of difficulty breathing. A radiologic scan from that hospital admission showed "diffuse metastatic disease involving the liver, visualized axial skeleton, pleura, with bilateral large probably malignant pleural and pericardial effusions."

31. The physicians who treated Patient 1 in Arizona in early July 2019 recommended palliative care, and admission to a skilled nursing facility near Patient 1's home in Arizona. Patient 1 refused this advice, stating that she preferred to return to Berkeley and resume treatment with respondent. One of Patient 1's Arizona physicians documented having spoken to respondent about this plan, and having explained that he did not believe Patient 1 could travel safely. Respondent agreed to help Patient 1 arrange admission to a skilled nursing facility in the Bay Area, however.

32. Patient 1 entered residential skilled nursing care at McClure Post-Acute in Oakland on July 12, 2019. Within about two weeks, she had lost more than five pounds because of poor appetite and difficulty swallowing. After about a month, Patient 1 began experiencing more severe and frequent pain.[6] In addition, as Patient 1 grew weaker from malnutrition and chronic pain, she began requiring more staff assistance to leave her bed.

33. Respondent's records state that Patient 1 received three more "side-effect free chemotherapy" treatment cycles between July 12, 2019, and August 18, 2019, while residing at McClure. The records also state that at the end of at least one of those cycles respondent gave Patient 1 300 milligrams of gemcitabine, a cytotoxic drug that sometimes is used in much larger doses as an adjunct to carboplatin.

34. Respondent wrote in his records, and testified, that he believed during this period that Patient 1's overuse of opioid pain medication was her chief medical problem. He persuaded Patient 1 and her husband that Patient 1 should reduce her consumption of such medication, on the theory that opioid medication would interfere with her chemotherapy treatment. As a pain-control alternative, he referred Patient 1 to a hypnotherapist, who respondent understood to have told Patient 1 that her constant chest pain derived from "her childhood," rather than from a breast tumor that had metastasized through her chest wall. Respondent's testimony that he believed Patient 1 to be overusing opioid pain medication in July and August 2019 is not credible; moreover, if respondent actually believes any of the statements he made in

[6] Liver and bone metastases cause excruciating pain.

testimony or in his records regarding Patient 1's pain and use of pain medication in July and August 2019, his beliefs are both cruel and delusional.

35. McClure staff physician Francesco Isolani, M.D., wrote in Patient 1's chart on August 20, 2019, "breast CA—pain, palliative tx not desired.....poor prognosis pt in denial, defer all care to oncologist." Deferring care to respondent was unwise: Respondent told Patient 1 and her husband at about this same time that Patient 1 did not need further treatment because her cancer was fully in remission. Based chiefly on respondent's advice, and despite advice from Dr. Isolani and from Patient 1's Arizona physicians, Patient 1 and her husband believed in late August 2019 that her two chief medical challenges were opioid addiction and unintentional weight loss, and that by ending opioid use and regaining body mass she would recover her health enough to leave the skilled nursing facility and return home.

36. On August 26, 2019, Patient 1 arrived at Summit Hospital in Oakland by ambulance, intending to request a gastrointestinal feeding tube. Hospitalist Mary Kathryn McClellan, M.D., admitted Patient 1 to the hospital. Dr. McClellan's medical note states that imaging showed Patient 1 to have "extensive metastatic disease including blastic osseous metastases involving nearly the entire visualized skeleton, numerous hepatic metastases and lung metastases, and a large left pleural effusion with collapse of the left lower lobe." Patient 1 died on August 30, 2019.

37. Dr. McClellan testified credibly that Patient 1 was "quite sick" when Dr. McClellan met her, but that neither Patient 1 nor her husband seemed to understand that Patient 1 would die soon from advanced metastatic cancer. Because Dr. McClellan did not understand what treatment Patient 1 had been receiving, or why she had continued to receive it even as her disease worsened, Dr. McClellan telephoned respondent. Respondent told Dr. McClellan that Patient 1's "large doses of morphine"

made further chemotherapy impossible, which he deemed unfortunate because his protocol had been so successful for Patient 1. Dr. McClellan immediately reported her concerns about respondent to the Board.

38. Respondent testified that he believes Patient 1 to have died from a pulmonary embolism and opioid addiction, and that he believes that Patient 1 still would be alive if she had not become addicted to opioids and discontinued treatment with him. This testimony is not credible; moreover, if respondent actually does believe that Patient 1 died from any cause other than metastatic cancer, his belief is delusional.

Unprofessional and Incompetent Conduct

39. In light of the opinions summarized above in Findings 16 and 17 and the training (or lack thereof) summarized in Findings 4 and 5, respondent's use of carboplatin to treat Patient 1 was an extreme departure from the standard of care. In addition, according to Dr. Hurvitz's persuasive testimony, respondent's use of gemcitabine was an extreme departure from the standard of care (because of his lack of oncology training relating to cytotoxic chemotherapy medications), and his underdosing of gemcitabine was a simple departure from the standard of care. Finally, in light of the opinions summarized above in Finding 15, respondent's use of mesna for Patient 1 as an "antidote" to carboplatin was both incompetent and an extreme departure from the standard of care.

40. Dr. Hurvitz testified credibly and persuasively that the standard of care for treating metastatic breast cancer is to monitor the patient's physical condition closely during treatment, with physical examinations and imaging studies; to document the patient's condition thoroughly; and to discontinue treatment if it is not

effective. According to her, "[c]ontinuing a chemotherapy regimen in the face of unequivocal progression of disease is an extreme departure from the standard of care." The course of treatment summarized in Findings 22 through 36 was incompetent, and was an extreme departure from the standard of care. In addition, even if respondent conducted more thorough physical examinations than his records reflect, his failure to document those examinations of Patient 1 regularly during treatment also would have been an extreme departure from the standard of care.

41. Dr. Hurvitz testified credibly and persuasively that an important component of the modern standard of care for treating cancers that originate in the breast is to determine whether the tumor cells express hormone receptors for estrogen or human epidermal growth factor. Drugs are available that are highly effective in many patients against cancers that express either or both of these hormone receptors, but ineffective against cancers that do not. Failure to evaluate a breast tumor's hormone receptiveness, and to tailor treatment accordingly, is incompetent and is an extreme departure from the standard of care.

42. Respondent's records do not reflect whether Patient 1 ever had undergone hormone receptor testing for her cancer, and respondent did not order any. Respondent's records also do not reflect that respondent advised Patient 1, or confirmed with her that someone else had advised her, about the treatment choices that such testing might offer her. Respondent's testimony did not demonstrate that he has any knowledge whatsoever about this topic. With respect to hormone receptor testing and to hormonally appropriate treatment, respondent's care for Patient 1 was incompetent, and was an extreme departure from the standard of care.

43. Dr. Hurvitz also testified credibly and persuasively that for patients with skeletal metastases, such as Patient 1, drugs are available to stabilize and strengthen

bones. These drugs do not eliminate metastatic cancer, but can prevent painful fractures that otherwise may occur as cancer causes the bones' structure to disintegrate. Failure to recommend such medication to a patient with breast cancer that has metastasized to the skeleton (but who does not have overt fractures) is a simple departure from the standard of care.

44. Respondent's records do not reflect that respondent advised Patient 1, or confirmed with her that someone else had advised her, that bone-stabilizing drugs might be appropriate to preserve her quality of life. Respondent's testimony did not demonstrate that he has any knowledge whatsoever about this topic. To the contrary, respondent testified that he believes that bone-stabilizing medication for Patient 1 would have impaired the effectiveness for her of his "side-effect free chemotherapy" protocol. With respect to Patient 1's skeletal metastases, respondent's care for Patient 1 was a simple departure from the standard of care.

45. Dr. Hurvitz testified credibly and persuasively that the standard of care where mesna is an appropriate component of cancer therapy is to document each dose in milligrams. She stated that respondent's practice of documenting Patient 1's mesna dose only in milliliters, without referencing its concentration to permit conversion to milligrams, was a simple departure from the standard of care. This opinion is consistent with respondent's records, and is persuasive.

46. Patient 1's medical records show her to have had medical insurance, and Dr. Hurvitz testified credibly that medical insurance carriers routinely cover carboplatin treatment if it is medically appropriate. They do not cover "potency" testing, however (as respondent described, summarized in Finding 10.e), because it is unnecessary. Dr. Hurvitz stated her opinion that charging patients for unnecessary procedures is an extreme departure from the standard of care.

