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

In the Matter of the Accusation Against: **RALPH S. WOLFSTEIN, M.D.** **Palm Court** **3995 Overland Avenue #104** **Culver City, CA 90232** **Physician's and Surgeon's Certificate** **No. C 21310,** Respondent.	Case No. 800-2016-025102 **DEFAULT DECISION AND ORDER** [Gov. Code, § 11520]

On August 2, 2019, an employee of the Medical Board of California (Board) sent by certified and first class mail a copy of Accusation No. 800-2016-025102 (Accusation), Statement to Respondent, Notice of Defense, Request for Discovery, and Government Code sections 11507.5, 11507.6, and 11507.7 to Ralph S. Wolfstein, M.D. (Respondent), at his address of record with the Board, which was and is Palm Court, 3995 Overland Avenue #104, Culver City, CA 90232. (Exhibit Package, Exhibit 1: Accusation, the related documents, Declaration of Service, and certified mail receipt card.[1]) On or about August 8, 2019, an individual signed the

[1] The evidence in support of this Default Decision and Order is contained in the accompanying "Exhibit Package."

USPS certified mail receipt card, confirming service of these documents. (*Ibid.*) Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505, subdivision (c).

Respondent failed to sign and return a Notice of Defense within fifteen days of service of the Accusation as required by law and as requested in the Statement to Respondent. On September 26, 2019, an employee of the Office of the Attorney General sent by certified mail a Courtesy Notice of Default to Respondent at his address of record. (Exhibit Package, Exhibit 2: Courtesy Notice of Default.) Respondent failed to respond to the Courtesy Notice of Default. (*Ibid.*)

FINDINGS OF FACT

I

Complainant Christine J. Lally is the Interim Executive Director of the Board. The charges and allegations in the Accusation were at all times brought and made solely in her official capacity as the Board's Interim Executive Director.

II

On November 20, 1959, the Board issued Physician's and Surgeon's Certificate No. C 21310 to Respondent. (Exhibit Package, Exhibit 3: Certificate of Licensure.) That certificate expired on August 31, 2018, and has not been renewed. (*Ibid.*) The Board retains jurisdiction over Respondent's Physician's and Surgeon's Certificate, under Business and Professions Code section 118, which states, in pertinent part:

> (b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the license on any such ground.

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III

On August 2, 2019, Respondent was served with the Accusation, alleging causes for discipline against him. (Exhibit 1.) The Accusation and accompanying documents were duly served on Respondent. (*Ibid.*) A Courtesy Notice of Default was thereafter served on Respondent. Respondent failed to file a Notice of Defense. (Exhibit 2.)

IV

Government Code section 11506 states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense, and the notice shall be deemed a specific denial of all parts of the accusation not expressly admitted. Failure to file a notice of defense shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

V

The Board served Respondent at his designated address of record. Respondent failed to file a Notice of Defense within fifteen days after service upon him of the Accusation, and therefore he waived his right to a hearing on the merits of the Accusation.

VI

Government Code section 11520 states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent.

VII

Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on Respondent's express admissions by way of default and the evidence before it contained in Exhibits 1-4, finds that the allegations in the Accusation are true.

VIII

The allegations of the Accusation are true as follows, (Exhibit Package, Exhibit 4: Declaration by Ronald Lau, M.D.):

At the time of his treatment of Patient 1, Respondent worked at Bicher Cancer Institute,

a.k.a, Valley Cancer Institute, a.k.a., Elite Oncology Medical Group (Elite Oncology). He was the director of Radiation Oncology and Principle Investigator of Research Study HYP-002, WIRB Protocol #20062274, Regional Hyperthermia For Superficial and Moderately Deep Cancer (Protocol).

Patient 1 was originally diagnosed with prostate cancer in 2002. For several years, his cancer was under control, with the Prostate-Specific Antigen (PSA) blood test levels staying very low. The levels began to rise and, by 2009, documented recurrence of cancer led to cryotherapy treatment of the prostate gland. Shortly thereafter, a pelvic lymph node biopsy showed metastatic cancer in the node(s) (Stage IV cancer), and physicians suggested watchful waiting or hormonal treatment.

On August 22, 2013, Respondent first saw Patient 1 at Elite Oncology. Respondent misclassified his cancer as Stage III and offered participation in a "research study" using hyperthermia and radiation to re-treat the prostate and also to treat the seminal vesicles and pelvic nodes, with the hope of curing the cancer. Patient 1 completed extensive treatment with Respondent and his associates at Elite Oncology and, in 2014, began to have symptoms indicating radiobiologic failure beginning in the organ systems of the pelvis. Patient 1 was eventually placed on comfort care and died in early 2015.

