

**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.)
)
Physician's and Surgeon's)
Certificate No. A 70967)
)
Respondent)
_____)

Case No. 800-2015-014936

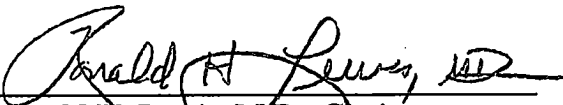
DECISION

The attached Stipulated Settlement and Disciplinary Order 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 July 12, 2019.

IT IS SO ORDERED: June 12, 2019.

MEDICAL BOARD OF CALIFORNIA



Ronald H. Lewis, M.D., Chair
Panel A

1 XAVIER BECERRA
Attorney General of California
2 MATTHEW M. DAVIS
Supervising Deputy Attorney General
3 MARTIN W. HAGAN
Deputy Attorney General
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8 *Attorneys for Complainant*

9
10 **BEFORE THE**
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
11 **STATE OF CALIFORNIA**

12
13 In the Matter of the Accusation Against:

14 **MICHAEL ANDREW ARATA, M.D.**
15 **4501 Birch Street**
Newport Beach, CA 92660

16 **Physician's and Surgeon's Certificate No.**
17 **A70967**

18 Respondent.

Case No. 800-2015-014936

OAH No. 2018081143

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

19 **IT IS HEREBY STIPULATED AND AGREED** by and between the parties to the above-
20 entitled proceedings that the following matters are true:

21 **PARTIES**

22 1. Kimberly Kirchmeyer (Complainant) is the Executive Director of the Medical Board
23 of California (Board). She brought this action solely in her official capacity and is represented in
24 this matter by Xavier Becerra, Attorney General of the State of California, by Martin W. Hagan,
25 Deputy Attorney General.

26 2. Respondent Michael Andrew Arata, M.D. (Respondent) is represented in this
27 proceeding by Raymond J. McMahon, Esq., of Doyle Schafer & McMahon, whose address is:
28 5440 Trabuco Road, Irvine, California 92620.

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3. On or about March 3, 2000, the Board issued Physician's and Surgeon's Certificate No. A70967 to Respondent. The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 800-2015-014936, and will expire on September 30, 2019, unless renewed.

JURISDICTION

4. On or about June 28, 2018, Accusation No. 800-2015-014936 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 28, 2018. Respondent timely filed his Notice of Defense contesting the Accusation. A true and correct copy of Accusation No. 800-2015-014936 is attached hereto as Exhibit A and incorporated herein by reference as if fully set forth herein.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 800-2015-014936. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

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1 CULPABILITY

2 8. Respondent agrees that, at an administrative hearing, Complainant could establish a
3 *prima facie* case with respect to the charges and allegations in Accusation No. 800-2015-014936,
4 and that he has thereby subjected his Physician's and Surgeon's Certificate No. A70967 to
5 disciplinary action. Respondent further agrees to be bound by the Board's imposition of
6 discipline as set forth in the Disciplinary Order below.

7 9. Respondent further agrees that if he ever petitions for early termination or
8 modification of probation, or if an accusation and/or petition for revocation of probation is filed
9 against him before the Board, all of the charges and allegations contained in Accusation No. 800-
10 2015-014936 shall be deemed true, correct and fully admitted by Respondent for purposes of that
11 proceeding or any other licensing proceeding involving Respondent in the State of California or
12 elsewhere.

13 10. Respondent further agrees that he will not seek reinstatement from or with the U.S.
14 Food and Drug Administration (FDA), pursuant to 21 C.F.R. section 812.119, subdivision (f), or
15 any other applicable authority, to have his eligibility reinstated to conduct clinical trials or
16 investigations for products regulated by the FDA, that was revoked by the FDA through their
17 Denial of Hearing and Disqualification Letter of May 21, 2018.

18 11. Respondent agrees that his Physician's and Surgeon's Certificate is subject to
19 discipline and he agrees to be bound by the Board's probationary terms as set forth in the
20 Disciplinary Order below.

21 CONTINGENCY

22 12. This stipulation shall be subject to approval by the Medical Board of California.
23 Respondent understands and agrees that counsel for Complainant and the staff of the Medical
24 Board of California may communicate directly with the Board regarding this stipulation and
25 settlement, without notice to or participation by Respondent or his counsel. By signing the
26 stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek
27 to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails
28 to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary

1 Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal
2 action between the parties, and the Board shall not be disqualified from further action by having
3 considered this matter.