47. Respondent admitted in his interview with Board investigators and in testimony, however, that he demanded and received cash payment from Patient 1, advised her that insurance would not pay or reimburse for her treatment with him, and incorporated the significant cost for his carboplatin "potency" testing into the price. In light of Dr. Hurvitz's persuasive opinion, this conduct is an extreme departure from the standard of care.

PATIENT 2

48. Patient 2 and her husband lived in Oakland. She sought treatment from respondent after having received treatment through Kaiser Permanente, where she also had worked before her illness. Respondent's treatment for Patient 2 cost her and her family more than $60,000. It diminished Patient 2's and her family's quality of life during her final six months, and hastened her death.

Treatment and Death

49. Patient 2 contacted respondent first in October 2019. She explained that she had undergone surgery and chemotherapy in 2016 for colon cancer, but had learned in July 2019 that her cancer had metastasized to her liver and lungs. Despite additional chemotherapy treatments at Kaiser Permanente in fall 2019, follow-up radiologic scans in October and November 2019 showed that Patient 2's liver and lung metastases had enlarged.

50. Respondent and Patient 2 exchanged email for several weeks before her first in-person visit.

a. Respondent told Patient 2 that "the reason our therapy is superior to ordinary chemo is because we use strategies to protect the body's immune cells called

the neutrophils." As noted above in Findings 11 and 15, respondent's implication that his protocol involves any neutrophil-protecting measures that "ordinary chemo" does not involve is false.

b. He also told her that he had treated other Kaiser Permanente patients, whose "oncologists are offended that their members are going out of Kaiser—they don't realize people don't really like to die and ordinary chemo is mostly toxicity and very little benefit."

c. Respondent told Patient 2 that treatment would cost between $5,600 and $7,700 per treatment cycle, "depending on complexity," and ascribed the majority of this cost to testing the "chemo agents" for "potency." When Patient 2 expressed concern about the cost of treatment, respondent's first answer was that he would lose money if he charged less than $6,500 per treatment cycle. When she then expressed interest in continuing treatment at Kaiser Permanente, respondent offered Patient 2 a "discount": $7,200 per treatment for the first six cycles, and $5,600 per treatment thereafter. Patient 2 accepted this offer.

51. Patient 2 and respondent met in person on November 18, 2019. His notes from their meeting say that he spent two hours discussing his protocol with her, including "side effects," and that the treatment plan would be to switch "from traditional chemo" to his "side-effect free" protocol.

52. Patient 2's treating oncologist at Kaiser Permanente (Ashok Pai, M.D.) had recommended a further chemotherapy regimen to Patient 2 in November 2019. Neither respondent's records nor his testimony show that he ever knew precisely what therapy Dr. Pai had recommended to Patient 2, or compared its potential risks and benefits for Patient 2 (accurately or otherwise) against the potential risks and benefits

to her of the "side-effect free chemotherapy" protocol he proposed. In addition, neither respondent's records nor his testimony show that he conferred in any way with Dr. Pai, such that Dr. Pai could give Patient 2 accurate information comparing the potential risks and benefits for her of the therapy he had recommended against the potential risks and benefits of the therapy respondent proposed.

53. Patient 2 agreed on November 18, 2019, to undergo "side-effect free chemotherapy," and signed a copy of the document described above in Finding 13 purporting to memorialize her informed consent to this protocol. Patient 2's document does not indicate whether she endorsed statement A (failed all prior care), statement B (understood but did not want other care), or both.

54. Respondent's records state that Patient 2 received 10 "side-effect free chemotherapy" treatment cycles between November 18, 2019, and April 8, 2020. Each treatment cycle followed the protocol described generally above in Finding 10.

55. Patient 2 experienced consistent abdominal pain and nausea throughout this period, which worsened in March 2020. Respondent's records occasionally mention Patient 2's physical condition, but do not report that he performed regular complete physical examinations of Patient 2 during her treatment.

56. Patient 2 had laboratory blood chemistry testing approximately biweekly between November 2019 and April 2020. Until January 2020, she had this testing through Kaiser Permanente, and brought the results to respondent herself. In February and March 2020, Patient 2 had most of this testing through a different laboratory, ordered by respondent.

a. The testing between November 2019 and January 2020 through Kaiser Permanente included measuring Patient 2's blood concentration of carcinoembryonic

antigen (CEA), which Patient 2 and Dr. Pai understood as an indicator of her overall bodily cancer load. This concentration rose steadily, from 236.7 nanograms per milliliter on November 10, 2019, to 566.8 nanograms per milliliter on January 22, 2020. Respondent's records include some of these test results, but do not reflect that he considered the results or discussed them with Patient 2.

b. On January 22, 2020, Patient 2's platelet count was very low. Respondent noted the result in his records, but nevertheless recorded that he administered carboplatin to Patient 2 on January 28, 2020. A repeat count on February 3, 2020, was only slightly higher, and showed as well that Patient 2 was anemic. Respondent recommended that Patient 2 go to the Kaiser Permanente emergency department, where she received a whole blood transfusion. Respondent recorded that he administered more carboplatin to Patient 2 on February 11, 2020.

c. On March 10, 2020, respondent ordered only a comprehensive metabolic panel for Patient 2, not a blood cell and platelet count. His records summarize her platelet count in mid-March as "good," however, and he again recorded administering carboplatin to her on March 17, 2020. In fact, Patient 2 also gave a blood sample at Kaiser Permanente on March 10, 2020, for a blood cell and platelet count, which again showed that her platelet count was dangerously low.

d. Respondent did order a blood cell and platelet count for Patient 2 on March 25, 2020, which revealed that her platelet count was critically low. Respondent's records include this laboratory result but do not reflect what, if anything, he did about it. On March 27, 2020, however, Patient 2 received a platelet transfusion in the Kaiser Permanente emergency department, after her primary care provider received a laboratory report showing that she had almost no circulating platelets.

e. Respondent ordered another blood cell and platelet count for Patient 2 on April 2, 2020. This test again showed her to have almost no circulating platelets. Kaiser Permanente records, but not respondent's records, state that respondent advised Patient 2 to go again to the Kaiser Permanente emergency department for a platelet transfusion, which she did on April 4, 2020. Respondent then documented administering more carboplatin to Patient 2 on April 7, 2020, despite noting that Patient 2 recently had received "2 units of platelets and one of blood."

57. Patient 2 had ultrasound abdominal imaging at Kaiser Permanente on January 7, 2020, that showed "many hepatic masses corresponding to known liver metastases." Respondent received this report and dismissed it as uninformative. He ordered similar imaging at Alta Bates Hospital in Berkeley on March 26, 2020, which also showed that Patient 2's liver was "severely enlarged," but that "[d]iscrete hepatic masses [were] difficult to delineate."

58. Patient 2 was hospitalized at the Kaiser Permanente hospital in Oakland between February 23 and 29, 2020. During this admission, on February 23, 2020, she had a radiologic scan that showed her liver and lung metastases to have grown. This report is not in respondent's records, but Kaiser Permanente records state that physicians there described it to respondent. These records also reflect that Patient 2 "insisted on leaving the hospital so that she could continue" in respondent's care.

59. Alyssa Cowell Luddy, M.D., a member of Patient 2's Kaiser Permanente care team during her February 2020 admission, wrote a chart note saying that she spoke to respondent on February 24, 2020, about Patient 2's condition and he insisted that her cancer was shrinking rather than growing. Dr. Luddy reported the team's concerns about respondent to the Board on February 27, 2020.

60. Despite the matters summarized in Findings 56.a and 57, respondent also assured Patient 2 and her husband repeatedly between November 2019 and March 2020 that his treatment for her was causing her cancer to shrink rather than to grow. As late as March 17, 2020, respondent documented having told Patient 2 that her severe pain was "indicative that we are hitting the target." In testimony, respondent endorsed these statements, stating that he "became encouraged" about Patient 2's treatment because she experienced such severe upper abdominal pain. As for Patient 1, respondent's testimony that he believed Patient 2's cancer to have regressed, rather than to have progressed, between November 2019 and March 2020 is not credible; and if he actually believes so, he is delusional.

61. When Patient 2 arrived at respondent's office on February 29, 2020, to begin her eighth treatment cycle, respondent noted in her record that she "came directly from hospital," but not how long she had been there or why. She was so weak that respondent had to meet her at the curb with a wheelchair to escort her into the office. The next day, respondent documented administering carboplatin to Patient 2.

62. On April 6, 2020, respondent administered mesna to Patient 2 while she remained in her car, because she was unable because of weakness or pain to move to respondent's office. As noted above in Finding 56.e, his records show that she received carboplatin the next day.

