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

In the Matter of the Accusation Against: **Michael Andrew Arata, M.D.** **4501 Birch Street** **Newport Beach, CA 92660** **Physician's and Surgeon's Certificate No. A 70967,** Respondent.	Case No. 800-2015-014936 **A C C U S A T I O N**

Complainant alleges:

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 or about March 3, 2000, the Medical Board issued Physician's and Surgeon's Certificate Number A 70967 to Michael Andrew Arata, 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 September 30, 2019, unless 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 unless otherwise indicated.

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

5. 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.

". . .

"(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.

". . . ."

6. 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."

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

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

8. Respondent is subject to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (b), in that he committed gross negligence in his care and treatment of patient A,[1] as more particularly alleged hereinafter:

9. On or about 2011, Respondent, an interventional radiologist, established Synergy Health Concepts, to research, promote and perform, venous balloon angioplasty in order to treat "autonomic dysfunction" for autonomic disorders allegedly associated with, but not limited to, multiple sclerosis, Parkinson's disease, traumatic brain injury, and chronic Lyme disease. One of the procedures utilized by Respondent was venous balloon angioplasty to treat chronic

[1] Patient A is being used in place of the patient's name or initials to maintain patient confidentiality.

cerebrospinal venous insufficiency (CCSVI), described as a "narrowing (stenosis) of specific veins in the neck and chest," the internal jugular and azygos veins.

10. On or about May 10, 2012, the United States Food and Drug Administration (FDA) issued a safety communication entitled "Chronic Cerebrospinal Venous Insufficiency [CCSVI] Treatment in Multiple Sclerosis Patient: FDA Safety Communication" (hereinafter "FDA Safety Communication"). In the FDA Safety Communication, CCSVI was described as using "balloon angioplasty devices or stents to widen the narrowed internal jugular or azygos veins" in a "procedure [that] is sometimes called 'liberation therapy' or the 'liberation procedure.'" The FDA warned, "[a]t this time, the FDA believes there is no reliable evidence from controlled studies that this procedure is effective in treating MS (multiple sclerosis)" and "the criteria used to diagnose CCSVI have not been adequately established." The FDA further warned "that using these medical devices in CCSVI treatment procedures posed a risk to patients for a variety of reasons[2] and that "[t]his communication [the Safety Communication] is also intended to notify physicians and clinical investigators planning on conducting clinical trials using medical devices to treat CCSVI that they must comply with FDA regulations for investigational devices."

11. On or about September 5, 2012, the FDA sent a "Warning Letter" to Respondent, who was identified as the President and Principal Investigator for Synergy Health Concepts, Inc. Respondent is a board certified diagnostic radiologist who completed a fellowship in interventional radiology. He admittedly does not have the training to "treat MS per se" but claims he can treat symptoms which are "autonomic in nature." The Warning Letter advised Respondent of objectionable conditions observed during the [FDA's] inspection conducted at Synergy Health

[2] These reasons included, but were not limited to, because: (1) "There is no clear diagnostic evidence that CCSVI exists as a distinct clinical disorder or is linked to MS," (2) "Venous stenoses seen on imaging tests may be normal variants that do not cause any symptoms or disease, since they are sometimes seen in healthy people," (3) "The safety and effectiveness of using balloon angioplasty devices or stents in the internal jugular or azygos veins has not been established in any clinical condition; nor has the FDA approved the use of these devices in these veins," (4) "There is no clear scientific evidence that the treatment of internal jugular or azygos venous stenosis is safe in MS patients, impacts the symptoms of MS, changes the overall course of MS or improves the quality of life for MS patients," and (5) "It is possible that stent placement can worsen any venous narrowing. This is because further narrowing has been shown to sometimes occur with stents placed in normal veins, due to the body's response to the implant."