The standard of care at the time of Patient 1's treatment by Respondent was that any lymph node positive for metastatic cancer was to be automatically classified as Stage IV. The down-staging of Patient 1's cancer to Stage III was an extreme departure from the standard of care.

The standard of care at the time of Patient 1's treatment by Respondent was to use hyperthermia and radiation to treat surface cancers that extend into the subcutaneous tissue. The Protocol is for superficial (meaning skin or subcutaneous) and moderately deep (meaning cancer that may go down some centimeters below the surface) cancer. The Protocol, using surface hyperthermia along with radiotherapy, is not meant to treat deep cancer, particularly not prostate cancer or metastatic disease to pelvic lymph nodes. Patient 1's prostate cancer was not included in the list of treatable cancers for the type of hyperthermia performed on him. His cancer was not at the surface level, but at a very deep level inside the pelvis. The lymph nodes were also at very

deep levels of the pelvis. The hyperthermia device is not capable of providing heat to this depth and could never treat to a depth or to the sites of Patient 1's cancer. Respondent's use of the device on Patient 1 was an extreme departure from the standard of care.

The standard of care at the time of Patient 1's treatment by Respondent was to have a basic knowledge of dosimetry, biology, and radiation dose limitations upon normal tissues and organs. Respondent's prescription for Patient 1 for energy 6mv beam, modality IMRT, total dose 7000cGy, and fractions of 180cGy times 10, 150CGy times 10, and 100cGy times 25, total fractions 55, was a non-standard dose fractionation schema that was not accepted practice. Giving this dose of radiation to Patient 1's prostate and separately to his pelvis and abdomen above was an extreme departure from the standard of care.

When using simulation and CT simulation on a patient, the standard of care at the time of Patient 1's treatment by Respondent was to have the patient in a supine position for treatment of the pelvis. A 3D laser alignment system allows placement of markers on the body's surface that are also shown on x-rays for indexing the patient on the initial simulation and to make sure alignment is maintained throughout the course of treatment. Upon completion of Patient 1's simulation and CT simulation, Respondent and his associates knew that there was major overlap of their proposed fields of treatment into the upper two thirds of the previous radiation fields of treatment by Patient 1's previous provider. Respondent's failure to fully indicate the size of the proposed fields of treatment and, thus, the true overlap with prior fields of treatment, was an extreme departure from the standard of care.

During the process of computer-aided treatment planning, CT cross-sectional pictures are used to identify the areas to be treated and normal tissue and organs are also marked and listed as targets to avoid. The standard of care at the time of Patient 1's treatment by Respondent was for the physician to review and specifically outline the targets to be treated. The CT scan films used to set up the 5-field Intensity Modulated Radiation Therapy (IMRT) treatment plan for Patient 1 intersected in the pelvis. No lymph nodes were designated to be treated. The prostate and seminal vesicles were not outlined and no attempt was made to use the computer-aided software to integrate the five fields, concentrate the dose into the target lymph nodes and prostate, and reduce

the dose to any normal tissue and organs. Respondent's failure to target the cancer resulted in total treatment of the normal tissues and organs of the lower abdomen and pelvis, so that the designated planned tumor volume (PTV) resulted in the intestines receiving the full dose that should have been intended for the target lymph nodes and prostate only. This was an extreme departure from the standard of care.

The standard of care for radiation treatment and medical record keeping at the time of Patient 1's treatment by Respondent was for weekly progress notes to include the achieved dose and the dose total. The rationale for continuing treatment above the prescribed dose of radiation should be documented. In the case of Patient 1, there was a complete lack of progress notes between December 18, 2013 and January 22, 2014. Respondent did not document any explanation for Patient 1's treatment to have continued beyond the initial planned 7000cGy, to 10000cGy. There was no way to ascertain or conclude how these additional 30 treatments occurred. This was an extreme departure from the standard of care.

DETERMINATION OF ISSUES

I

Pursuant to the foregoing Findings of Fact, Respondent's license is subject to discipline pursuant to Business and Professions Code section 2234, subdivisions (b) (gross negligence) and (c) (repeated negligent acts), and section 2266 (failure to maintain adequate and accurate records), in that Respondent engaged in the conduct described above, including but not limited to the following:

A. Respondent failed to classify Patient 1's cancer as Stage IV.

B. Respondent used a hyperthermia device to treat Patient 1's cancer, even though said device was not capable of providing heat to or treating at the depth of the sites of Patient 1's cancer.

C. Respondent improperly prescribed a non-standard radiation dose to Patient 1's prostate and separately to his pelvis and abdomen.