63. On April 9, 2020, both Patient 2 and her husband spoke by telephone with Kaiser Permanente palliative care physician Bonnie Gar-Mon Chen, M.D. Dr. Chen's note regarding the call describes Patient 2 as "screaming 'Please! Get me to the ER! I'm in pain!'" while her husband described Patient 2 as "delirious" and asked Dr. Chen to refer Patient 2 for physical therapy. Dr. Chen advised Patient 2's husband to bring Patient 2 to the hospital emergency department. She noted, "I was frank with

husband that patient is dying and likely has days, and she is suffering. He seems to be in complete denial or not processing what I'm saying."

64. Patient 2 again was admitted to the Kaiser Permanente hospital in Oakland on April 9, 2020. She insisted on remaining in the hospital because she feared that if she returned home, even with hospice care, her husband would insist that she resume "aggressive care" to extend her life. She also revoked her husband's health care power of attorney, and instructed hospital staff members to refuse to allow her husband to visit her. Patient 2 died on April 13, 2020.

65. Respondent testified that he believes Patient 2 to have died because treating physicians at Kaiser Permanente were "so stingy" with platelets. He believes, and persuaded Patient 2's husband to believe, that she should have received further platelet transfusions and nutritional support during her April 2020 hospital admission, rather than the comfort care she requested, because if she had regained strength she could have continued "side-effect free chemotherapy" until it had cured her cancer. This testimony is not credible. Also, if respondent actually does believe that Patient 2 died from any cause other than metastatic cancer, his belief is delusional. Finally, whether dishonest or delusional, respondent's efforts to encourage Patient 2 and her husband to pursue further treatment rather than palliative care were cruel.

Unprofessional and Incompetent Conduct

66. In light of the opinions summarized above in Finding 16 and 17 and the training (or lack thereof) summarized in Findings 4 and 5, respondent's use of carboplatin to treat Patient 2 was an extreme departure from the standard of care. In addition, in light of the opinions summarized above in Finding 15, respondent's use of

mesna for Patient 2 as an "antidote" to carboplatin was both incompetent and an extreme departure from the standard of care.

67. Dr. Benjamin testified credibly and persuasively that the standard of care for treating metastatic colon cancer is to monitor the patient's physical condition closely during treatment, with physical examinations and imaging studies; to document the patient's condition thoroughly; and to discontinue treatment if it is not effective. He believes that no reasonable physician would have treated Patient 2 as respondent did, because "clinicians must offer treatment choices that are not futile" rather than offering "false hope" that increases rather than decreases dying patients' suffering. The course of treatment summarized in Findings 54 through 62 was incompetent, and was an extreme departure from the standard of care.

68. Dr. Benjamin testified credibly that although carboplatin is an effective treatment for some cancers, no clinical evidence ever has shown carboplatin to be effective against metastatic colon cancer. For this reason as well, he deems respondent's use of carboplatin for Patient 2 to have been an extreme departure from the standard of care. This opinion is persuasive.

69. Dr. Benjamin testified credibly that giving cytotoxic chemotherapy to a patient who is too weak to leave her car is an extreme departure from the standard of care. In addition, giving cytotoxic chemotherapy intravenously in a car, rather than in a clean, controlled clinical environment, is an extreme departure from the standard of care regardless of the patient's strength. In light of this persuasive opinion, respondent committed extreme departures from the standard of care with respect to Patient 2 by giving her carboplatin on March 1, 2020, and on April 7, 2020.

70. Dr. Benjamin also testified credibly and persuasively that continuing carboplatin therapy for a patient with clear evidence of thrombocytopenia, as respondent did for Patient 2 (summarized in Finding 56) is an extreme departure from the standard of care, reflecting reckless disregard for patient safety as well as gross incompetence.

71. Dr. Benjamin testified credibly that respondent's failure to document physical examinations of Patient 2, and in particular his failure to document her weight and to intervene as her weight and apparent nutritional status declined, was an extreme departure from the standard of care. He also testified credibly that respondent's failure to document referring Patient 2 for platelet transfusions was a simple departure from the standard of care. These opinions are consistent with respondent's records, and are persuasive.

72. Like Dr. Hurvitz, Dr. Benjamin believes that testing carboplatin for "potency" is unnecessary. He also observes that the absence of any testing records suggests that respondent may not even have conducted the testing for which he charged Patient 2. His persuasive opinion is that whether respondent actually did such testing or not, he committed an extreme departure from the standard of care by representing to Patient 2 that she needed to pay for this process.

PATIENT 3

73. Patient 3 lived in San Diego, but traveled to Berkeley approximately twice a month for about five months for respondent to treat her. Despite self-reported financial hardship, she paid respondent about $30,000, and also incurred travel and lodging costs, for futile care. This experience significantly diminished Patient 3's quality of life during her final year.

Treatment and Death

74. Patient 3 contacted respondent for the first time in June 2019. She told him that she had received a diagnosis of pancreatic cancer in October 2017. Patient 3 had received chemotherapy and radiation therapy in San Diego, but learned in June 2019 that her cancer had metastasized.

75. Patient 3 corresponded by email with respondent for a few weeks about the prospect that he might treat her. She expressed concern about the price of treatment, travel, and lodging, to which respondent answered that he had "asked our billing"[7] and "was told" that he could discount her treatment cost to $4,200 per cycle.

76. Respondent and Patient 3 met for the first time on July 29, 2019. She agreed to undergo "side-effect free chemotherapy," and signed a copy of the document described above in Finding 13 purporting to memorialize her informed consent to this protocol. Patient 3's document does not indicate whether she endorsed statement A (failed all prior care), statement B (understood but did not want other care), or both.

77. Respondent's records do not reflect what information, if any, Patient 3 sent or brought to him about her prior treatment in San Diego. They also do not reflect that respondent ever conferred in any way with other physicians who had treated or who were treating Patient 3. For this reason, neither respondent's records nor his testimony show that he ever compared (accurately or otherwise) the potential risks and benefits for Patient 3 of any therapy she might receive by continuing

[7] Respondent does not have a billing service or any administrative employees.

treatment with her San Diego team against the potential risks and benefits to her of the "side-effect free chemotherapy" protocol he proposed.

78. According to respondent's records, Patient 3 had seven "side-effect free chemotherapy" treatment cycles between July 29, 2019, and November 8, 2019, conforming generally to the protocol described above in Finding 10.

79. Patient 3 complained regularly of abdominal pain and nausea during her treatment, and her weight dropped steadily. Respondent's records occasionally mention Patient 3's physical condition, but do not report that he performed regular complete physical examinations of Patient 3 during her treatment.

80. In September and October 2019, Patient 3 began experiencing greater back pain, and learned from radiologic scanning in San Diego that she had at least one vertebral fracture. Respondent's notes from her visit to him on October 7, 2019, acknowledge this development, but do not reflect that he counseled Patient 3 about it or changed his treatment course in any way.

81. Respondent did not order any radiologic imaging for Patient 3 while he treated her.

82. Patient 3 had laboratory blood chemistry testing regularly between July and November 2019. Respondent's records include only a few laboratory printouts from these tests, but indicate that Patient 3 also either showed or told him results from testing at laboratories in San Diego.

a. Patient 3 had regular tests of her blood concentration of a protein known as CA19-9. Such tests are routine during pancreatic cancer treatment, because higher

blood concentrations of CA19-9 correlate with greater pancreatic cancer burden. These concentrations rose significantly during Patient 3's treatment with respondent.

b. Patient 3 had regular blood cell and platelet counts. In mid-August 2019, she had a low platelet count and anemia (likely caused by gastrointestinal bleeding). In September 2019, her platelet count fell further, and respondent's notes indicate that he did not treat Patient 3 in late September 2019 because of her low platelet count. Nevertheless, respondent's records show that he gave carboplatin to Patient 3 in early November 2019, when her platelet count remained similarly and dangerously low.

c. On July 30, 2019, and September 10, 2019, respondent took blood samples from Patient 3 and sent them to a German laboratory to test her blood concentration of "circulating tumor cells." The two results were identical.

83. Respondent prescribed Zarxio to Patient 3 in September 2019. His records do not reflect why, and they do not reflect what if any instructions he gave to Patient 3 about when or how to use this medication.

84. As he had for Patients 1 and 2, respondent told Patient 3 regularly during treatment that he believed that her cancer was regressing. His notes state that he told her in early September and in early October that her increasing CA19-9 concentrations were good signs. He also testified that Patient 3's persistent pain indicated to him that treatment was effective. Respondent's testimony that he believed Patient 3's cancer to have regressed, rather than to have progressed, between July and November 2019 is not credible; and if he actually believed or believes so, he was or is delusional.