4 13. The parties agree that this Stipulated Settlement and Disciplinary Order shall be
5 null and void and not binding upon the parties unless approved and adopted by the Board, except
6 for this paragraph, which shall remain in full force and effect. Respondent fully understands and
7 agrees that in deciding whether or not to approve and adopt this Stipulated Settlement and
8 Disciplinary Order, the Board may receive oral and written communications from its staff and/or
9 the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify
10 the Board, any member thereof, and/or any other person from future participation in this or any
11 other matter affecting or involving respondent. In the event that the Board does not, in its
12 discretion, approve and adopt this Stipulated Settlement and Disciplinary Order, with the
13 exception of this paragraph, it shall not become effective, shall be of no evidentiary value
14 whatsoever, and shall not be relied upon or introduced in any disciplinary action by either party
15 hereto. Respondent further agrees that should this Stipulated Settlement and Disciplinary Order
16 be rejected for any reason by the Board, respondent will assert no claim that the Board, or any
17 member thereof, was prejudiced by its/his/her review, discussion and/or consideration of this
18 Stipulated Settlement and Disciplinary Order or of any matter or matters related hereto.

19 **ADDITIONAL PROVISIONS**

20 14. This Stipulated Settlement and Disciplinary Order is intended by the parties herein to
21 be an integrated writing representing the complete, final and exclusive embodiment of the
22 agreements of the parties in the above-entitled matter.

23 15. The parties agree that copies of this Stipulated Settlement and Disciplinary Order,
24 including copies of the signatures of the parties, may be used in lieu of original documents and
25 signatures and, further, that such copies shall have the same force and effect as originals.

26 16. In consideration of the foregoing admissions and stipulations, the parties agree the
27 Board may, without further notice to or opportunity to be heard by Respondent, issue and enter
28 the following Disciplinary Order:

1 **DISCIPLINARY ORDER**

2 **IT IS HEREBY ORDERED** that Physician's and Surgeon's Certificate No. A70967
3 issued to Respondent Michael Andrew Arata, M.D. is revoked. However, the revocation is stayed
4 and Respondent is placed on probation for five (5) years on the following terms and conditions.

5 1. **EDUCATION COURSE.** Within 60 calendar days of the effective date of this
6 Decision, and on an annual basis thereafter, Respondent shall submit to the Board or its designee
7 for its prior approval educational program(s) or course(s) which shall not be less than 40 hours
8 per year, for each year of probation. The educational program(s) or course(s) shall be aimed at
9 correcting any areas of deficient practice or knowledge and shall be Category I certified. The
10 educational program(s) or course(s) shall be at Respondent's expense and shall be in addition to
11 the Continuing Medical Education (CME) requirements for renewal of licensure. Following the
12 completion of each course, the Board or its designee may administer an examination to test
13 Respondent's knowledge of the course. Respondent shall provide proof of attendance for 50
14 hours of CME of which 25 hours were in satisfaction of this condition.

15 2. **MEDICAL RECORD KEEPING COURSE.** Within 60 calendar days of the
16 effective date of this Decision, Respondent shall enroll in a course in medical record keeping
17 approved in advance by the Board or its designee. Respondent shall provide the approved course
18 provider with any information and documents that the approved course provider may deem
19 pertinent. Respondent shall participate in and successfully complete the classroom component of
20 the course not later than six (6) months after Respondent's initial enrollment. Respondent shall
21 successfully complete any other component of the course within one (1) year of enrollment. The
22 medical record keeping course shall be at Respondent's expense and shall be in addition to the
23 Continuing Medical Education (CME) requirements for renewal of licensure.

24 A medical record keeping course taken after the acts that gave rise to the charges in the
25 Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board
26 or its designee, be accepted towards the fulfillment of this condition if the course would have
27 been approved by the Board or its designee had the course been taken after the effective date of
28 this Decision.

1 Respondent shall submit a certification of successful completion to the Board or its
2 designee not later than 15 calendar days after successfully completing the course, or not later than
3 15 calendar days after the effective date of the Decision, whichever is later.