D. Respondent failed to fully indicate the size of the proposed fields of radiation treatment and caused a true overlap with prior fields of treatment.

E. Respondent's treatment plan failed to target Patient 1's cancer, resulting in total treatment of the normal tissues and organs of the lower abdomen and pelvis, such that the designated planned tumor volume (PTV) resulted in the intestines receiving the full dose that should have been limited to the target lymph nodes and prostate only.

F. Respondent failed to document Patient 1's treatment between December 18, 2013, and January 22, 2014. Respondent's progress notes failed to include the achieved dose and the dose total, the rationale for continuing treatment above the prescribed dose of radiation, and the reason or statement regarding why Patient 1's treatment continued beyond the initial planned 7000cGy, to 10000cGy.

ORDER

IT IS SO ORDERED that Physician's and Surgeon's Certificate No. C 21310, heretofore issued to Respondent Ralph S. Wolfstein, M.D., is **REVOKED**.

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on APR 09 2020.

It is so ORDERED MAR 10 2020

Christine J. Lally, Interim Executive Director
FOR THE MEDICAL BOARD OF
CALIFORNIA, DEPARTMENT OF
CONSUMER AFFAIRS

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STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO august 2 20 19
BY K. Vong ANALYST

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

In the Matter of the Accusation Against: RALPH S. WOLFSTEIN, M.D. 3995 Overland Avenue #104 Culver City, CA 90232 Physician's and Surgeon's Certificate No. C 21310, Respondent.	Case No. 800-2016-025102 **A C C U S A T I O N**

PARTIES

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

2. On November 20, 1959, the Board issued Physician's and Surgeon's Certificate Number C 21310 to Ralph S. Wolfstein, M.D. (Respondent). That license expired on August 31, 2018, and has not been renewed.

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JURISDICTION

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

4. Section 118 of the Code states:

"(a) The withdrawal of an application for a license after it has been filed with a board in the department shall not, unless the board has consented in writing to such withdrawal, deprive the board of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground.

"(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

"(c) As used in this section, board includes an individual who is authorized by any provision of this code to issue, suspend, or revoke a license, and 'license' includes 'certificate,' 'registration,' and 'permit.'"

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 which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

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

"(g) The practice of medicine from this state into another state or country without meeting the legal requirements of that state or country for the practice of medicine. Section 2314 shall not apply to this subdivision. This subdivision shall become operative upon the implementation of the proposed registration program described in Section 2052.5.

"(h) The repeated 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."

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."

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FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

8. Respondent's license is subject to disciplinary action under section 2234, subdivision (b), of the Code in that he committed gross negligence in his care of Patient 1. The circumstances are as follows:

9. At all times relevant to the allegations herein, Respondent worked at Bicher Cancer Institute, a.k.a, Valley Cancer Institute, a.k.a., Elite Oncology Medical Group (Elite Oncology). He was the director of Radiation Oncology and Principle Investigator of Research Study HYP-002, WIRB Protocol #20062274, Regional Hyperthermia For Superficial and Moderately Deep Cancer (Protocol).

10. Patient 1 was originally diagnosed with prostate cancer in 2002. For several years, his cancer was under control with the Prostate-Specific Antigen (PSA) blood test levels staying very low. The levels began to rise and, by 2009, documented recurrence of cancer led to Cryotherapy treatment of the prostate gland. Shortly thereafter, a pelvic lymph node biopsy showed metastatic cancer in the node(s) (Stage IV) and physicians suggested watchful waiting or hormonal treatment.

11. On August 22, 2013, Patient 1 was first seen at Elite Oncology. He was misclassified as Stage III cancer and offered participation in a "research study" using hyperthermia and radiation to re-treat the prostate, and also treat the seminal vesicles and pelvic nodes, with the hope of curing the cancer.

12. Patient 1 completed extensive treatment with Respondent and his associates at Elite Oncology and, in 2014, began to have symptoms indicating radiobiologic failure beginning in the organ systems of the pelvis. Patient 1 was eventually placed on comfort care and died in early 2015.

13. The standard of care is that any lymph node positive for metastatic cancer is automatically classified as Stage IV. The down-staging of Patient 1's cancer to Stage III is an extreme departure from the standard of care.

14. The standard of care is to use hyperthermia and radiation to treat surface cancers that

extend into the subcutaneous tissue.