85. On November 5, Patient 3 was too weak to come to respondent's office to receive mesna. He came to her lodging on a "house call," and administered carboplatin to her the next day.

86. When Patient 3 returned to San Diego after receiving mesna from respondent on November 8, 2019, she went directly to a hospital emergency department complaining of severe back pain. She returned to the hospital emergency room on November 12 and was diagnosed with a small bowel obstruction.

87. Patient 3 never returned to respondent for further treatment. She moved from San Diego to Oregon to be nearer to her husband and children, and died in February 2020. Her husband filed a complaint about respondent with the Board in April 2020.

88. Respondent testified that he believes Patient 3 to have died because she abandoned her treatment with him despite its success. This testimony is not credible. Also, if respondent actually does believe that further "side-effect free chemotherapy," might have cured Patient 3's metastatic pancreatic cancer, this belief is delusional.

Unprofessional and Incompetent Conduct

89. Dr. Shin testified credibly that no clinical evidence ever has shown carboplatin therapy, in the manner respondent provided it, to be effective against metastatic pancreatic cancer. His opinion that the course of treatment summarized in Findings 78 through 85 was an extreme departure from the standard of care is persuasive.

90. Dr. Shin also testified credibly that neither mesna nor Zarxio has a routine role in treating metastatic pancreatic cancer. Although Zarxio may be appropriate for some patients whose therapy impairs their neutrophil production, Dr. Shin saw no evidence in respondent's records to support its use for Patient 3. Providing these drugs to Patient 3 exposed her to their risks, with no corresponding benefits, and was an extreme departure from the standard of care. This opinion also is persuasive.

91. Dr. Shin testified credibly and persuasively that the standard of care for treating metastatic pancreatic cancer is to monitor the patient's treatment response closely, particularly using both imaging studies and blood testing, and to discontinue futile therapy.

a. The German "circulating tumor cells" test that respondent ordered has not demonstrated clinical effectiveness, according to Dr. Shin's credible testimony.

b. Although respondent attended to Patient 3's CA19-9 level, Dr. Shin deems respondent's stated belief that its increase reflected treatment effectiveness, rather than treatment failure, to be incompetent.

c. Dr. Shin stated that imaging studies are more important than blood testing for assessing whether treatment is effective. Respondent's failure to order any was a departure from the standard of care.

d. Respondent's stated belief that Patient 3's disease had regressed and that further "side-effect free chemotherapy" was appropriate represents "a profound deficit in clinical judgment."

For all these reasons, Dr. Shin deems the course of treatment summarized in Findings 78 through 85 to have been an extreme departure from the standard of care. This opinion is persuasive.

92. Finally, Dr. Shin testified credibly and persuasively that the standard of care for any medical practitioner is to communicate truthfully with patients about their own conditions and about their treatment options. For the reasons summarized in Findings 12, 13.c, 75, 77, and 84, his opinion that respondent committed extreme

departures from the standard of care by lying to Patient 3 about "side-effect free chemotherapy" and about her own medical condition is persuasive.

Treatment of Additional Patients

93. Respondent offered testimony from one patient and from family members of two other patients, and a letter from a fourth patient. These persons' testimony suggested that respondent's treatment for these patients was similar in its incompetence and unprofessionalism to his treatment of Patients 1, 2, and 3.

94. Patient B.A. testified that he received "side-effect free chemotherapy" from respondent for bladder cancer and later for colon cancer. After learning in 2015 that he had bladder cancer, B.A. consulted several oncologists, all of whom recommended the same "cookie cutter" chemotherapy protocol. B.A. elected instead to pursue "side-effect free chemotherapy" with respondent, because respondent persuaded B.A. that respondent had a "really good track record" with a customized protocol that would be "more powerful than standard chemo with less side effects." B.A. later returned to respondent for more "side-effect free chemotherapy" when B.A. developed a colon tumor. He believes himself currently to be cancer-free.

95. C.M. and L.M. testified regarding respondent's treatment for their late daughter, and wrote a letter summarizing their opinions regarding respondent. C.M.'s and L.M.'s daughter had breast cancer, and refused all conventional treatment. She consulted respondent in September 2019 and died in September 2020. Beginning in spring 2020, respondent came to their home in Tracy to administer "side-effect free chemotherapy" to this patient. C.M. recalled these house calls as an accommodation relating to the COVID-19 pandemic, but L.M. recalled the house calls as having occurred because their daughter was in too much pain from bone metastases to travel

by car between Tracy and Berkeley. C.M. and L.M. understand their daughter's breast cancer to have been in remission as of early 2020. They believe that she died not from breast cancer but from congenital "auto-immune thrombocytopenia," which no physician had identified before their daughter began treatment with respondent but which caused her to be "unable to produce blood platelets in sufficient amounts to keep her alive."

96. D.R. testified regarding respondent's treatment for her late husband, and wrote a letter summarizing her opinion regarding respondent. D.R.'s husband learned in September 2021 that he had a fast-growing, invasive brain tumor. He consulted oncologists at Memorial Sloan-Kettering Cancer Center and Columbia University Irving Medical Center in New York, and at the Dana-Farber Cancer Institute in Boston, who recommended radiation therapy but advised him that his prognosis for long-term survival was poor. Upon advice from a nutritional adviser (a "keto specialist"), and after being persuaded by respondent that the "side-effect free chemotherapy" protocol had a much greater likelihood of success than the treatments proposed by physicians at any of the three East Coast centers they had consulted, D.R. and her husband elected to relocate from New York to Berkeley. D.R.'s husband received treatment from respondent between October 2022 and January or February 2023, during which time D.R.'s husband became physically weak enough that respondent had to come to their hotel to treat him rather than asking him to come to respondent's office. D.R. and her husband believed respondent to have cured the cancer, but D.R.'s husband developed aspiration pneumonia and died after a six-week hospitalization.

97. A letter from patient D.K. praised respondent's care, without identifying precisely when or for what cancer he treated her. A note accompanying this letter signed by D.K.'s friend states that D.K. died soon after writing it.

Additional Evidence

98. As summarized in Findings 23, 28, 35, 36, 56 through 59, 80, and 86, Patients 1, 2, and 3 received treatment from other California medical providers while also receiving sham treatment from respondent. Likewise, as summarized in Finding 8, respondent professes to have been offering his sham treatment for about 20 years, to hundreds of patients. The evidence does not establish that any other members of the California medical community before Dr. McClellan had reported concerns about respondent's practice to the Board, however.

99. Although all patients whose care was in evidence during this hearing already were terminally ill with metastatic cancer when respondent began treating them, respondent testified that ordinarily he refuses treatment to terminally ill patients. This testimony is not credible. Rather, the evidence in aggregate shows that respondent preys on vulnerable patients and their families by exploiting their fear and denial about impending death to extract payment for worthless treatments. This conduct is despicable.

100. Moreover, if respondent had treated patients whose cancers were or might have been curable when they began treatment with respondent, his treatment would have caused actual harm to these patients by encouraging them to substitute his ineffective treatment for potentially curative treatment. Respondent's testimony about his patient selection demonstrated no insight into the profound public health hazard his practice represents.

Costs

101. Since January 1, 2022, the Board has incurred $9,410.50 in costs for investigative services relating to this matter. Complainant's claim for reimbursement of

these costs is supported by a declaration that complies with California Code of Regulations, title 1, section 1042, subdivision (b)(1). These costs are reasonable.

102. Since January 1, 2022, the Board has incurred $26,300.00 in costs for legal services provided to complainant by the California Department of Justice in this matter. Complainant's claim for reimbursement of these costs is supported by a declaration that complies with California Code of Regulations, title 1, section 1042, subdivision (b)(2). These costs are reasonable.

LEGAL CONCLUSIONS

1. The Board may discipline respondent's physician's and surgeon's certificate only upon clear and convincing proof, to a reasonable certainty, of the facts establishing cause for discipline. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence supports the factual findings above.

Causes for Discipline

2. The Board may suspend or revoke respondent's physician's and surgeon's certificate if he has engaged in unprofessional conduct. (Bus. & Prof. Code, §§ 2227, 2234.) Unprofessional conduct includes medical practice reflecting gross negligence (acts involving extreme departures from the professional standard of care), repeated negligence (simple departures from the professional standard of care), or incompetence. (Bus. & Prof. Code, § 2234, subds. (b), (c), (d).)