4 3. **PROFESSIONALISM PROGRAM (ETHICS COURSE)**. Within 60 calendar
5 days of the effective date of this Decision, Respondent shall enroll in a professionalism program,
6 that meets the requirements of Title 16, California Code of Regulations (CCR) section 1358.1.
7 Respondent shall participate in and successfully complete that program. Respondent shall
8 provide any information and documents that the program may deem pertinent. Respondent shall
9 successfully complete the classroom component of the program not later than six (6) months after
10 Respondent's initial enrollment, and the longitudinal component of the program not later than the
11 time specified by the program, but no later than one (1) year after attending the classroom
12 component. The professionalism program shall be at Respondent's expense and shall be in
13 addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

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

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

22 4. **SOLO PRACTICE PROHIBITION**. Respondent is prohibited from engaging in
23 the solo practice of medicine. Prohibited solo practice includes, but is not limited to, a practice
24 where: 1) Respondent merely shares office space with another physician but is not affiliated for
25 purposes of providing patient care, or 2) Respondent is the sole physician practitioner at that
26 location.

27 If Respondent fails to establish a practice with another physician or secure employment in
28 an appropriate practice setting within 60 calendar days of the effective date of this Decision,

1 Respondent shall receive a notification from the Board or its designee to cease the practice of
2 medicine within three (3) calendar days after being so notified. The Respondent shall not resume
3 practice until an appropriate practice setting is established.

4 If, during the course of the probation, the Respondent's practice setting changes and
5 the Respondent is no longer practicing in a setting in compliance with this Decision, the
6 Respondent shall notify the Board or its designee within five (5) calendar days of the practice
7 setting change. If Respondent fails to establish a practice with another physician or secure
8 employment in an appropriate practice setting within 60 calendar days of the practice setting
9 change, Respondent shall receive a notification from the Board or its designee to cease the
10 practice of medicine within three (3) calendar days after being so notified. The Respondent shall
11 not resume practice until an appropriate practice setting is established.

12 5. **NOTIFICATION.** Within seven (7) days of the effective date of this Decision, the
13 Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the
14 Chief Executive Officer at every hospital where privileges or membership are extended to
15 Respondent, at any other facility where Respondent engages in the practice of medicine,
16 including all physician and locum tenens registries or other similar agencies, and to the Chief
17 Executive Officer at every insurance carrier which extends malpractice insurance coverage to
18 Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15
19 calendar days. This condition shall apply to any change(s) in hospitals, other facilities or
20 insurance carrier.

21 6. **SUPERVISION OF PHYSICIAN ASSISTANTS AND ADVANCED**
22 **PRACTICE NURSES.** During probation, Respondent is prohibited from supervising physician
23 assistants and advanced practice nurses.

24 7. **OBEY ALL LAWS.** Respondent shall obey all federal, state and local laws, all rules
25 governing the practice of medicine in California and remain in full compliance with any court
26 ordered criminal probation, payments, and other orders. This shall include Respondent obeying
27 the FDA's revocation of his eligibility to conduct clinical trials or investigations for products
28 regulated by the FDA, that was revoked by the FDA through their Denial of Hearing and

1 Disqualification Letter of May 21, 2018. Respondent further agrees that he will not seek
2 reinstatement from or with the FDA, pursuant to 21 C.F.R. section 812.119, subdivision (f), or
3 any other applicable authority, to have his eligibility reinstated to conduct clinical trials or
4 investigations for products regulated by the FDA.

5 8. **QUARTERLY DECLARATIONS.** Respondent shall submit quarterly declarations
6 under penalty of perjury on forms provided by the Board, stating whether there has been
7 compliance with all the conditions of probation. Respondent shall submit quarterly declarations
8 not later than 10 calendar days after the end of the preceding quarter.

9 9. **GENERAL PROBATION REQUIREMENTS.**

10 **Compliance with Probation Unit:** Respondent shall comply with the Board's probation
11 unit.

12 **Address Changes:** Respondent shall, at all times, keep the Board informed of
13 Respondent's business and residence addresses, email address (if available), and telephone
14 number. Changes of such addresses shall be immediately communicated in writing to the Board
15 or its designee. Under no circumstances shall a post office box serve as an address of record,
16 except as allowed by Business and Professions Code section 2021(b).

17 **Place of Practice:** Respondent shall not engage in the practice of medicine in Respondent's
18 or patient's place of residence, unless the patient resides in a skilled nursing facility or other
19 similar licensed facility.

20 **License Renewal:** Respondent shall maintain a current and renewed California physician's
21 and surgeon's license.