15. The Protocol is for superficial, meaning skin or subcutaneous cancer, and moderately deep, meaning cancer that may go down some centimeters below the surface. The Protocol, using surface hyperthermia along with radiotherapy, is not meant to treat deep cancer, particularly not prostate cancer or metastatic disease to pelvic lymph nodes. Patient 1's prostate cancer is not included in the list of treatable cancers for the type of hyperthermia performed on him. His cancer was not at the surface level, but at a very deep level inside the pelvis. The lymph nodes were also at very deep levels of the pelvis. The hyperthermia device is not capable of providing heat to this level of depth and could never treat to a depth or to the sites of Patient 1's cancer. Use of the device on Patient 1 was an extreme departure from the standard of care.

16. The standard of care is to have the basic knowledge of dosimetry, biology, and dose limitations upon normal tissues and organs.

17. Respondent's prescription for Patient 1 for energy 6mv beam, modality IMRT, total dose 7000cGy, and fractions of 180cGy times 10, 150CGy times 10, and 100cGy times 25, total fractions 55 is a non-standard dose fractionation schema that is not accepted practice. Giving this dose to Patient 1's prostate and separately to his pelvis and abdomen above is an extreme departure from the standard of care.

18. When using simulation and CT simulation on a patient, the standard of care is to have the patient set up in the supine position for treatment of the pelvis. A 3D laser alignment system allows placement of markers on the body's surface that will also be shown on x-rays for indexing the patient on the initial simulation and to make sure alignment is maintained throughout the course of treatment.

19. Upon completion of simulation and CT simulation, Respondent and his associates knew that there was major overlap of their proposed fields of treatment into the upper two thirds of the previous radiation fields of treatment by Patient 1's previous provider. Respondent's failure to fully indicate the size of the proposed fields of treatment and, thus, the true overlap with prior fields of treatment is an extreme departure from the standard of care.

20. During the process of computer-aided treatment planning, CT cross-sectional pictures

are used to identify the areas to be treated and normal tissue and organs are also marked and listed as targets to avoid. The standard of care is for the physician to review and specifically outline the targets to be treated.

21. The CT scan films used to set up the 5-field Intensity Modulated Radiation Therapy (IMRT) treatment plan for Patient 1 intersected in the pelvis. No lymph nodes were designated to be treated. The prostate and seminal vesicles were not outlined and no attempt was made to use the computer-aided software to integrate the five fields, concentrate the dose into the target lymph nodes and prostate, and reduce the dose to any normal tissue and organs. Respondent's failure to target the cancer resulted in total treatment of the normal tissues and organs of the lower abdomen and pelvis so that the designated planned tumor volume (PTV) resulted in the intestines receiving the full dose that should have been intended for the target lymph nodes and prostate only. This is an extreme departure from the standard of care.

22. The standard of care is for weekly progress notes to include the achieved dose and the dose total. The rationale for continuing treatment above the prescribed dose of radiation should be documented.

23. In the case of Patient 1, there is a complete lack of progress notes between December 18, 2013 and January 22, 2014. There is no reason or statement documented regarding why Patient 1's treatment continued beyond the initial planned 7000cGy, to 10000cGy. There is no way to ascertain or conclude how these additional 30 treatments occurred. This is an extreme departure from the standard of care.

24. Respondent's acts and/or omissions as set forth in Paragraphs 9 through 23, inclusive, above, whether proven individually, jointly, or in any combination thereof, constitute gross negligence, pursuant to section 2234, subdivision (b), of the Code. Therefore, cause for discipline exists.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Act)

25. Respondent's license is subject to disciplinary action under section 2234, subdivision (c), of the Code in that Respondent engaged in repeated negligent acts during his care and

treatment of Patient 1. The circumstances are as follows:

26. The allegations of the First Cause for Discipline are incorporated by reference as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Records)

27. Respondent's license is subject to disciplinary action under section 2266 of the Code. The circumstances are as follows:

28. The allegations set forth in paragraphs 22 and 23 are incorporated by reference as if fully set forth herein.

DISCIPLINARY CONSIDERATIONS

29. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on August 25, 2003, in a prior disciplinary action entitled *In the Matter of the Accusation Against Ralph S. Wolfstein, M.D.*, before the Medical Board of California, in Case No. 04-2000-113992, Respondent was issued a public letter of reprimand and ordered to complete medical record keeping and education courses. That decision is now final and is incorporated by reference as if fully set forth herein.

PRAYER

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

1. Revoking or suspending Physician's and Surgeon's Certificate Number C 21310, issued to Ralph S. Wolfstein, M.D.;

2. Revoking, suspending or denying approval of Ralph S. Wolfstein, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Ralph S. Wolfstein, M.D., if placed on probation, to pay the Board the costs of probation monitoring; and

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

DATED: August 2, 2019

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

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