3. Respondent prescribed and administered carboplatin and gemcitabine to Patient 1 negligently, incompetently, and without proper training, as summarized in

Findings 17, 24, 33, 39, 41, and 42. He continued cytotoxic chemotherapy for Patient 1 even though her cancer was advancing rather than responding favorably to treatment, as summarized in Findings 21, 26, 28 through 30, 32, 33, and 40. He failed to document Patient 1's condition, failed to document her treatment fully or accurately, and failed either to give or to document giving accurate information to the patient about her treatment choices, all as summarized in Findings 22, 25, 40, 42, and 44. He failed to address Patient 1's bone metastases competently, as summarized in Findings 21, 43, and 44. He charged Patient 1 excessive fees for useless testing, as summarized in Findings 19, 46, and 47. In all, respondent's conduct with respect to Patient 1 was incompetent, repeatedly and grossly negligent, and cruel. It constitutes cause to revoke his physician's and surgeon's certificate.

4. Respondent prescribed and administered carboplatin and mesna to Patient 2 negligently, incompetently, and without proper training, as summarized in Findings 17, 54, 66, and 68. He continued cytotoxic chemotherapy for Patient 2 even though her cancer was advancing rather than responding favorably to treatment, as summarized in Findings 55, 56.a, 57, 58, 60, and 67, and even though she had severe thrombocytopenia, as summarized in Findings 56.b through 56.e and 70. He treated Patient 2 in an unsafe setting (a car), and when she was too weak to support treatment, as summarized in Findings 61, 62, and 69. Respondent failed to document Patient 2's condition, failed to document her treatment fully or accurately, and failed either to give or to document giving accurate information to the patient about her treatment choices, all as summarized in Findings 50.a, 51, 52, 55, 60, and 71. He charged Patient 2 excessive fees for useless testing that he may not even have performed, as summarized in Findings 10.e, 48, 50.c, and 72. In all, respondent's conduct with respect to Patient 2 was incompetent, repeatedly and grossly negligent, and cruel. It constitutes cause to revoke his physician's and surgeon's certificate.

5. Respondent prescribed and administered carboplatin and mesna, and prescribed Zarxio, to Patient 3 negligently and incompetently, as summarized in Findings 17, 78, 83, 89, and 90. He failed to use appropriate measures to monitor Patient 3's response to treatment, and misinterpreted the measures he did use, as summarized in Findings 79 through 82, 84, and 91. Respondent lied to Patient 3, as summarized in Findings 75, 77, 84, and 92. In all, respondent's conduct with respect to Patient 3 was incompetent, repeatedly and grossly negligent, and cruel. It constitutes cause to revoke his physician's and surgeon's certificate.

6. A physician's failure to maintain adequate and accurate patient care records is unprofessional conduct. (Bus. & Prof. Code, § 2266.) The matters summarized with respect to Patients 1, 2, and 3 in Findings 25, 29, 40, 42, 45, 52, 55, 56, 61, 71, 77, 79, and 83 constitute cause to revoke respondent's physician's and surgeon's certificate.

Alternative or Complementary Medicine

7. Respondent contends that his care for Patients 1, 2, and 3 was not unprofessional or incompetent, but rather qualified as "alternative or complementary medicine" for which Business and Professions Code section 2234.1 precludes discipline. This argument is meritless.

8. In the first place, Business and Professions Code section 2234.1, subdivision (b), defines "alternative or complementary medicine" as treatment that is not only uncommon, but also offers "a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method." As summarized in Findings 9 through 12 and 14 through 17, respondent's "side-effect free chemotherapy" is uncommon only because it is an incompetent use of

standard cytotoxic chemotherapy agents, not because it is a uniquely insightful use of these agents. Moreover, and as summarized in Finding 11, to the extent that any of respondent's patients experience "side-effect free" carboplatin treatment (which Patients 1, 2, and 3 certainly did not), they do so because they receive the same anti-nausea and pro-marrow medications they would receive from any oncologist. Finally, and as summarized in Findings 14, 39, 41, 43, 67, 68, 89, and 90, this protocol offered no potential for therapeutic gain for any of Patients 1, 2, or 3. Instead, these drugs risked increasing these patients' discomfort and weakening their already-frail bodies for no reason. These facts confirm that Business and Professions Code section 2234.1 does not apply to the sham treatment respondent offered.

9. In the second place, "alternative or complementary medicine" is exempt from discipline only if the physician rendering this treatment has performed a "good-faith prior examination of the patient." (Bus. & Prof. Code, § 2234.1, subd. (a)(1).) As summarized in Findings 22, 25, 51, 52, 55, 77, and 79, respondent neither conducted any such examination for any of Patients 1, 2, or 3 nor obtained records about them from other providers that would have allowed him to evaluate their conditions thoroughly, prudently, and accurately.

10. In the third place, "alternative or complementary medicine" is exempt from discipline only if the physician rendering this treatment has secured the patient's consent to the treatment after giving the patient complete, accurate information both about conventional treatments for the patient's illness and about the potential risks and benefits of the "alternative or complementary" treatment. (Bus. & Prof. Code, § 2234.1, subds. (a)(1), (a)(2).) As summarized in Findings 9, 13, 26, 29, 34, 35, 42, 44, 50, 52, 60, 65, 75, 77, 84, and 88, respondent did no such thing. Rather, he gave his patients and their families wildly inaccurate information about the potential benefits

and risks of the treatment he offered, about the benefits and risks of other available treatments, and about the patients' own conditions.

11. Finally, "alternative or complementary medicine" is exempt from discipline only if the physician rendering this treatment has described to the patient his own "education, experience, and credentials . . . related to the alternative or complementary medicine." As summarized above in Findings 4 through 9, 13, 50, 94, and 96, respondent lied to his patients about his experience and qualifications, and continued this misrepresentation to the Board at this hearing.

Disciplinary Considerations

12. All matters stated in Findings 8 through 100 and in Legal Conclusions 3 through 11 confirm that respondent has harmed numerous terminally ill people and their families, including Patients 1, 2, and 3. As summarized in Findings 29, 34, 38, 60, 65, 84, and 88, two possibilities exist to explain this conduct: (1) respondent is profoundly dishonest, or (2) respondent is profoundly delusional. Regardless of the explanation for respondent's cruel and dangerous conduct, clear and convincing evidence shows that respondent intends to continue it as long as he retains his medical license. Public safety requires the Board to revoke this license.

Costs

13. A physician who has committed a violation of the laws governing medical practice in California may be required to pay the Board the reasonable costs of the investigation and enforcement of the case, but only as incurred on and after January 1, 2022. (Bus. & Prof. Code, § 125.3.) The matters stated in Findings 101 and 102 establish that these costs for this matter total $35,710.50.

14. In *Zuckerman v. State Bd. of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court set forth the standards by which a licensing board or bureau must exercise its discretion to reduce or eliminate cost awards to ensure that the board or bureau does not deter licensees with potentially meritorious claims from exercising their administrative hearing rights. The court held that a licensing board requesting reimbursement for costs relating to a hearing must consider the licensee's "subjective good faith belief" in the merits of his position and whether the licensee has raised a "colorable challenge" to the proposed discipline. (*Id.*, at p. 45.) The board also must consider whether the licensee will be "financially able to make later payments." (*Ibid.*) Last, the board may not assess full costs of investigation and enforcement when it has conducted a "disproportionately large investigation." (*Ibid.*)

15. All these matters have been considered. They do not justify any reduction in respondent's obligation to reimburse the Board for its reasonable costs.

ORDER

1. Physician's and Surgeon's Certificate No. G 20670, held by respondent Kenneth Naoyuki Matsumura, M.D., is revoked.

2. Respondent Matsumura shall reimburse the Medical Board of California for its enforcement costs in this matter by paying the Board $35,710.50 within 30 days after the effective date of this order.

DATE: 09/19/2023

Juliet E. Cox

JULIET E. COX
Administrative Law Judge
Office of Administrative Hearings

ROB BONTA
Attorney General of California
GREG W. CHAMBERS
Supervising Deputy Attorney General
State Bar No. 237509
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3382
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Second Amended Accusation Against: **KENNETH NAOYUKI MATSUMURA, M.D.** **2705 Webster St. Unit 5885** **Berkeley, CA 94705-5049** **Physician's and Surgeon's Certificate No. G 20670,** Respondent.	Case No. 800-2019-059098 **SECOND AMENDED ACCUSATION**

PARTIES

1. Reji Varghese (Complainant) brings this Second Amended Accusation solely in his official capacity as the Interim Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about July 1, 1971, the Medical Board issued Physician's and Surgeon's Certificate Number G 20670 to Kenneth Naoyuki Matsumura, 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 May 31, 2023, unless renewed.