22 **Travel or Residence Outside California:** Respondent shall immediately inform the Board
23 or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts,
24 or is contemplated to last, more than thirty (30) calendar days. In the event Respondent should
25 leave the State of California to reside or to practice, Respondent shall notify the Board or its
26 designee in writing 30 calendar days prior to the dates of departure and return.

27 10. **INTERVIEW WITH THE BOARD OR ITS DESIGNEE.** Respondent shall be
28 available in person upon request for interviews either at Respondent's place of business or at the

1 probation unit office, with or without prior notice throughout the term of probation.

2 11. **NON-PRACTICE WHILE ON PROBATION.** Respondent shall notify the Board
3 or its designee in writing within 15 calendar days of any periods of non-practice lasting more than
4 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is
5 defined as any period of time Respondent is not practicing medicine as defined in Business and
6 Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct
7 patient care, clinical activity or teaching, or other activity as approved by the Board. If
8 Respondent resides in California and is considered to be in non-practice, Respondent shall
9 comply with all terms and conditions of probation. All time spent in an intensive training
10 program which has been approved by the Board or its designee shall not be considered non-
11 practice and does not relieve Respondent from complying with all the terms and conditions of
12 probation. Practicing medicine in another state of the United States or Federal jurisdiction while
13 on probation with the medical licensing authority of that state or jurisdiction shall not be
14 considered non-practice. A Board-ordered suspension of practice shall not be considered as a
15 period of non-practice.

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

21 Respondent's period of non-practice while on probation shall not exceed two (2) years.

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

23 Periods of non-practice for a Respondent residing outside of California will relieve
24 Respondent of the responsibility to comply with the probationary terms and conditions with the
25 exception of this condition and the following terms and conditions of probation: Obey All Laws;
26 General Probation Requirements; and Quarterly Declarations.

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1 12. **COMPLETION OF PROBATION.** Respondent shall comply with all financial
2 obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the
3 completion of probation. Upon successful completion of probation, Respondent's certificate shall
4 be fully restored.

5 13. **VIOLATION OF PROBATION.** Failure to fully comply with any term or
6 condition of probation is a violation of probation. If Respondent violates probation in any
7 respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke
8 probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to
9 Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation,
10 the Board shall have continuing jurisdiction until the matter is final, and the period of probation
11 shall be extended until the matter is final.

12 14. **LICENSE SURRENDER.** Following the effective date of this Decision, if
13 Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy
14 the terms and conditions of probation, Respondent may request to surrender his or her license.
15 The Board reserves the right to evaluate Respondent's request and to exercise its discretion in
16 determining whether or not to grant the request, or to take any other action deemed appropriate
17 and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent
18 shall within 15 calendar days deliver Respondent's wallet and wall certificate to the Board or its
19 designee and Respondent shall no longer practice medicine. Respondent will no longer be subject
20 to the terms and conditions of probation. If Respondent re-applies for a medical license, the
21 application shall be treated as a petition for reinstatement of a revoked certificate.

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

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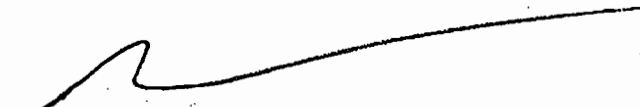
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1 ACCEPTANCE

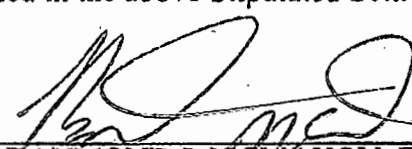
2 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
3 discussed it with my attorney, Raymond J. McMahon, Esq. I understand the stipulation and the
4 effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated
5 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
6 bound by the Decision and Order of the Medical Board of California.

7
8 DATED: 4/24/19


9 MICHAEL ANDREW ARATA, M.D.
Respondent

10 I have read and fully discussed with Respondent Michael Andrew Arata, M.D. the terms
11 and conditions and other matters contained in the above Stipulated Settlement and Disciplinary
12 Order. I approve its form and content.

13 DATED: April 24, 2019


14 RAYMOND J. MCMAHON, ESQ.
Attorney for Respondent

15
16 ENDORSEMENT

17 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
18 submitted for consideration by the Medical Board of California.