Concepts, Inc. (Synergy Health) from April 10, 2012, to May 15, 2012, by an investigator from the FDA Los Angeles District Office." According to the Warning Letter, "[t]he inspection was conducted ... to ensure that data and information contained in requests for Investigational Device Exemption (IDE), Premarket Approval (PMA) applications, and Premarket Notification Submissions [were] scientifically valid and accurate" and also "to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations." The "objectionable" conditions related to "Synergy Health in its role as a sponsor" and Respondent "[a]s a clinical investigator." In regard to "Synergy Health in its role as a sponsor," the FDA warned of the following objectionable conditions: (1) "Failure to submit an Application to the FDA and obtain IRB (Investigational Review Board) and FDA approval prior to allowing subjects to participate in the investigation..." and (2) "Failure to maintain accurate, complete, and current device shipment records...." In regard to being a clinical investigator, the FDA warned of the following objectionable conditions: (1) "Failure to ensure that informed consent was obtained in accordance with [federal regulations]" and (2) "Failure to maintain accurate, complete, and current records related to your participation in the investigation..."[3]

12. On or about late 2014, patient A, a then-71-year old female, who had been diagnosed with MS in 2011, discovered Respondent after doing online research concerning possible treatments for MS symptoms. Believing that Respondent's treatment could potentially provide relief for her MS symptoms, she sent an email to his office and was contacted shortly thereafter by a nurse that worked for Respondent. The nurse did an initial patient intake interview over the phone in which patient A was asked a series of questions about her MS and related symptoms. In response to the questions, patient A advised the nurse she was diagnosed with MS in 2011 and reported that in the past year she had suffered severe symptoms with chronic fatigue and tiredness, chest tightness (more severe at night), cold intolerance, bowel disturbances, and cramping in her right leg. When asked, patient A also identified other symptoms classified as mild to moderate.

[3] The Warning Letter noted, "[t]he violations described above are not intended to be an all inclusive list of problems that may exist with your firm and your clinical study. It is your firm's responsibility as a study sponsor; and you, as a clinical investigator, to ensure compliance with the Act and applicable regulations."

This information was documented on a "TVAM [Transvascular Autonomic Modulation] Intake" form. After discussing her current symptoms, patient A was advised her symptoms were most likely the result of "venous compression" and "autonomic dysfunction" which Respondent could treat with a procedure that would cost thirteen thousand dollars. The nurse claimed the costs would be covered by Medicare and her secondary insurance, Anthem Blue Cross. Patient A agreed to pay an initial deposit of one thousand dollars and an appointment was scheduled for January 12, 2015, at Respondent's office in Newport Beach, California.

13. According to Respondent's certified medical records, at some time before the scheduled office visit with patient A, a lab order was placed for a comprehensive metabolic panel, complete blood count, "PT/PTT/INR," a "Salivary Cortisol Test," and a "SIBO Breath test kit" with directions to fax the lab results back to Respondent "Attention Clinical Coordinator." The Genova Diagnostics test kit for the salivary cortisol test was collected on January 7, 2015, and completed on January 12, 2015. While the Genova Diagnostics SIBO breath test kit was sent to patient A after her scheduled procedure was performed, patient A claims the results of the lab tests "...were not shared with me the patient, and seemed to have no relevancy to the procedure."

14. On or about January 12, 2015, patient A had a pre-procedure visit at Respondent's office. Patient A was asked to pay another $2,000, which she refused to do, and advised one of Respondent's staff that they could seek reimbursement through her insurance. During this brief office visit, patient A's vital signs were obtained and she also signed a number of forms, that were not fully discussed with her, relating to the procedure to be performed the next day, which allegedly would provide relief for her MS symptoms. Patient A was not adequately informed, among other things, that the procedure to be performed was not generally accepted within the medical community,[4] she was not advised of the FDA Safety Communication of May 10, 2012,

[4] According to patient A, she was never advised there was disagreement in the medical community about the TVAM procedure that was performed on January 13, 2015. An informed consent of January 12, 2015, failed to mention there was disagreement in the medical community concerning the procedure. Additionally, while there is a type-written procedure note dated January 13, 2015, with a section entitled "INFORMED CONSENT," which indicates patient A was advised of "the incomplete agreement in the medical community of the benefits of the procedure...," that is categorically denied by patient A who claims she was never advised of any disagreement in the medical community regarding the procedure performed on her.

and she was unaware Respondent was being scrutinized by the FDA for his off-label use of angioplasty balloon devices that FDA deemed "significant risk devices" under applicable federal regulations. During this visit, there was no detailed pre-procedure history obtained, no physical examination performed by Respondent, and no cardiovascular or neurological assessment. According to Respondent's medical records, certain "Autonomic" tests were performed which included a Heart Rate Deep Breathing (HRDB) Test, a HRDB Analysis, HRDB (R-R) Analysis, Valsalva Maneuver Test and Sweat Response Test.

15. On or about January 13, 2015, patient A arrived early at Respondent's office where she was prepped for her outpatient procedure which, according to the available medical records, would be performed under conscious sedation. Once again, there was no indication of any detailed history and/or physical examination.[5] According to the medical record for this visit, patient A's procedure diagnosis was "Venous compression, Autonomic Dysfunction" and the procedures to be performed were listed as: "(1) Bilateral internal jugular vein, cerebral sinuses, left renal, left iliac, azygos and subclavian venograms; (2) Ballooning of internal jugular vein: 12 mm left, 14 mm right; (3) Ballooning of the azygos vein: 6 mm; (4) Ballooning of the left renal vein: 10 mm; (5) ballooning of the left iliac vein: 10 mm; [and] (6) Intravascular ultrasound interrogation." The alleged indication for the procedure was "[t]he patient has chronic venous compression and dysautonomia." Following the procedure, Respondent documented, "INTERPRETATION: Successful bilateral jugular and sinus, azygos, SVC, IVC, left iliac, and left renal venography [with] Venous compressive disease identified and successfully treated..." Patient A was advised, at some point during this visit, that some patients have immediate improvement in their symptoms, other patients take longer to see improvement, but all patients who had undergone the same procedure had improvement of their MS symptoms. After the procedure, patient A was picked up by her daughter and returned to her hotel room.

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[5] Respondent acknowledged in his interview before a Department of Consumer Affairs, Health Quality Investigation Unit ("HQIU") investigator that he failed to document a history and physical examination.

16. On or about January 14, 2015, patient A returned to Respondent's office for her post-procedure visit. At this time, Respondent advised patient A the procedure was "a success." He identified the procedure as the TVAM procedure and indicated it was very similar to the CCSVI procedure. Respondent provided patient A with a compact disc and a packet which contained information on stem cell therapy. Respondent then told patient A that many of his patients also opted to have stem cell therapy, in addition to the TVAM procedure, and the patients who did so reported better outcomes.[6] Patient A was told that if she extended her stay one more day, she could receive the stem cell treatment, and was quoted a price of ten thousand dollars ($10,000). Patient A politely declined. Near the end of the visit, patient A was given directions to a pharmacy that was fifteen to twenty minutes away, where she could obtain the medications recommended by Respondent. When patient A arrived at the pharmacy, she received two to three more calls from one of Respondent's staff members, who attempted to persuade her to stay one extra day for the stem cell therapy, with the staff member ultimately quoting a revised price of six thousand dollars ($6,000). Once again, Patient A declined.

17. According to Respondent, at some time after the procedure on January 13, 2015, patient A was contacted by a nurse who worked for Respondent advising her she would be receiving an additional test kit from Genova Diagnostics. Patient A provided the sample for the test and returned the sample to Genova Diagnostics. According to the medical records, a Bacterial Overgrowth of the Small Intestine Breath Test was collected on May 21, 2015, and completed on May 28, 2015. Patient A was never advised of the results of this test and never received any additional follow up from Respondent or any of his staff.

18. In or about June 2015, patient A received a billing statement from Respondent requesting payment in the amount of $16,174.39. After doing some additional investigation, patient A obtained documentation indicating that Respondent billed $113,821.08 to Medicare and

[6] In his interview before an HQIU investigator, Respondent stated "the stem cells may have been presented as one of the treatments that we provide, but that is not something that I offer" and "I think that the stem cell applications, um, are interesting and they – they have potential, but it's not something I'd say, 'I think this is going to help you.' It's – yeah, it could." Patient A disputes Respondent's claim that he did not encourage her to undergo stem cell therapy after having the TVAM procedure.

nearly $47,000 to her secondary insurance, Anthem Blue Cross, for services related to the procedure performed on January 13, 2015. Patient A contacted Respondent's office to complain and was told that the company that handled Respondent's billing made errors in regard to the charges submitted to Medicare and Anthem Blue Cross and steps had been taken, or were being taken, to address the issue.

19. On or about September 13, 2016, the FDA sent Respondent a "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)." The NIDPOE stated, among other things, "[b]ased on our evaluation of information obtained by the Agency, we believe that you, as a sponsor-investigator, have repeatedly or deliberately violated regulations governing the proper conduct of clinical studies involving investigational products ..." The violations were listed as: "(1) You repeatedly failed to submit an application to the FDA and obtain institutional review board (IRB) and FDA approval prior to allowing subjects to participate in the investigation...; (2) You deliberately allowed subjects to participate in a study before obtaining approval from the reviewing IRB prior to initiation of the study; (3) You deliberately failed to ensure that IRB-approved informed consent was obtained from study subjects and adheres to informed consent requirements...; (4) You deliberately represented a device as safe and effective for the purpose of treating various diseases other than those for which FDA has approved them...; and (5) You repeatedly failed to maintain accurate and complete records of receipt, use and disposition of devices...."

20. On or about March 8, 2017, the FDA issued a safety communication entitled "FDA Concern over Experimental Procedures that Use Balloon Angioplasty Devices to Treat Autonomic Dysfunction." In this safety communication, the FDA stated its purpose of the safety communication was:

> "**Purpose**: To alert the audiences listed above ["health care providers" and "people considering treatment options for autonomic dysfunction"] about an experimental procedure called Transvascular Autonomic Modulation (TVAM). This procedure may put patients at risk because [it] is being promoted as a treatment for a variety of conditions even though it has not been formally studied in clinical trials. The procedure uses balloon angioplasty devices outside the scope of the FDA-approved indications for use.

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> "This safety communication supplements a 2012 safety communication [with a link to the FDA's earlier safety communication of May 10, 2012] and warning letter [with a link to the FDA's warning letter to Respondent of September 5, 2010] addressing the risk of serious injuries and death associated with similar experimental procedures, using the same medical devices, to treat Chronic Cerebrospinal Venous Insufficiency (CCSVI).
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> "**Summary of Problem and Scope**: TVAM consists of threading a catheter into a patient's venous system, such as the jugular vein, where a balloon attached to the catheter inflates to widen the vein walls. *At least one physician, Dr. Michael Arata claims the procedure treats the signs and symptoms of autonomic dysfunction in a number of neurological disorders. The FDA has not reviewed any data that supports the safety and effectiveness of balloon angioplasty devices for this intended use.*" (Emphasis added.)

The FDA Safety Communication reported "[t]here is no clear scientific evidence to support that the treatment of internal jugular venous stenosis: is safe in any patients, including those with autonomic dysfunction; impacts the symptoms on autonomic dysfunction; changes the overall course of health conditions derived from autonomic dysfunction; or approves the quality of life for patients with autonomic dysfunction." Additionally, the FDA warned that "TVAM and other similar experimental procedures have been associated with serious complications" by stating, in pertinent part:

> "After the safety communication issued in May 2012, the FDA received at least one medical device report of a balloon rupturing during placement in a patient's jugular vein. Physicians ultimately determined the balloon had migrated to the patient's lung, requiring surgery to remove the ruptured balloon. [¶] "Other serious complications reported to the FDA or discussed in medical journals include: at least one death, blood clots in a vein in the brain (which may lead to stroke), cranial nerve damage, and abdominal bleeding."

Once again, all interested parties were warned "[t]he FDA is aware of at least one physician, Dr. Michael Arata, who has continued to conduct unauthorized clinical research using these devices [and] [t]he expanded list of neurological disorders he claims to treat warrant an update to the 2012 safety communication on the subject."

21. On or about June 21, 2017, the FDA hand delivered a Notice of Opportunity of Hearing (NOOH) letter to Respondent, identified as the President of Synergy Health Concepts, Inc. The NOOH letter advised Respondent of the numerous violations, as generally discussed herein, and his repeated violations, some of which were previously identified when "...FDA conducted an inspection from April 10 through May 15, 2012, which resulted in FDA issuing to

[Respondent] a Warning Letter dated September 5, 2012..." In general, the violations identified in the NOOH letter concerned Respondent's use of a balloon angioplasty technique and device "the internal jugular veins, and azygos veins (vascular lesions) ... which were not approved for dilation of jugular, azygos, renal or iliac veins" with the FDA noting the technique and device had not been properly approved for such use and "[a]s a result, you continued to place subjects at increased risk of serious harm, despite having received the 2012 WL [Warning Letter]." Moreover, the FDA found that Respondent, as a sponsor-investigator, had deliberately represented in various publications that the use of the balloon angioplasty technique and device was safe and effective "for the purpose of investigating various diseases other than those for which the FDA has approved them" with citation to various publications. These representations were made when there was no reliable evidence from controlled clinical trials to support such claims.

22. On or about May 21, 2018, the FDA issued Respondent a Notice of Denial of Hearing and Disqualification Letter to Respondent.

23. Patient A has received no relief from her MS symptoms since the TVAM procedure was performed on her by Respondent on or about January 13, 2015.

24. Respondent committed gross negligence in his care and treatment of patient A which included, but was not limited to, the following:

(a) Respondent performed a risky and disproven invasive procedure on patient A on or about January 13, 2015.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

25. Respondent is further subject to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (c), of the Code, in that he committed repeated negligent acts in his care and treatment of patient A, as more particularly alleged herein:

26. Respondent committed repeated negligent acts in his care and treatment of patient A which included, but was not limited to, the following:

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(a) Paragraphs 8 through 24, above, are hereby incorporated by reference and realleged as if fully set forth herein;

(b) Respondent performed a risky and disproven invasive procedure on patient A on or about January 13, 2015;

(c) Respondent failed to obtain and/or document a comprehensive history and failed to perform and/or document a comprehensive physical examination on patient A;

(d) Respondent performed excessive and unnecessary laboratory testing on patient A which included, but were not limited to, a Salivary Cortisol Test, Heart Rate Deep Breathing (HRDB) Test, a HRDB Analysis, HRDB (R-R) Analysis, Valsalva Maneuver Test and Sweat Response Test;

(e) Respondent treated patient A without performing appropriate testing on patient A to rule out other possible etiologies of her symptoms including, but not limited to, sleep evaluation, testing for abdominal discomfort, blood tests for thyroid, nutrient evaluation and heavy metal testing, cardiac imaging, evaluation of upper gastrointestinal system, evaluation of cortisol levels, and possible biofeedback; and

(f) Respondent had billing irregularities in regard to his office visits and the procedure he performed on patient A.

THIRD CAUSE FOR DISCIPLINE

(Dishonesty or Corruption)

27. Respondent is further subject to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (e), of the Code, in that he has engaged in an act or acts of dishonesty or corruption substantially related to the qualifications, functions, or duties of a physician, as more particularly alleged in paragraphs 8 through 24, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

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FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate or Accurate Records)

28. Respondent is further subject to disciplinary action under sections 2227 and 2234, as defined by section 2266, of the Code, in that he failed to maintain adequate and accurate records in his care and treatment of patient A, as more particularly alleged in paragraphs 8 through 24, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(General Unprofessional Conduct)

29. Respondent is further subject to disciplinary action under sections 2227 and 2234, as defined by section 2234, of the Code, in that he has engaged in conduct which breached the rules or ethical code of the medical profession or which was unbecoming a member in good standing of the medical profession, and which demonstrates an unfitness to practice medicine, as more particularly alleged in paragraphs 8 through 28, above, are hereby incorporated by reference and realleged as if fully set forth herein.

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PRAYER

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

1. Revoking or suspending Physician's and Surgeon's Certificate Number A 70967, issued to Respondent Michael Andrew Arata, M.D.;

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

3. Ordering Respondent Michael Andrew Arata, M.D., if placed on probation, to pay the Board the costs of probation monitoring; and

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

DATED: June 28, 2018

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

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