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JURISDICTION

3. This Second Amended 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.

4. Section 2220 of the Code states:

Except as otherwise provided by law, the Board may take action against all persons guilty of violating this chapter. The Board shall enforce and administer this article as to physician and surgeon certificate holders, including those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders, and the Board shall have all the powers granted in this chapter for these purposes including, but not limited to:

(a) Investigating complaints from the public, from other licensees, from health care facilities, or from the Board that a physician and surgeon may be guilty of unprofessional conduct. The Board shall investigate the circumstances underlying a report received pursuant to Section 805 or 805.01 within 30 days to determine if an interim suspension order or temporary restraining order should be issued. The Board shall otherwise provide timely disposition of the reports received pursuant to Section 805 and Section 805.01.

(b) Investigating the circumstances of practice of any physician and surgeon where there have been any judgments, settlements, or arbitration awards requiring the physician and surgeon or his or her professional liability insurer to pay an amount in damages in excess of a cumulative total of thirty thousand dollars ($30,000) with respect to any claim that injury or damage was proximately caused by the physician's and surgeon's error, negligence, or omission.

(c) Investigating the nature and causes of injuries from cases which shall be reported of a high number of judgments, settlements, or arbitration awards against a physician and surgeon.

5. 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, or such other action taken in relation to discipline as the Board deems proper.

6. Section 2234 of the Code states:

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.

(d) Incompetence.

(e) The commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon.

(f) Any action or conduct that would have warranted the denial of a certificate.

(g) The failure by a certificate holder, in the absence of good cause, to attend and participate in an interview by the board. This subdivision shall only apply to a certificate holder who is the subject of an investigation by the board.

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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.

COST RECOVERY

8. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DEFINITIONS

9. Abraxne is a chemotherapy drug that combines paclitaxel with a protein called albumin. It may help stop cancer cells from dividing and making new cells. Abraxane works by blocking the action of proteins called microtubules.

10. Carboplatin is a chemotherapy treatment used by itself or in combination with other chemotherapy drugs. Carboplatin interferes with the genetic material in a cell, which halts the cell division, killing the cell.

11. Gemcitabine is a chemotherapy medication used by itself or in combination with other chemotherapy drugs. Gemcitabine interferes with the growth of cancer cells.

12. Mesna is not a chemotherapy medication. Mesna is used to reduce the risk of hemorrhagic cystitis – a condition that causes inflammation of the bladder and can result in serious bleeding – in people who receive ifosfamide or cyclophosphamide, medications used for the treatment of cancer. Mesna works by protecting the bladder against some of the harmful effects of certain chemotherapy medications. Mesna is inactive in the blood, is reactivated in the kidneys and in the bladder where it binds to and inactivates acrolein.

13. Morphine is for use in patients who require a potent opioid analgesic for relief of moderate to severe pain. Morphine is a dangerous drug as defined in section 4022 of the Code,

and a schedule II controlled substance and narcotic as defined by section 11055, subdivision (b)(1) of the Health and Safety Code.

14. Neupogen is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count in cancer patients receiving chemotherapy. It is not considered a controlled substance.

15. A taxane is a type of chemotherapy drug that blocks cell growth by stopping mitosis (cell division). Taxanes interfere with microtubules (cellular structures that help move chromosomes during mitosis). A taxane is a type of mitotic inhibitor and a type of anti-microtubule agent used to treat cancer.

16. Zarxio reduces the risk of infection in patients with some tumors who are receiving strong chemotherapy that may cause severe neutropenia with fever. Zarxio belongs to a class of drugs called Hematopoietic Growth Factors.

FACTUAL ALLEGATIONS

PATIENT 1

17. At all relevant times, Respondent was a physician and surgeon in California without American Board of Medical Specialties (ABMS) board certification, fellowship or residency training in oncology or hematology.

18. On June 18, 2018, Patient 1,[1] provided Respondent with intake information that Patient 1 had been diagnosed in July 2010 with pre-cancer (DCIS) and refused all traditional treatment; and that she took supplements, altered her diet and underwent hyperthermia treatment in Germany. Patient 1 described her cancer as now being Stage III,[2] involving her entire breast and regional lymph nodes, though she had never had a scan done to evaluate the extent of the disease.

[1] Numbers are used to protect patient privacy. Respondent may learn the names of the patients through the discovery process.

[2] Stage I: Cancer is localized to a small area and has not spread to lymph nodes or other tissues. Stage II: Cancer has grown, but it has not spread. Stage III: Cancer has grown larger and has possibly spread to lymph nodes or other tissues. Stage IV: Cancer has spread to other organs or areas of your body.

19. On July 18, 2018, Patient 1 underwent a PET/CT scan in Arizona. The results indicated evidence of extensive left-sided breast cancer with distant metastases – Stage IV – including multiple liver metastases and bony metastases throughout the skeleton.

20. On July 29, 2018, Respondent examined Patient 1 for the first time. Respondent wrote in the records, "Discussed at length my concern regarding: possible fracture at head of femur . . . ," in reference to the July 18, 2018 PET/CT that showed "widespread osseous metastases...noted throughout the entire axial skeleton...the sternum and the proximal femurs. There are minimal radiographic abnormalities." Yet, Respondent did not order imaging of the femur, did not prescribe bone stabilizer therapy, and did not refer Patient 1 to surgery or radiation oncology.

21. On July 29, 2018, Patient 1 signed an Informed Consent to receive "side effect-reduced, neutrophil potentiated (SEF) chemotherapy treatment." This signed Informed Consent refers to phase II clinical trial results of SEF[3] [4] showing "a substantial reduction of side effects of chemo agent carboplatin, in particular, in protecting blood circulating levels of platelets and white blood cell neutrophils (neutrophils are believed to be beneficial during chemotherapy by helping chemo agents kill and dissolve cancer cells not outright killed directly by chemo agents but seriously damaged by such chemo agents, thereby eradicate cancers more thoroughly)." The signed Informed Consent form also included statements such as, "the likelihood of these benefits is still being measured, but early data indicate the likelihood is substantially greater than conventional chemotherapy and with less side effects."

22. While the Informed Consent documentation indicates that Patient 1 was apprised of other treatments available, there is no documentation that identifies specifically the other treatment options discussed, such as anti-hormonal (endocrine based) options, or cyclin dependent kinase 4/6 (CDK4/6) inhibitor therapy.

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[3] If a new treatment is found to be safe in phase I clinical trials, a phase II clinical trial is done to see if it works in certain types of cancer. A group of 25 to 100 patients with the same type of cancer receive the new treatment in a phase II study. The patients are treated using the dose and method found to be the safest and most effective in phase I studies.

[4] No phase II trial results regarding SEF are publicly available through published peer-reviewed literature.

23. Even though carboplatin and mesna are agents covered by insurance, Respondent charged Patient 1 to test the potency of each carboplatin dose prior to administration. The patient's insurance did not cover the cost of this testing for drug potency performed by Respondent. Carboplatin and mesna are generically available, FDA approved medications, manufactured under controlled conditions. There is generally no need for an administering physician to perform such testing for drug potency, and no need for patients to pay for potency testing done by administering physicians. Respondent stated the cost to him was $5,400 per dosing cycle and that he charged the patient $7,500 per dosing cycle, or $15,000 per month.

24. From July 30, 2018 through May 2019, Patient 1 received SEF treatment from Respondent, who administered the chemotherapy himself. Each two-week treatment cycle was comprised of daily doses of mesna on days 1 through 4 and carboplatin on day 2.[5] The carboplatin doses varied from cycle to cycle, ranging from AUC[6] 1.5 to 4. Mesna dosing was different each day without explanation and with no calculation noted in the records. Specifically, quantification of mesna was provided in milliliters without reference to concentration or total milligrams documented in the records. Patient 1 was provided Neupogen as needed and vital signs, complete blood count and metabolic panel were monitored roughly every cycle.

25. On October 10, 2018, Patient 1 expressed concern that cancer was growing, complained of unbearable pain, and reported an episode of being suicidal. Respondent told Patient 1 that she was mistaken in "thinking our therapy was not working," and told her that new lumps were likely due to recently receiving a reduced dose of carboplatin.

26. At the end of October 2018, Respondent referred Patient 1 to a surgeon for a skin and nipple sparing mastectomy. On November 19, 2018, Patient 1 underwent a left simple mastectomy with left axillary mass excision by another treatment provider, which revealed invasive ductal carcinoma comprising the majority of the specimens with invasion of dermal lymphatics and positive margins. No tumor biomarkers were reported.