19 Dated: 4/24/2019

20 Respectfully submitted,

21 XAVIER BECERRA
Attorney General of California
22 MATTHEW M. DAVIS
Supervising Deputy Attorney General

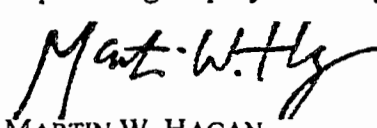
23 
24 MARTIN W. HAGAN
25 Deputy Attorney General
26 Attorneys for Complainant

Exhibit A

Accusation No. 800-2015-014936

1 XAVIER BECERRA
Attorney General of California
2 MATTHEW M. DAVIS
Supervising Deputy Attorney General
3 MARTIN W. HAGAN
Deputy Attorney General
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6 San Diego, CA 92186-5266
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7 Facsimile: (619) 645-2061

8 *Attorneys for Complainant*

FILED
STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO June 28 20 18
BY K. Voong ANALYST

10 **BEFORE THE**
11 **MEDICAL BOARD OF CALIFORNIA**
12 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

13 In the Matter of the Accusation Against:
14 **Michael Andrew Arata, M.D.**
15 **4501 Birch Street**
Newport Beach, CA 92660
16 **Physician's and Surgeon's Certificate**
17 **No. A 70967,**
18 Respondent.

Case No. 800-2015-014936

A C C U S A T I O N

19 Complainant alleges:

20 **PARTIES**

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

24 2. On or about March 3, 2000, the Medical Board issued Physician's and Surgeon's
25 Certificate Number A 70967 to Michael Andrew Arata, M.D. (Respondent). The Physician's and
26 Surgeon's Certificate was in full force and effect at all times relevant to the charges brought
27 herein and will expire on September 30, 2019, unless renewed.

28 ////

JURISDICTION

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

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

8 5. Section 2234 of the Code states:

9 “The board shall take action against any licensee who is charged with
10 unprofessional conduct. In addition to other provisions of this article,
11 unprofessional conduct includes, but is not limited to, the following:

12 “(a) Violating or attempting to violate, directly or indirectly, assisting in or
13 abetting the violation of, or conspiring to violate any provision of this
14 chapter.

15 “(b) Gross negligence.

16 “(c) Repeated negligent acts. To be repeated, there must be two or more
17 negligent acts or omissions. An initial negligent act or omission followed by
18 a separate and distinct departure from the applicable standard of care shall
19 constitute repeated negligent acts.

20 “(1) An initial negligent diagnosis followed by an act or omission
21 medically appropriate for that negligent diagnosis of the patient shall
22 constitute a single negligent act.

23 “(2) When the standard of care requires a change in the diagnosis,
24 act, or omission that constitutes the negligent act described in paragraph (1),
25 including, but not limited to, a reevaluation of the diagnosis or a change in
26 treatment, and the licensee’s conduct departs from the applicable standard of
27 care, each departure constitutes a separate and distinct breach of the standard
28 of care.

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

3 10. On or about May 10, 2012, the United States Food and Drug Administration (FDA)
4 issued a safety communication entitled “Chronic Cerebrospinal Venous Insufficiency [CCSVI]
5 Treatment in Multiple Sclerosis Patient: FDA Safety Communication” (hereinafter “FDA Safety
6 Communication”). In the FDA Safety Communication, CCSVI was described as using “balloon
7 angioplasty devices or stents to widen the narrowed internal jugular or azygos veins” in a
8 “procedure [that] is sometimes called ‘liberation therapy’ or the ‘liberation procedure.’” The
9 FDA warned, “[a]t this time, the FDA believes there is no reliable evidence from controlled
10 studies that this procedure is effective in treating MS (multiple sclerosis)” and “the criteria used to
11 diagnose CCSVI have not been adequately established.” The FDA further warned “that using
12 these medical devices in CCSVI treatment procedures posed a risk to patients for a variety of
13 reasons² and that “[t]his communication [the Safety Communication] is also intended to notify
14 physicians and clinical investigators planning on conducting clinical trials using medical devices
15 to treat CCSVI that they must comply with FDA regulations for investigational devices.”

16 11. On or about September 5, 2012, the FDA sent a “Warning Letter” to Respondent, who
17 was identified as the President and Principal Investigator for Synergy Health Concepts, Inc.
18 Respondent is a board certified diagnostic radiologist who completed a fellowship in
19 interventional radiology. He admittedly does not have the training to “treat MS per se” but claims
20 he can treat symptoms which are “autonomic in nature.” The Warning Letter advised Respondent
21 of objectionable conditions observed during the [FDA’s] inspection conducted at Synergy Health
22

23 ² These reasons included, but were not limited to, because: (1) “There is no clear
24 diagnostic evidence that CCSVI exists as a distinct clinical disorder or is linked to MS,” (2)
25 “Venous stenoses seen on imaging tests may be normal variants that do not cause any symptoms
26 or disease, since they are sometimes seen in healthy people,” (3) “The safety and effectiveness of
27 using balloon angioplasty devices or stents in the internal jugular or azygos veins has not been
28 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.”

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

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

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

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

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

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

24 ⁴ According to patient A, she was never advised there was disagreement in the medical
25 community about the TVAM procedure that was performed on January 13, 2015. An informed
26 consent of January 12, 2015, failed to mention there was disagreement in the medical community
27 concerning the procedure. Additionally, while there is a type-written procedure note dated
28 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.

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

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

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

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

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

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

25 ⁶ In his interview before an HQUI investigator, Respondent stated "the stem cells may
26 have been presented as one of the treatments that we provide, but that is not something that I
27 offer" and "I think that the stem cell applications, um, are interesting and they – they have
28 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.

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

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

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

24 "Purpose: To alert the audiences listed above ["health care providers" and "people
25 considering treatment options for autonomic dysfunction"] about an experimental
26 procedure called Transvascular Autonomic Modulation (TVAM). This procedure
27 may put patients at risk because [it] is being promoted as a treatment for a variety of
28 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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1 “This safety communication supplements a 2012 safety communication [with a link to
2 the FDA’s earlier safety communication of May 10, 2012] and warning letter [with a
3 link to the FDA’s warning letter to Respondent of September 5, 2010] addressing the
4 risk of serious injuries and death associated with similar experimental procedures,
5 using the same medical devices, to treat Chronic Cerebrospinal Venous Insufficiency
6 (CCSVI).

7 **“Summary of Problem and Scope:** TVAM consists of threading a catheter into a
8 patient’s venous system, such as the jugular vein, where a balloon attached to the
9 catheter inflates to widen the vein walls. At least one physician, Dr. Michael Arata
10 claims the procedure treats the signs and symptoms of autonomic dysfunction in a
11 number of neurological disorders. The FDA has not reviewed any data that supports
12 the safety and effectiveness of balloon angioplasty devices for this intended use.”
13 (Emphasis added.)

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

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

28 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

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

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

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

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

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

21 **SECOND CAUSE FOR DISCIPLINE**

22 **(Repeated Negligent Acts)**

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

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

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- 1 (a) Paragraphs 8 through 24, above, are hereby incorporated by reference
2 and realleged as if fully set forth herein;
- 3 (b) Respondent performed a risky and disproven invasive procedure on
4 patient A on or about January 13, 2015;
- 5 (c) Respondent failed to obtain and/or document a comprehensive history
6 and failed to perform and/or document a comprehensive physical
7 examination on patient A;
- 8 (d) Respondent performed excessive and unnecessary laboratory testing on
9 patient A which included, but were not limited to, a Salivary Cortisol
10 Test, Heart Rate Deep Breathing (HRDB) Test, a HRDB Analysis,
11 HRDB (R-R) Analysis, Valsalva Maneuver Test and Sweat Response
12 Test;
- 13 (e) Respondent treated patient A without performing appropriate testing on
14 patient A to rule out other possible etiologies of her symptoms
15 including, but not limited to, sleep evaluation, testing for abdominal
16 discomfort, blood tests for thyroid, nutrient evaluation and heavy metal
17 testing, cardiac imaging, evaluation of upper gastrointestinal system,
18 evaluation of cortisol levels, and possible biofeedback; and
- 19 (f) Respondent had billing irregularities in regard to his office visits and
20 the procedure he performed on patient A.

21 **THIRD CAUSE FOR DISCIPLINE**

22 **(Dishonesty or Corruption)**

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

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1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Adequate or Accurate Records)**

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

7 **FIFTH CAUSE FOR DISCIPLINE**

8 **(General Unprofessional Conduct)**

9 29. Respondent is further subject to disciplinary action under sections 2227 and 2234, as
10 defined by section 2234, of the Code, in that he has engaged in conduct which breached the rules
11 or ethical code of the medical profession or which was unbecoming a member in good standing of
12 the medical profession, and which demonstrates an unfitness to practice medicine, as more
13 particularly alleged in paragraphs 8 through 28, above, are hereby incorporated by reference and
14 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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