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[5] Respondent stated that he believes mesna is an antidote for the cytopenic effects of carboplatin.

[6] The area under the plot of plasma concentration of a drug versus time after dosage – "**area under the curve**" or AUC – gives insight into the extent of exposure to a drug and its clearance rate from the body.

27. Patient 1 continued treatment with Respondent, and on December 20, 2018, Patient 1 complained of new nodules, which Respondent reassured her was due to the recent low dose chemotherapy treatment. On January 2, 2019, Patient 1 complained of a new lump in her mid-chest and Respondent documented in the medical records that, "pain in affected area for 2 days which is proof therapy was affecting her cancer." Patient 1 continued to complain of pain throughout January 2019, and on January 29, 2019, Patient 1 and Respondent agreed that the lumps under the patient's right arm and mid-anterior chest were growing, with the medical record noting only, "I concur on exam."

28. Respondent routinely failed to document any physical examination of Patient 1. He did not document objective measures of tumor size or location in the breast, chest wall or regional lymph nodes by description, photography or sketch. The only documentation of a formal physical examination was on Patient 1's first visit.

29. Respondent did not order imaging for Patient 1 until February 1, 2019, an ultrasound of the liver, which was performed on February 12, 2019, and showed "extensive hepatic metastatic disease (largest 2.0 x 1.8 cm), retroperitoneal adenopathy, right lower quadrant mass (5.1 x 4.9 x 3.4 cm) and periumbilical mass extending to the left." On February 13, 2019, Respondent wrote, "US report was poorly written despite effort to tell them what we are looking for but speaking to another radiologist he kept asking about lesions in liver. He says are you sure she has cancer in liver – there's two in left and 3 in right lobe but they all look like benign cyst – there is no uptake of color – no circulation." Respondent's records do not acknowledge the areas of new disease growth (retroperitoneal lymph nodes or a mass in right lower quadrant and periumbilical mass). Respondent continued Patient 1 on her current course of therapy despite evidence that the treatment was not effective.

30. On February 14, 2019, Respondent recorded in Patient 1's medical records that "Patient will discuss with insurance company regarding early payment (life insurance)."

31. At the end of May 2019, Patient 1 discontinued treatment with Respondent and commenced treatment with a Florida-based provider, an integrative oncologist. In June 2019, Patient 1 developed a pulmonary embolism and pleural effusion that required draining. And, on

July 2, 2019, Patient 1 was admitted to the hospital in Arizona, where healthcare providers informed her that she was dying of cancer.

32. On July 11, 2019, Respondent admitted Patient 1 to McClure Post Acute, a skilled nursing facility in Oakland, California. On July 12, 2019, Respondent directed that Patient 1 be treated with 12 milliliters of mesna, while also recording that Patient 1 should be treated with low dose carboplatin, which would then be alternated on the fifth day with 300 milligrams of gemcitabine. Respondent did not note any justification for gemcitabine dosing, or dosage calculation.

33. On July 13, 2019, Respondent resumed treating Patient 1 with carboplatin, AUC 2 and documented that he suspected that Patient 1's chest pain was from narcotic (morphine) withdrawal, not pain related to cancer.

34. On August 6, 2019, Respondent again noted that Patient 1's pain was attributable to narcotic withdrawal. Because Patient 1 was unable to transport from her skilled nursing facility to his office, Respondent made a house call to infuse 200 milligrams of gemcitabine.

35. Respondent's last treatment of Patient 1 occurred on August 18, 2019, when Respondent provided 15 milliliters of mesna to Patient 1.

36. On August 26, 2019, Patient 1 was admitted to Alta Bates Summit Medical Center with severe malnutrition, cancer cachexia, acute respiratory failure, severe pain and sepsis. Patient 1 was subsequently placed on comfort care in light of her failing condition.

37. On August 27, 2019, Respondent wrote to another physician, "where ordinary chemo cannot deliver more than 25-30 cumulative AUC of carboplatin, we are routinely able to deliver 50, 75 or more by the use of mesna, which I believe you know is an FDA approved antidote to alkylating agents like ifosfamide and carboplatin."[7]

[7] Standard of care – carboplatin is administered at an AUC of 2 every week (or AUC of 6 every three weeks), and most often it is administered in combination with another chemotherapy agent, i.e., a taxane or gemcitabine). In the metastatic setting it is given until disease progression, which can be many months for some. Thus, standard of care carboplatin can reach cumulative AUC of more than 70 (without use of mesna). On average, Respondent was treating Patient 1 with a weekly AUC equivalent ranging from 0.5 to no more than 2.

38. On August 30, 2019, Patient 1 passed away. The cause of death was identified as acute respiratory failure; bilateral pleural effusion; and breast cancer metastatic to lung, liver and bone.

PATIENT 2

39. Patient 2, a 57-year old female at the time of her death in 2020, was originally diagnosed with colorectal cancer in 2017. She had surgery and chemotherapy at that time. In August 2019 the cancer returned and Patient 2 was treated with chemotherapy at Kaiser for three months. The chemotherapy did not work and the cancer spread to her liver and lungs.

40. Patient 2 first met with Respondent on November 18, 2019. Respondent's records from that date note that he was aware that Patient 4 had stage IV colon cancer. He noted that the plan was to switch Patient 2 from "traditional chemo to SEF Chemo." Respondent documented Patient 2's pulse, blood pressure, and temperature, but did not document height. This would be the last time Respondent documented Patient 2's vital signs throughout her treatment. On this date Respondent treated Patient 2 with 13 ml. of mesna.

41. The next day, November 19, 2019, Respondent treated Patient 2 with 490 mg. of carboplatin, which Respondent determined to be AUC 4. Respondent did not record Patient 2's creatinine in his notes or refer to any review of Patient 2's labs. Respondent did not record a height for Patient 2 in his records, so it is not clear how Respondent was able to calculate the 490 mg. dose equivalent to the AUC 4.

42. On November 20, 2019, Respondent gave Patient 2 mesna, 10 ml., and on November 21, 2019, gave Patient 2 mesna, 7 ml.

43. Respondent's treatment of Patient 2 consisted of numerous rounds or cycles of carboplatin and mesna.

44. On January 13, 2020, Respondent noted that a mass was found on Patient 2's liver.

45. On January 29, 2020, Respondent wrote, "Pain of mid abdomen increased again after carbo so carbo even at 1.5 dose is affecting her tumor – good."

46. On February 19, 2020, Patient 2 had a CBC (complete blood count) that revealed a platelet[8] count of 303, which is normal. At that point Patient 2 had undergone seven cycles of treatment with Respondent.

47. Patient 2 underwent cycle nine on March 16, 2020. Patient 2 was given carboplatin at an "AUC" of 2.5 or milligram dose of 350 mg.

48. On March 10, 2020, Patient 2 had a CBC at Kaiser that revealed a platelet count of 72. On March 25, 2020, Patient 2 had a CBC ordered by Respondent that revealed a critical thrombocytopenia at a platelet count of 16.[9]

49. On March 27, 2020, Patient 2 had a CBC with Kaiser and the platelet count was 8. Later that day, a Kaiser physician advised Patient 2 and her husband to go to the ER as soon as possible. On March 30, 2020, another Kaiser physician wrote an email to Patient 2, informing her that she received one unit of platelets as a transfusion.

50. On April 2, 2020, Patient 2 had another CBC ordered by Respondent and this test revealed a platelet count of 7, which was flagged by LabCorp as a critical value and called Respondent on April 3, 2020 at 8:23 a.m. EST. That same day, Patient 2 returned to the ER at the Oakland Kaiser facility and her platelet count was measured at 6. Patient 2 received a platelet transfusion x 2 units and one unit of red blood cells. Patient 2 was discharged from the ER after that visit.

51. There is no record in Respondent's clinical notes that he reviewed lab tests or contacted Patient 2 about her results or gave her instructions.

52. On April 6, 2020, Respondent commenced cycle 10 of this treatment plan for Patient 2. On April 6, 2020, Respondent wrote in Patient 2's records, "Assisting pt by giving meds in her

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[8] Platelets are fragments of blood that assist in blood clotting and prevention of bleeding (hemostasis).

[9] Thrombocytopenia is a deficiency of platelets in the blood. This causes bleeding into the tissues, bruising and slow blood clotting after injury. Carboplatin is known to cause thrombocytopenia.

car. Mesna 8ml." There is no documentation why Patient 2 could not be treated in a clinical setting.

53. On April 7, 2020, Patient 2 received 125 mg. of carboplatin. On April 9, 2020, Patient 2 again presented to Kaiser Oakland ER, this time with a platelet count of 2.

54. At the time of her admission to Kaiser on April 9, 2020, the admitting clinician noted that Patient 2 had endured "20 days of terrible abdominal pain and distention as well as diffuse body pain all over." Respondent failed to note Patient's 2 pain in his records and failed to chart any understanding or reflections of Patient 2's clinical deterioration.

55. Respondent failed to document clinical examinations after Patient 2's first visit with him. Respondent kept no record of lab data or radiology results on any visit past the first visits. There was no documentation of pain or performance status and no documentation of prognosis discussion or offer of hospice. Respondent failed to note in his records that Patient 2 was malnourished. Additionally, Respondent failed to document information subsequent to Patient 2's emergency room visit for platelet transfusion due to critical thrombocytopenia.

56. On April 13, 2020, Patient 2 passed away. The cause of death was identified as cardiopulmonary arrest; colorectal cancer; metastatic disease to lung; and metastatic disease to the liver.

PATIENT 3

57. Patient 3, a 65-year old female, was diagnosed with metastatic pancreatic cancer in October 2017 and was initially treated at the Scripps Cancer Center in La Jolla, California with gemcitabine and Abraxane chemotherapy. Treatment continued until February 2019, and during this time she received over 70 chemotherapy treatments. This was followed by radiation therapy in March and April of 2019 that was divided into 28 treatments. Despite these treatments a PET CT on June 7, 2019 and pelvis MRI on June 12, 2019 showed that her disease had progressed, and Scripps recommended resuming gemcitabine and Abraxane chemotherapy.

58. In June 2019 she reached out to Respondent who offered "SEF chemotherapy" - carboplatin and mesna.

59. Apparently, Respondent quoted Patient 3 a cost of $4,200 for each two-week cycle of

Chemotherapy, which Respondent noted was a discount compared to other patients who pay up to $8,200 per cycle, and he recommended that Patient 3 start with at least 8 cycles of SEF chemotherapy.

60. Patient 3 commenced SEF chemotherapy on July 29, 2019 with a dose of mesna followed by her first infusion of carboplatin on July 30, 2019. Her second cycle began on August 13, 2019, but this was complicated by bloody vomiting on August 14, 2019, which necessitated an ER visit. An endoscopy was unrevealing, and Patient 3 received 3 units of blood.

61. From August 14, 2019 through November 8, 2019, Patient 3 received 7 cycles of SEF chemotherapy. This also included Zarxio. On September 10, 2019, Patient 3 received her 4th cycle of SEF Chemotherapy, and Respondent sent a CTC (circulating tumor cell) test to Germany because her tumor marker count was rising. He noted that this "could be a good sign of our therapy."

62. On November 5, 2019, Patient 3 did not feel well enough to come into the office so Respondent administered the 7th cycle of SEF chemotherapy in Patient 3's place of residence. Patient 3's carboplatin dose was reduced at this time to AUC 2.5. Patient 3 complained of epigastric pain and low urination, and she was advised to drink more water.

63. As Patient 3's condition worsened, Respondent failed to order imaging.

64. In December 2019, Patient 3 was diagnosed with worsening metastatic pancreatic cancer. From January through February 2020, Patient 3 was repeatedly admitted at Oregon Health & Science University (OHSU) due to bowel obstructions requiring total parenteral nutrition and the placement of a venting gastric tube.

65. On February 4, 2020, Patient 3 was admitted to the hospital for severe sepsis due to a perforated gallbladder and liver abscess. Patient 3 was deemed not to be a surgical candidate, and she ultimately decided to pursue comfort care with inpatient hospice. On February 14, 2020, a little over six months after commencing treatment with Respondent, Patient 3 died. Her cause of death was pancreatic adenocarcinoma.

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FIRST CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Gross Negligence; Repeated Negligent Acts; Incompetence – Patient 1)

66. Paragraphs 17 through 38 are incorporated by reference as if fully set forth.

67. Respondent Kenneth Naoyuki Matsumura, M.D. is subject to disciplinary action under sections 2234 and/or 2234(b) and/or 2234(c) and/or 2234(d) in that Respondent engaged in unprofessional conduct and was grossly negligent, and/or repeatedly negligent, and/or incompetent in his care and treatment of Patient 1, including but not limited to:

A. Prescribing and administering chemotherapy without training or expertise; using mesna to lessen carboplatin side effects; and prescribing gemcitabine at the wrong dose.

B. Continuing a chemotherapy regimen in the face of unequivocal progression of disease.

C. Failing to keep accurate and adequate records regarding discussions with the patient regarding standard available treatments; the mesna dosages provided to the patient; and breast cancer biomarkers, physical examinations findings and objective measures of response to treatment; and infusion orders and administration documentation that were inconsistent and incomplete;

D. Failing to offer bone stabilization therapy and/or refer the patient to a specialist.

E. Testing chemotherapy potency of an already FDA-approved drug prior to giving to the patient and then charging the patient for the testing.

SECOND CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Gross Negligence; Repeated Negligent Acts; Incompetence – Patient 2)

68. Paragraphs 17, and 39 through 56 are incorporated by reference as if fully set forth.

69. Respondent Kenneth Naoyuki Matsumura, M.D. is subject to disciplinary action under sections 2234 and/or 2234(b) [gross negligence] and/or 2234(c) [repeated negligent acts] and/or 2234(d) [incompetence] in that Respondent engaged in unprofessional conduct and was grossly negligent, and/or repeatedly negligent, and/or incompetent in his care and treatment of Patient 2, including but not limited to:

A. Prescribing and administering chemotherapy without training or expertise; using mesna to lessen carboplatin side effects during the treatment of colorectal cancer.

B. Continuing a chemotherapy regimen in the face of unequivocal progression of disease.

C. The use of a chemotherapy protocol – carboplatin and mesna – which has no clinical studies to support its use in treating colorectal cancer, and no documentation to note that Patient 2 was part of a clinical study.

D. Rendering a chemotherapy infusion treatment to Patient 2 in a car, rather than in a clinical setting.

E. Continuing to treat Patient 2 with chemotherapy treatment even though Patient 2 had severe thrombocytopenia.

F. Failing to keep accurate and adequate records regarding discussions with the patient regarding standard available treatments; the mesna dosages provided to the patient; records of clinical examinations past the first visit; records of lab data or radiology results on any visit note past the first visit; documentation of pain or performance status; or documentation of prognosis discussion or offer of hospice.

G. Testing chemotherapy potency of an already FDA-approved drug prior to giving to the patient and then charging the patient for the testing.

THIRD CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Gross Negligence; Repeated Negligent Acts; Incompetence – Patient 3)

70. Paragraphs 17, and 57 through 65 are incorporated by reference as if fully set forth.

71. Respondent Kenneth Naoyuki Matsumura, M.D. is subject to disciplinary action under sections 2234 and/or 2234(b) [gross negligence] and/or 2234(c) [repeated negligent acts] and/or 2234(d) [incompetence] in that Respondent engaged in unprofessional conduct and was grossly negligent, and/or repeatedly negligent, and/or incompetent in his care and treatment of Patient 3, including but not limited to:

A. Treating Patient 3 with low-dose carboplatin which has no proven efficacy in metastatic pancreatic cancer,

B. The unnecessary use of both mesna and Zarxio put Patient 3 at risk for many side effects.

C. Monitoring Patient 3's response to treatment by relying only on tumor marker and circulating tumor cell assessments.

D. Portraying SEF chemotherapy as being safer and more effective compared to conventional chemotherapy was not based on scientific evidence and did not meet the requirements of proper informed consent.

E. Demonstrating critical deficit in clinical judgment by interpreting increasing symptom burden and tumor marker load as being indicators of cancer treatment efficacy, thereby misinforming the patient.

FOURTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Failure to Keep Adequate and Accurate Medical Records)

72. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 20670 to disciplinary action under sections 2227 and/or 2234, and/or 2266 of the code, in that he failed to keep adequate and accurate medical records in his care and treatment of Patient 1, Patient 2, and Patient 3, as more particularly alleged in paragraphs 17 through 65 above, which are hereby incorporated by reference and re-alleged 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 Number G 20670, issued to Respondent Kenneth Naoyuki Matsumura, M.D.;

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

3. Ordering Respondent Kenneth Naoyuki Matsumura, M.D., to pay the Board the costs of the investigation and enforcement of this case, and if placed on probation, the costs of probation monitoring; and

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

DATED: APR 21 2023

REJI VARGHESE
Interim Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant