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

In the Matter of the Accusation Against:	)	
JAMES FREDERICK MCGUCKIN, M.D.	)	Case No. 800-2015-017645
Physician's and Surgeon's Certificate No. G 87992	)	
Respondent	)	

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on March 1, 2017.

IT IS SO ORDERED January 30, 2017.

MEDICAL BOARD OF CALIFORNIA

By: Michelle Anne Bholat MD
Michelle Anne Bholat, M.D., Chair
Panel B

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

In the Matter of the Accusation Against: JAMES FREDERICK MCGUCKIN, M.D., Physician's and Surgeon's Certificate No. G87992 Respondent.	Case No. 800-2015-017645 OAH No. 2016060685

PROPOSED DECISION

Administrative Law Judge Jill Schlichtmann, State of California, Office of Administrative Hearings, heard this matter on November 3, 2016, in Oakland, California.

Deputy Attorney General Joshua M. Templet represented complainant Kimberly Kirchmeyer, Executive Director, Medical Board of California, Department of Consumer Affairs.

Gary Wittenberg, Attorney at Law, represented respondent James McGuckin, M.D., who was present throughout the administrative hearing.

The record closed and the matter was submitted for decision on November 3, 2016.

FACTUAL FINDINGS

1. On March 30, 2007, the Medical Board of California (Board) issued Physician's and Surgeon's Certificate No. G87992 to James Frederick McGuckin, M.D. (respondent). The license has been active at all times relevant here.

2. Kimberly Kirchmeyer (complainant) is the Executive Director of the Board. On March 3, 2016, complainant issued the accusation against respondent in her official capacity. The accusation alleges that respondent's California license is subject to discipline because of action taken by the Washington Medical Quality Assurance Commission (Washington Commission).

Respondent's Background

3. Respondent graduated from the University of Notre Dame in 1983 with bachelor's degrees in pre-medicine and mechanical engineering. He earned his medical degree from Hahnemann University School of Medicine in 1987, where he was a member of the Alpha Omega Alpha Honor Society. Respondent completed an internship in general surgery at the University Hospitals of Cleveland in 1988. He then obtained a master's degree in biomedical engineering from the University of Pennsylvania in 1991. In 1995, respondent completed his residency in diagnostic imaging at Temple University Hospital in Philadelphia, where he served as chief resident and earned the Isidore Friedman Memorial Research Award. Respondent attended a fellowship in interventional radiology at the University of Pennsylvania Medical Center from 1995 to 1996. Respondent has been board certified in diagnostic radiology with the added qualification of vascular and interventional radiology since 1997.

4. Respondent co-founded Rex Medical in 1999 in Conshohocken, Pennsylvania. The company develops minimally invasive medical devices. Respondent serves as the Director of Research and directs engineering teams on the company's projects. Respondent has had eight medical devices approved by the Federal Drug Administration (FDA), and has had over 150 patents pending or issued. Respondent has worked with the FDA on various projects since 1999. Rex Medical will begin two new clinical trials soon. The first is an atherectomy device used to remove plaque from a blocked vessel; the second is a "closer," a device designed to close a hole in an artery made during surgery.

5. Respondent has been the Medical Director of the Philadelphia Vascular Institute since 2002. He has a busy practice and estimates performing five to eight vascular procedures daily, and seeing 1,000 patients per year. Respondent estimates that 95 percent of his work is performed in Pennsylvania.

6. In 2005, respondent founded Vascular Access Centers; he serves as the company's Medical Director and Chief Executive Officer. Vascular Access Centers has offices in numerous states, including one in Downey, California. Respondent is licensed to practice medicine in Pennsylvania, California, Texas, Louisiana, Georgia, New York, North Carolina, Indiana, New Jersey, Tennessee, Maryland, Illinois, Florida, Maine, Virginia, and the District of Columbia.

7. When Vascular Access Centers opens an office outside of Pennsylvania, respondent works in that state to train the staff and physicians. He returns to out-of-state offices as needed to train physicians, or to fill in for physicians who are on vacation.

Circumstances Underlying Discipline Imposed by Washington Commission

8. In approximately 2010, respondent was treating a patient for an obstruction. In the course of treatment, respondent learned that the patient suffered from multiple sclerosis (MS). Symptoms of MS are neurological and cause visual, motor and sensory

disabilities. The patient reported being treated for chronic cerebrospinal venous insufficiency (CCVSI) outside of the United States and having had a remarkable result from the procedure. CCSVI is a theoretical condition based upon the hypothesis that blockage of the major veins in the neck and chest causes and contributes to the progression of MS. The CCSVI procedure uses balloon angioplasty and sometimes stent placement to treat blocked veins. The CCSVI procedure purports to provide symptom relief to MS patients by treating the blocked veins to increase blood drainage from the brain and spinal cord. The CCSVI procedure poses risks and complications inherent to endovascular treatment. The CCSVI procedure is not recognized as a standard or approved treatment for MS.

9. CCVSI therapy is not durable and the patient's vein had narrowed and re-occluded. The patient had lost the benefits of the procedure and wanted to re-open the vein. Respondent confirmed the blockage[1] and opened it, and the patient's symptoms improved. Respondent was amazed at the result, which allowed the patient much better neuromuscular control.

10. Respondent learned that Paolo Zamboni, a physician in Italy, had pioneered the theory of CCVSI on patients with MS. He traveled to a meeting of the International Society of Neurovascular Disease in Italy where the procedure was being discussed by physicians from around the world. Respondent learned that 30 physicians in the United States were performing the CCVSI procedure, and 60 physicians were performing the procedure in other countries.

11. The CCVSI procedure was investigational and experimental and could only be performed on MS patients as a scientific research study under the Institutional Review Board (IRB) to ensure safety of human subjects. An IRB research study must have approval from the FDA Investigational Device Exemption (IDE) program.

12. While he was in Italy, respondent met Dr. Hubbard of the Hubbard Foundation. The Hubbard Foundation was sponsoring a multi-center research study, or registry, for CCSVI treatment. The registry is an organized system that uses observational study methods to collect uniform data about a specific disease or treatment. Bio-Med IRB approved the registry and established a registry protocol outlining the study design and purpose. The protocol also outlined specific patient inclusion and exclusion criteria. Adherence to the protocol is crucial in order to ensure patient safety and for the registry data to have any scientific validity.

13. Dr. Hubbard invited respondent to be a participant in the study. BioMed IRB approved respondent to be a principal investigator for the CCSVI multi-center registry. However, BioMed IRB did not obtain the required FDA IDE approval and failed to monitor respondent's adherence to the registry protocol.

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[1] Significant venous blockage, or stenosis, is usually defined as vein reduction of at least 50 percent.

14. On May 10, 2012, the FDA released a Safety Communication stating balloon angioplasty and stents are inefficacious in treating MS symptoms and pose risks to patients. The FDA found no clear evidence that CCSVI exists or is linked to MS.

Washington Commission Allegations and Disciplinary Action

15. Respondent was licensed to practice as a physician and surgeon in Washington on March 13, 2007. Vascular Access Centers has a facility in Tukwila, Washington. Respondent performed CCSVI procedures on seven MS patients at the Tukwila facility in 2011. The patients did not have a neurologist referral.

16. On November 25, 2014, the Executive Director of the Washington Commission issued a statement of charges against respondent involving the CCSVI procedures he performed in that state.

17. On October 1, 2015, the Washington Commission accepted a Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order), signed by respondent, resolving the statement of charges. One of the findings contained in the Agreed Order was that respondent performed the CCSVI procedures without ensuring that Bio-Med IRB obtained an approved IDE from the FDA.

18. The Agreed Order also states that respondent deviated from the approved study protocol in the following ways:

a) Only patients diagnosed with MS through proper neurologic examination were to be included in the registry. Respondent represented that CCSVI patients were admitted after a comprehensive intake process. However, patient records indicated respondent did not obtain or review MS examination records from the patients' neurologists. None of the patients had a recorded neurologic examination before or after the CCSVI procedure. There was not documentation that patients had obtained a required Expanded Disability Status Scale rating before and after the procedure.

b) Respondent did not obtain MRI or Doppler testing post-procedure as required.

c) Respondent did not conduct adequate physical evaluations and he relied on patients' self-reporting of MS diagnosis and symptoms in determining whether patients met the inclusion criteria.

d) Respondent did not include one patient in the registry and performed CCSVI treatment on her before the Bio-Med IRB protocol was approved.

e) The registry excluded patients with "abnormal kidney function." There is no documentation for three patients having undergone laboratory testing to assess kidney function prior to CCSVI treatment.

f) The registry lists pregnancy as an exclusion. Respondent did not document that four patients underwent laboratory testing to exclude pregnancy prior to the procedure.

g) Follow-up protocol states that patients would be seen in the office and evaluated for complications and would undergo review of the procedure results. Respondent reported that he would typically see patients the following day after the CCSVI procedure. However, the records did not indicate any office visit or physical evaluation by respondent following treatment. Patient follow-up calls were noted as brief notations on a form by facility staff. Respondent failed to perform a physical evaluation of the seven patients post-procedure.

19. The Agreed Order further provides that:

a) Respondent diagnosed the seven patients with CCSVI by listing chronic venous hypertension with complications, without corroborating reports or examinations. Respondent did not obtain magnetic resonance imaging (MRI) or magnetic resonance venography (MRV) reports identifying blood flow abnormalities. Respondent's reported vascular findings for the seven patients were disputable.

b) In his procedure reports, respondent reported stenosis to be more severe than those seen on the radiologic spot images. Review of the patients' spot images demonstrated abnormalities that would not be considered significant or justified in requiring endovascular treatment. Respondent claimed that the findings seen at angiography are not fully demonstrated in the spot images.

c) It was not evident that respondent forwarded his procedure notes to the patients' neurologists or primary care providers, or if respondent ever established any post-procedure medical

evaluation of patients to determine the efficacy or benefits of CCSVI treatment.

20. In the Agreed order, the Washington Commission found, and respondent agreed, that he had committed unprofessional conduct. Respondent stipulated to the following disciplinary action in the Agreed Order:

a) Respondent shall not perform angioplasty and stenting procedures of the venous system for CCSVI or MS patients in Washington State;

b) Respondent must attend and successfully complete a professional/problem based ethics (ProBE) course offered by the Center for Personalized Education for Physicians (CPEP) within six months. To satisfy this condition respondent must obtain an "unconditional pass" at the conclusion of the course. CPEP will submit respondent's essay to the Commission. Respondent's failure to obtain an unconditional pass could result in his retaking the course or being subject to discipline;

c) Respondent must renew his expired license if he plans to practice medicine in the State of Washington;

d) Respondent must pay a fine of $17,500;

e) Respondent must refund the cash fees to patients who received the CCSVI procedure after May 10, 2012, and who did not have insurance or third-party payors; and,

f) Respondent must provide semi-annual reports to the Commission.

21. The Agreed Order allowed respondent to petition to modify the terms of the Agreed Order no sooner than 12 months from the effective date of the order.

22. On October 6, 2016, respondent reported to the Washington Commission as follows:

a) Respondent had not performed angioplasty and stenting procedures of the venous system for CCSVI for MS patients in Washington state since the Agreed Order;

b) Respondent did not receive an "unconditional pass" following the ProBE courses he attended. He was arranging

individual tutoring/mentoring sessions through ProBE, and would be resubmitting his essay following those sessions;

c) Respondent did not seek to renew his Washington license;

d) Respondent had paid the fine in full; and,

e) Respondent had refunded his fees to the patients and had sent proof to the Washington Commission as directed.

23. There is no evidence that patients were harmed as a result of respondent performing CCSVI procedures.

Respondent's Evidence

24. Respondent disagreed with some of the Factual Findings contained in the Agreed Order, but felt he had no choice but to sign it.

25. Respondent accepts responsibility for becoming an active participant in the Hubbard Foundation study without ensuring that Bio-Med IRB obtained an approved IDE from the FDA. He is very familiar with the FDA approval process and agrees with the strict requirements. Because the study was ongoing when he became an active participant, he assumed that FDA approval was in place. Respondent was not compensated for participating in the study; to the contrary, he paid per patient to participate.

26. Respondent concedes that he deviated from the protocol, but states he had a verbal agreement with Dr. Hubbard to do so. Respondent reports that he conditioned his participation in the study on the deviations he proposed. Respondent did not offer corroborating evidence of this assertion.

27. Respondent described his deviations from the protocol as follows:

a) Respondent felt that requiring the patients to obtain approval from their treating physicians or neurologists was an invasion of privacy. The treatment was experimental and not all treating physicians agreed with it. Respondent did not obtain the patients' records and was not capable of performing a neurological examination himself because he is not a neurologist. Respondent considered the patients to have the right to make their own decisions about the procedure.

b) Respondent does not have MRI or MRV equipment in his facility, unlike Dr. Hubbard. He considered it to be too

expensive and unnecessary for his patients to order MRI and MRV reports before or after to the procedure.

c) Respondent reports that none of his patients was pregnant; however, pursuant to his understanding with Dr. Hubbard, he did not document this.

d) Respondent relied on the patients' self-report of an MS diagnosis. He trusted the patients and respected their privacy concerns. Respondent examined the patients, but did not perform a neurological examination because he is not a neurologist. Post-procedure, respondent would follow up with the patients by telephone.

e) Respondent reports that he did not perform CCSVI therapy unless the patient had at least 50 percent stenosis.

Respondent applied the protocol changes consistently.

28. Respondent no longer performs CCSVI on MS patients. He stopped as soon as he learned that the FDA was investigating and/or when the FDA issued its letter.

29. Respondent anticipates completing his essay for the ProBE course in the near future. Once it is approved, he will petition to be released from the Washington Commission's reporting requirements.

30. Respondent provided his continuing medical education certificates for 2014, 2015 and 2016. Respondent regularly exceeds the minimum continuing medical education requirements.

31. Respondent has family in California and plans to purchase a home here; although he has no current plans to relocate to California or to practice here full-time. There is a Vascular Access Clinics facility in Downey, California, near where respondent was raised. He also travels to Santa Rosa several days per year to work on medical research that is performed on animals. Respondent would like to keep his California medical license, but he is unable to comply with a probationary order that would require him to work in California for 40 hours per month.

32. Numerous other states have considered disciplinary action as a result of the Agreed Order. Respondent reports, however, that other states have simply ordered him to comply with the Washington Commission's Agreed Order and have not imposed other conditions or probation. Disciplinary action is pending in Florida and Indiana. Respondent has lost hospital privileges at three hospitals in Pennsylvania and a hospital in New Jersey. He has been unable to participate in various insurance programs as a result of the Agreed Order. The consequences to respondent's ability to practice medicine have been profound.

33. Respondent apologizes for his failure to confirm FDA approval and to obtain documentation of the protocol changes. He has now hired extra staff to confirm that processes are followed. Respondent is committed to remaining in compliance with FDA processes. Since this investigation, the FDA has cleared him for his future projects.

34. Respondent provided reference letters from three colleagues. Scott Hollander, D.O, is an interventional radiologist who works as the Medical Director at Vascular Access Center in Mays Landing, New Jersey. Dr. Hollander completed his fellowship at Yale University – New Haven Hospital before joining Vascular Access Center. Respondent worked closely with Dr. Hollander from July 1, 2014 to October 14, 2014. He assisted respondent with over 100 peripheral arterial disease cases and over 30 dialysis access procedures. Dr. Hollander considers respondent to be his mentor and consults with him on complex procedural cases. Dr. Hollander is aware of the disciplinary action in Washington and the underlying circumstances. Nevertheless, Dr. Hollander reports that respondent is one of the most knowledgeable and specialized physicians in the field of interventional radiology. Dr. Hollander urges the Board not to restrict respondent's licensure.

35. Stephen Kolakowski, Jr., M.D., wrote a letter for the Board's consideration dated August 10, 2016. Dr. Kolakowski is employed at the Vascular Access Center in Eatontown, New Jersey. Dr. Kolakowski has known respondent for six years and has worked closely with him on many patients. Dr. Kolakowski considers respondent to provide excellent quality of care and to have a wealth of experience second to none. He recommends respondent without reservation.

36. Micah Watts, M.D., wrote a reference letter dated August 7, 2016. Dr. Watts works at Main Line Vascular Institute, LLC, in King of Prussia, Pennsylvania. Dr. Watts is a board certified interventional radiologist with a certificate of advance qualification. Dr. Watts was an assistant professor of clinical radiology at the University of Pennsylvania from June 2012 to June 2016. During that time, Dr. Watts was the Director of Interventional Radiology at the Philadelphia VA Medical Center. Dr. Watts reports that respondent has an excellent reputation in Philadelphia. His clinical excellence and patient care focus is a model for younger physicians. Dr. Watts worked with respondent when he was the president of the Philadelphia Angiography and Interventional Radiology Society. He finds respondent to be engaging, enthusiastic and passionate about his work.

Dr. Watts has joined as a partner in respondent's practice and has observed his excellent care first hand. Dr. Watts considers respondent to be a person of high moral character, who is honest and respectful, and has dedicated himself to his profession. Dr. Watts considers respondent to be a pillar in the local interventional radiology community. Dr. Watts supports respondent's unrestricted licensure.

LEGAL CONCLUSIONS

1. The burden of proof in this matter is on the Board and the standard of proof is clear and convincing evidence. (*Ettinger v. Bd. of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.)

2. Pursuant to Business and Professions Code sections 141 and 2305, the Board is authorized to impose discipline on a licensee who has been disciplined in another state, without a broad inquiry into the underlying facts. (*Marek v. Board of Podiatric Medicine* (1993) 16 Cal.App.4th 1089.) This is true even where the respondent has not admitted to the truth of the allegations recited in a stipulation to a disciplinary order or consent decree. (*Ibid.*)

3. Business and Professions Code section 2305 provides:

> The revocation, suspension, or other discipline, restriction, or limitation imposed by another state upon a license or certificate to practice medicine issued by that state, or the revocation, suspension, or restriction of the authority to practice medicine by any agency of the federal government, that would have been grounds for discipline in California of a licensee under this chapter, shall constitute grounds for disciplinary action for unprofessional conduct against the licensee in this state.

Cause for discipline in California exists pursuant to Business and Professions Code section 2305. (Factual Findings 15 through 21.)

4. Whether discipline should be imposed in California must also be evaluated pursuant to Business and Professions Code section 141, subdivision (a), which provides:

> For any licensee holding a license issued by a board under the jurisdiction of a department, a disciplinary action by another state, by any agency of the federal government, or by another country for any act substantially related to the practice regulated by the California license, may be a ground for disciplinary action by the respective state licensing board. A certified copy of the record of the disciplinary action taken against the licensee by another state, an agency of the federal government, or another country shall be conclusive evidence of the events related therein.

Cause for discipline also exists pursuant to Business and Professions Code section 141. (Factual Findings 15 through 21.)

Disciplinary Considerations

5. The purpose of the Medical Practice Act[2] is to assure the high quality of medical practice; in other words to keep unqualified persons and those guilty of unprofessional conduct out of the medical profession. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 574.) The purpose of physician discipline is to protect the public and to aid in the rehabilitation of licensees. (Bus. & Prof. Code, § 2229.)

6. The Board has adopted guidelines to assist in the evaluation of physician discipline. (Manual of Model Disciplinary Orders and Disciplinary Guidelines, 11th Edition.) The guidelines state that, in out-of-state discipline cases, the minimum level of discipline should be the same as that for a similar violation in California; the maximum is revocation. Complainant recommends the minimum discipline, which is revocation, stayed during a five-year probationary period, with conditions recommended by the guidelines. Respondent requests that a public letter of reprimand be issued because he is unable to comply with a probationary condition requiring him to practice at least 40 hours per month in California. Respondent resides in Pennsylvania and is in California only a few days each year.

7. Respondent has had a very successful career as a physician and an inventor of medical devices. He is held in high regard by his colleagues. Respondent was excited at the prospect of helping patients suffering from MS and agreed to actively participate in an ongoing study. He readily acknowledges that he should have ensured that Bio-Med IRB had obtained an approved IDE from the FDA. And he concedes he should have had any agreed protocol deviations documented in writing. The FDA investigated his involvement and has cleared him; two Rex Medical products will soon begin clinical trials under FDA approval. The Washington Commission has disciplined respondent appropriately for his misconduct in that state. Respondent no longer treats MS patients with CCSVI procedures and stopped as soon as he learned of the lack of FDA approval of the study. There is no evidence that any patients were harmed by respondent's CCSVI procedures, or that respondent has been disciplined previously in his 20 years of practice.

The circumstances involved here warrant a deviation from the guidelines. Respondent has apologized sincerely for his misconduct, has learned from this experience and improved his practices. The issuance of a public reproval will ensure that respondent's misconduct will remain a matter of public record, and doing so protects the public by serving as a continuing reminder to respondent of his responsibilities as a physician, surgeon and business person. Respondent shall be publicly reproved pursuant to Business and Professions Code sections 495 and 2227, subdivision (a)(4).

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[2] Business and Professions Code sections 2000 through 2521.

ORDER

James Frederick McGuckin, M.D., holder of Physician's and Surgeon's Certificate No. G 87992, is publicly reproved.

DATED: November 8, 2016

DocuSigned by:
Jill Schlichtmann
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JILL SCHLICHTMANN
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Accusation Against: **James Frederick McGuckin, M.D.** **11411 Brookshire Avenue, Suite 301** **Downey, CA 90241** **Physician's and Surgeon's Certificate No. G87992,** Respondent.	Case No. 800-2015-017645 **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 30, 2007, the Medical Board issued Physician's and Surgeon's Certificate Number G87992 to James Frederick McGuckin, 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 November 30, 2016, 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 2004 of the Code provides that the Medical Board shall have the responsibility for the enforcement of the disciplinary and criminal provisions of the Medical Practice Act.

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 141 of the Code states:

> (a) For any licensee holding a license issued by a board under the jurisdiction of the department, a disciplinary action taken by another state, by any agency of the federal government, or by another country for any act substantially related to the practice regulated by the California license, may be a ground for disciplinary action by the respective state licensing board. A certified copy of the record of the disciplinary action taken against the licensee by another state, an agency of the federal government, or another country shall be conclusive evidence of the events related therein.
>
> (b) Nothing in this section shall preclude a board from applying a specific statutory provision in the licensing act administered by that board that provides for discipline based upon a disciplinary action taken against the licensee by another state, an agency of the federal government, or another country.

7. Section 2305 of the Code states:

> The revocation, suspension, or other discipline, restriction or limitation imposed by another state upon a license or certificate to practice medicine issued by that state, or the revocation, suspension, or restriction of the authority to practice medicine by any agency of the federal government, that would have been grounds for discipline in California of a licensee under this chapter [Chapter 5, the Medical Practice Act] shall constitute grounds for disciplinary action for unprofessional conduct against the licensee in this state.

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CAUSE FOR DISCIPLINE

(Discipline, Restriction or Limitation Imposed by another State)

8. On November 25, 2014, the Washington Medical Quality Assurance Commission ("Washington Board") filed a Statement of Charges against Respondent. On October 1, 2015, the Washington Board filed an Agreed Order resolving the Statement of Charges. A copy of the Statement of Charges and the Agreed Order are attached as **Exhibit A** and incorporated herein.

9. Respondent and the Washington Board acknowledge that the evidence is sufficient to justify the following findings of fact made by the Washington Board in the Agreed Order:

> Respondent specializes in vascular and interventional radiology. Respondent is the founder and Chief Executive Officer of Vascular Access Centers . . . . and travels to different facilities, including the Tukwila, Washington, location to perform endovascular procedures. Between 2010 and 2013, Respondent treated chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis (MS) patients at the Tukwila facility.
>
> The diagnosis and treatment of CCSVI is investigational and experimental. The CCSVI procedure should be performed as a scientific research study under an Institutional Review Board (IRB) to ensure safety of human subjects. Furthermore, an IRB research study must have approval from the Food and Drug Administration (FDA) Investigational Device Exemption program.
>
> In 2010, . . . Bio-Med IRB approved [a] registry and established a registry protocol outlining [a study of CCSVI treatment]. . . . Adherence to the protocol is crucial in order to ensure patient safety and for the registry data to have any scientific validity. Bio-Med IRB approve Respondent to be principal investigator for the CCSVI multi-center registry. However, Bio-Med IRB did not obtain the required FDA Investigational Device Exemption (IDE) approval and failed to monitor Respondent's adherence to the registry protocol.
>
> Respondent performed CCSVI procedures on patients without ensuring Bio-Med IRB obtained an approved IDE from the FDA. Moreover, Respondent represented to the [Washington Board] that he adhered to the Bio-Med IRB protocol when in fact he deviated from it. Respondent's participation in CCSVI research lacked the scientific rigor in determining the effectiveness of treating MS patients.
>
> . . . .
>
> Between calendar years 2010 and 2013, Respondent performed CCSVI treatment on 233 patients . . . . None of the patients had a neurological referral. Respondent failed to meet the standard of care in performing an experimental treatment on MS patients. In doing so, Respondent created an unreasonable risk of harm by conducting angioplasty and stent placement to treat a non-vascular disease. Respondent failed to adhere to the Bio-Med IRB protocol, and Respondent's diagnosis and treatment documentation contained multiple discrepancies raising concerns about proper patient assessment and accurate procedure notes.
>
> Respondent failed to adhere to the registry protocol [in various ways detailed in the

Agreed Order] . . . .

> Respondent diagnosed [patients] with CCSVI by listing chronic venous hypertension with complications, without corroborating reports or exams. Respondent failed to obtain patients' MRI or magnetic resonance venography reports identifying blood flow abnormalities. Respondent's reported vascular findings for [his patients] are disputable.
>
> In his procedure reports, Respondent reported stenosis to be more severe than those seen on the radiologic spot images Review of patients' spot images demonstrated abnormalities that would not be considered significant or justified in requiring endovascular treatment . . . .
>
> It is not evident that Respondent forwarded his procedure notes to [his patients'] neurologist or primary care provider, or if Respondent ever established any post-procedure medical evaluation of patients to determine the efficacy or benefits of CCSVI treatment.

10. In the Agreed Order, Respondent and the Washington Board agreed to the entry of several conclusions of law, including that "Respondent has committed unprofessional conduct in violation of Washington state law," and that his "violations provide grounds for imposing sanctions . . . ."

11. The Agreed Order imposed the following terms and conditions, among others, on Respondent's practice of medicine in Washington:

- An agreement not to perform CCSVI procedures;
- Completion of an ethics course;
- Payment of a $17,500 fine; and
- Payment of full refunds of fees charged to patients who received CCSVI procedures at the Tukwila facility.

12. Respondent's conduct and the action of the Washington Board as set forth above constitute unprofessional conduct within the meaning of section 2305 and conduct subject to discipline within the meaning of section 141(a).

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 G87992, issued to James Frederick McGuckin, M.D.;

2. Revoking, suspending or denying approval of James Frederick McGuckin, M.D.'s authority to supervise physician assistants, pursuant to section 3527 of the Code;

3. Ordering James Frederick McGuckin, 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: March 3, 2016

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

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EXHIBIT A

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **JAMES F. MCGUCKIN, MD** License No. MD00047625 Respondent.	No. M2013-185 **STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER**

The Medical Quality Assurance Commission (Commission), through Phi V. Ly, Commission Licensed Legal Intern, Larry Berg, Supervising Attorney, and Respondent, represented by counsel, D.K. Yoshida, stipulate and agree to the following.

1. PROCEDURAL STIPULATIONS

1.1 On November 25, 2014, the Commission issued a Statement of Charges against Respondent.

1.2 In the Statement of Charges, the Commission alleges that Respondent violated RCW 18.130.180(4), (7), (13), (16), (22), and 21 CFR § 56.103, 21 CFR § 812.100, and 21 CFR § 812.110(a).

1.3 The Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 The Commission has the authority to impose sanctions pursuant to RCW 18.130.160 if the allegations are proven at a hearing.

1.6 The parties agree to resolve this matter by means of this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.7 Respondent waives the opportunity for a hearing on the Statement of Charges if the Commission accepts this Agreed Order.

1.8 This Agreed Order is not binding unless it is accepted and signed by the Commission.

1.9 If the Commission accepts this Agreed Order, it will be reported to the National Practitioner Data Bank (45 CFR Part 60), the Federation of State Medical Boards' Physician Data Center and elsewhere as required by law.

1.10 This Agreed Order is a public document. It will be placed on the Department of Health's website, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). It may be disclosed to the public upon request pursuant to the Public Records Act (Chapter 42.56 RCW). It will remain part of Respondent's file according to the state's records retention law and cannot be expunged.

1.11 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

2. FINDINGS OF FACT

Respondent and the Commission acknowledge that the evidence is sufficient to justify the following findings, and the Commission makes the following findings of fact.

2.1 On March 13, 2007, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active. Respondent is board certified in radiology.

2.2 Respondent specializes in vascular and interventional radiology. Respondent is the founder and Chief Executive Officer of Vascular Access Centers (VAC) which has multiple facilities in several states. Respondent travels to different facilities, including the Tukwila, Washington, location to perform endovascular procedures. Between 2010 and 2013, Respondent treated chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis (MS) patients at the Tukwila facility.

2.3 The diagnosis and treatment of CCSVI is investigational and experimental. The CCSVI procedure should be performed as a scientific research study under an Institutional Review Board (IRB) to ensure safety of human subjects. Furthermore, an IRB research study must have approval from the Food and Drug Administration (FDA) Investigational Device Exemption program.

2.4 In 2010, the Hubbard Foundation sponsored a multi-center research study, or registry, for CCSVI treatment. The registry is an organized system that uses observational

study methods to collect uniform data about a specific disease or treatment. Bio-Med IRB approved the registry and established a registry protocol outlining the study design and purpose. The protocol also outlined specific patient inclusion and exclusion criteria. Adherence to the protocol is crucial in order to ensure patient safety and for the registry data to have any scientific validity. Bio-Med IRB approved Respondent to be principal investigator for the CCSVI multi-center registry. However, Bio-Med IRB did not obtain the required FDA Investigational Device Exemption (IDE) approval and failed to monitor Respondent's adherence to the registry protocol.

2.5 Respondent performed CCSVI procedures on patients without ensuring Bio-Med IRB obtained an approved IDE from the FDA. Moreover, Respondent represented to the Commission that he adhered to the Bio-Med IRB protocol when in fact he deviated from it. Respondent's participation in CCSVI research lacked the scientific rigor in determining the effectiveness of treating MS patients.

2.5.1 MS is an immune-mediated disease and not a circulatory disorder. MS lesions are caused by inflammatory injury of the nerve fibers in the brain and spinal cord resulting in significant and disabling neurological symptoms such as focal motor and sensory disabilities. The underlying cause of MS is unknown. MS diagnosis is determined by neurologic studies and magnetic resonance imaging (MRI) identifying lesions in nerve fibers. MS is often treated with medication.

2.5.2 CCSVI is a theoretical condition based upon the hypothesis that blockage of the major veins in the neck and chest causes and contributes to the progression of MS. The CCSVI procedure purports to provide symptom relief to MS patients by treating these blocked veins to increase blood drainage from the brain and spinal cord. The CCSVI procedure poses risks and complications inherent to endovascular treatment.

2.6 The CCSVI procedure uses balloon angioplasty and sometimes stent placement to treat blocked veins. Significant venous blockage, or stenosis, is usually defined as vein reduction of at least 50% compared with normal adjacent veins. Stenosis may cause venous hypertension symptoms such as swelling, pain, warmth, skin discoloration, superficial varicosities, or interference with dialysis. In contrast, MS symptoms are neurological and cause visual, motor, sensory, balance, cognitive, and autonomic dysfunction.

2.7 In the CCSVI procedure, the skin is punctured, and a catheter is placed through the femoral vein and then guided to other veins in the body. Contrast is injected into these veins to identify vein abnormalities. If an abnormality is noted, a balloon is inserted and used to dilate the affected vein. In some cases, a stent may be placed to maintain widening of the veins. Though the invasive procedure is done on an outpatient basis without deep sedation, complications and risks exist.

2.8 Angioplasty and stenting of veins are long-standing and well-accepted therapies for venous blockages. Causes of these blockages include catheters, dialysis access, pacemaker leads, tumors, abnormal blood clotting, and bony compression. Complications and risks for CCSVI treatment and of angioplasty and stenting in general include: vein rupture; blood clotting and dissection within treated veins; need to surgically remove ruptured balloons; stent migration requiring surgical removal; stroke; nerve injury; paralysis; and death from bleeding. Both angioplasty and stent placement may also incite further narrowing of the treated vein or restenosis. These therapies are not recognized as standard or approved treatments for MS.

2.9 To date, there are no randomized, controlled, blinded studies proving the existence of CCSVI or the efficacy of treating it with angioplasty or stenting. On May 10, 2012, the FDA released a Safety Communication stating balloon angioplasty and stents are inefficacious in treating MS symptoms and pose risks to patients. Additionally, the FDA found no clear evidence that CCSVI exists or is linked to MS. Accordingly, CCSVI procedures performed after the release of the FDA Safety Study Communication are considered not effective.

2.10 Respondent's reply letter to the Commission dated August 29, 2014, stated that as of May 2012, the scope of CCSVI practice is no longer listed on the VAC website and that VAC is not treating CCSVI patients. However, review of VAC's website reveals that CCSVI is still listed as a scope of venous practice. Respondent claims he had directed his staff to remove all CCSVI content from the website on two occasions.

2.11 Between calendar years 2010 and 2013, Respondent performed CCSVI treatment on 233 patients, including Patients A through G, at the Tukwila facility. None of the patients had a neurologist referral. Respondent failed to meet the standard of care in performing an experimental treatment on MS patients. In doing so, Respondent created an

unreasonable risk of harm by conducting angioplasty and stent placement to treat a non-vascular disease. Respondent failed to adhere to the Bio-Med IRB protocol, and Respondent's diagnosis and treatment documentation contained multiple discrepancies raising concerns about proper patient assessment and accurate procedure notes.

2.12 Respondent failed to adhere to the registry protocol in the following ways:

2.12.1 Only patients diagnosed with MS through proper neurologic examination are to be included in the registry. Respondent represented to the Commission that CCSVI patients are admitted after a comprehensive intake process. However, patient records indicate Respondent's did not obtain or review MS examination records from the patients' neurologist. None of the patients have a recorded neurologic exam before or after the CCSVI procedure. There is no documentation that patients obtained a required Expanded Disability Status Scale rating before and after the procedure.

2.12.2 Respondent did not obtain required magnetic resonance imaging or Doppler testing post-procedure as required for Patients A through G.

2.12.3 Respondent did not conduct adequate physical evaluations, and he relied on patients' self-reporting of MS diagnosis and symptoms in determining whether or not patients met the inclusion criteria.

2.12.4 Respondent did not include Patient D in the registry and performed CCSVI treatment on her before the Bio-Med IRB protocol was approved.

2.12.5 The registry excludes patients with "abnormal kidney function." There is no documentation showing Patients A, C, and G underwent laboratory testing to assess kidney function prior to CCSVI treatment.

2.12.6 The registry lists Pregnancy as an exclusion. There is no documentation that Patients A, B, F, and G underwent laboratory testing to exclude pregnancy prior to the procedure.

2.12.7 Follow-up protocol states patients will be seen in the office and evaluated for complications and will undergo review of the procedure results. Respondent states that patients are typically seen the following day after the CCSVI procedure. However, Patients A through G's records do not indicate any office visit or physical evaluation by Respondent following treatment. Patient follow-up calls are

noted as brief notations on a form by VAC staff. Respondent failed to conduct any physical evaluation of Patients A through G post-procedure.

2.13 Respondent diagnosed Patients A through G with CCSVI by listing chronic venous hypertension with complications, without corroborating reports or exams. Respondent failed to obtain Patients A, B, C, D, F, and G's MRI or magnetic resonance venography (MRV) reports identifying blood flow abnormalities. Respondent's reported vascular findings for Patients A through G are disputable.

2.14 In his procedure reports, Respondent reported stenoses to be more severe than those seen on the radiologic spot images. Review of patients' spot images demonstrated abnormalities that would not be considered significant or justified in requiring endovascular treatment. Respondent claims that the findings seen at angiography are not fully demonstrated in the spot images.

2.15 It is not evident that Respondent forwarded his procedure notes to Patients A through G's neurologist or primary care provider, or if Respondent ever established any post-procedure medical evaluation of patients to determine the efficacy or benefits of CCSVI treatment.

3. CONCLUSIONS OF LAW

The Commission and Respondent agree to the entry of the following Conclusions of Law.

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(4) and (16).

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order.

4.1 <u>Agreement to not perform CCSVI procedure.</u> Respondent shall not perform angioplasty and stenting procedures of the venous system for CCSVI or MS patients in Washington State.

4.2 **Ethics Course.** Within six (6) months of the effective date of this Order Respondent shall attend and successfully complete the Professional/Problem Based Ethics (ProBE) Course, offered by the Center for Personalized Education for Physicians (CPEP). To satisfy this provision, the Respondent must obtain an "unconditional pass" at the conclusion of the course. Respondent will permit CPEP to communicate with the Commission regarding his participation in this course and will provide the Commission a copy of the essay the Respondent writes as part of the course. A failure by the Respondent to obtain an "unconditional pass" upon completion of the coursework may result in the Commission requiring the Respondent to re-take the course, or may result in additional charges for noncompliance under RCW 18.130.180(9). Respondent will submit proof of the successful completion of the course to the Commission within thirty (30) days.

4.3 **Renewal of License.** Respondent's license is set to expire November 7, 2015. Respondent must file an application for reactivation in lieu of renewal if he seeks to continue practicing in the state of Washington subsequent to the expiration of his license.

4.4 **Fine.** Respondent shall pay a fine to the Commission in the amount of seventeen thousand five hundred dollars ($17,500) which must be received by the Commission within three (3) months of the effective date of this Order. The fine will be paid by certified or cashier's check or money order, made payable to Department of Health and mailed to:

Department of Health
Medical Quality Assurance Commission
P.O. Box 1099
Olympia, Washington 98507-1099

4.5 **Refund to patients.** Within twelve (12) months of the effective date of this Order, Respondent must refund the cash fees to patients who received the CCSVI procedure at the Tukwila facility after May 10, 2012, and who did not have insurance or third-party payors. Failure to fully refund fees to patients shall be a violation of this Order

4.5.1 Respondent shall provide to the Commission documented proof of completed patients' refunds. Proof of payment will list: patient's name and address, check number, amount paid, and date of payment, and will be mailed to:

Department of Health
Compliance Manager, Medical Quality Assurance Commission
P.O. Box 47866

Olympia, Washington 98504-7866

4.6 **Reporting.** Respondent will provide to the Commission a semi-annual report that states how he is in compliance with all terms and conditions of this Order. Respondent will submit the report at six (6) months and twelve (12) months after the effective date of this Order. The reports must be sent to:

Department of Health
Compliance Manager, Medical Quality Assurance Commission
P.O. Box 47866
Olympia, Washington 98504-7866

4.7 **Modification.** Respondent may petition the Commission in writing to modify the terms and conditions of this Agreed Order no sooner than twelve (12) months from the effective date of this Agreed Order. If Respondent files a written petition to modify then the Commission may require personal appearance where Respondent must present evidence and respond to questions. The Commission has sole discretion whether to grant or deny Respondent's petition to modify this Agreed Order.

4.8 **Obey all laws.** Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.9 **Costs.** Respondent is responsible for all costs of complying with this Agreed Order.

4.10 **Violation of Order.** If Respondent violates any provision of this Agreed Order in any respect, the Commission may initiate further action against Respondent's license.

4.11 **Change of Address.** Respondent shall inform the Commission and the Adjudicative Clerk Office, in writing, of changes in Respondent's residential and/or business address within thirty (30) days of the change.

4.12 **Effective Date of Order.** The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

5. COMPLIANCE WITH SANCTION RULES

5.1 The Commission applies WAC 246-16-800, *et seq.*, to determine appropriate sanctions. Tier B of the "Practice Below Standard of Care" schedule, WAC 246-16-810,

applies to cases where substandard practices caused moderate patient harm or risk of moderate to severe patient harm. Respondent performed invasive vascular interventional treatment on patients. This posed an unreasonable risk of moderate to severe patient harm because known complications from angioplasty and stenting are life threatening and can range from vein rupture to death. Tier C of the "Practice Below Standard of Care" schedule applies when a patient suffers severe harm or death. There is no evidence Respondent's substandard practices actually caused severe injury or death to a patient. Tier B applies to this matter.

5.2 WAC 246-16-800(3)(c) directs the Commission to identify aggravating or mitigating factors to determine appropriate sanctions. There are mitigating and aggravating factors present in this case. It is mitigating that Respondent has no prior discipline on his license. It is also mitigating that Respondent had closed his Tukwila, Washington, facility in 2013, and he no longer participates in the Hubbard Study or BioMed IRB. It is aggravating that Respondent's substandard care involved multiple MS patients who were highly vulnerable to the false hope provided by Respondent's CCSVI treatment. Respondent failed to ensure that the Hubbard Foundation and BioMed IRB obtained an IDE before engaging the in research study as a Principal Investigator. Respondent's failure to strictly adhere to the study's registry protocol without written approval for any deviations raised patient safety concerns as well as concerns about the study's scientific validity. It is also aggravating that Respondent's reported vascular findings for Patients A through G are disputable.

5.3 Tier B requires the imposition of sanctions ranging from two years of oversight to five years of oversight, unless revocation. However, WAC 246-16-800(2)(d) states that the Commission may deviate if the sanction schedule does not adequately address the facts of the case. This Order is a deviation from the sanctions schedule because Respondent maintains his regular practice in another state and infrequently travels to Washington State. Furthermore, Respondent has ceased performing CCSVI treatment in Washington. This case qualifies for a deviation under WAC 246-16-800(2)(c).

5.4 Respondent's agreement to not perform angioplasty and stenting procedures of the venous system for CCSVI or MS patients in Washington State, attend an ethics course, pay a fine, and refund fees to patients as outlined in this Agreed Order, is adequate in protecting the public.

6. FAILURE TO COMPLY

Protection of the public requires practice under the terms and conditions imposed in this order. Failure to comply with the terms and conditions of this order may result in suspension of the license after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Commission may hold a hearing to require Respondent to show cause why the license should not be suspended. Alternatively, the Commission may bring additional charges of unprofessional conduct under RCW 18.130.180(9). In either case, Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

7. RESPONDENT'S ACCEPTANCE

I, James F. McGuckin, Respondent, have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

JAMES F. MCGUCKIN, MD
RESPONDENT

9/3/15
DATE

D.K. YOSHIDA, WSBA# 17365
ATTORNEY FOR RESPONDENT

09/03/2015
DATE

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ORIGINAL

8. COMMISSION'S ACCEPTANCE AND ORDER

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: 1 Oct, 2015.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

W E Goltholdan
PANEL CHAIR

PRESENTED BY:

PHI V. LY, WSBA# 9451564
COMMISSION RULE 9 LEGAL INTERN

LAWRENCE J. BERG, WSBA# 22334
COMMISSION STAFF ATTORNEY

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **JAMES MCGUCKIN, MD** License No. MD00047625 Respondent.	No. M2013-185 **STATEMENT OF CHARGES**

The Executive Director of the Medical Quality Assurance Commission (Commission) is authorized to make the allegations below, which are supported by the evidence contained in file number 2011-156405. The patients referred to in this Statement of Charges are identified in the attached Confidential Schedule.

1. ALLEGED FACTS

1.1 On March 13, 2007, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active. Respondent is board certified in radiology.

1.2 Respondent specializes in vascular and interventional radiology. Respondent is the founder and Chief Executive Officer of Vascular Access Centers (VAC) which has multiple facilities in several states. Respondent travels to different facilities, including the Tukwila, Washington, location to perform endovascular procedures. Between 2010 and 2013, Respondent treated chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis (MS) patients at the Tukwila facility.

1.3 The diagnosis and treatment of CCSVI is investigational and experimental. The CCSVI procedure should only be performed as a scientific research study under an Institutional Review Board (IRB) to ensure safety of human subjects. Furthermore, an IRB research study must have approval from the Food and Drug Administration (FDA) Investigational Device Exemption program.

1.4 In 2010, the Hubbard Foundation sponsored a multi-center research study, or registry, for CCSVI treatment. The registry is an organized system that uses observational study methods to collect uniform data about a specific disease or treatment. Bio-Med IRB approved the registry and established a registry protocol outlining the study

design and purpose. The protocol also outlined specific patient inclusion and exclusion criteria. Strict adherence to the protocol is crucial in order to ensure patient safety and for the registry data to have any scientific validity. Bio-Med IRB approved Respondent to be principal investigator for the CCSVI multi-center registry. However, Bio-Med IRB did not obtain the required FDA Investigational Device Exemption (IDE) approval and failed to monitor Respondent's adherence to the registry protocol.

1.5 Respondent performed CCSVI procedures on patients without ensuring Bio-Med IRB obtained an approved IDE from the FDA. Moreover, Respondent represented to the Commission that he adhered to the Bio-Med IRB protocol when in fact he deviated from it. Respondent put patients' safety at risk, and his registry data is suspect. Respondent's participation in CCSVI research lacked any scientific rigor in determining the effectiveness of treating MS patients.

1.5.1 MS is an autoimmune chronic disease and not a circulatory disorder. MS lesions are caused by inflammatory injury of the nerve fibers in the brain and spinal cord resulting in significant and disabling neurological symptoms such as focal motor and sensory disabilities. The underlying cause of MS is unknown. MS diagnosis is determined by neurologic studies and magnetic resonance imaging (MRI) identifying lesions in nerve fibers. MS is treated with medication.

1.5.2 CCSVI is a theoretical condition based upon the hypothesis that blockage of the major veins in the neck and chest causes and contributes to the progression of MS. The CCSVI procedure purports to provide symptom relief to MS patients by treating these blocked veins to increase blood drainage from the brain and spinal cord. The CCSVI procedure poses risks and complications inherent to endovascular treatment.

1.6 The CCSVI procedure uses balloon angioplasty and sometimes stent placement to treat blocked veins. Significant venous blockage, or stenosis, is usually defined as vein reduction of at least 50% compared with normal adjacent veins. Stenosis may cause venous hypertension symptoms such as swelling, pain, warmth, skin discoloration, superficial varicosities, or interference with dialysis. In contrast, MS symptoms are neurological and cause visual, motor, and sensory disabilities.

1.7 In the CCSVI procedure, the skin is punctured, and a catheter is placed through the femoral vein and then guided to other veins in the body. Contrast is injected

into these veins to identify vein abnormalities. If an abnormality is noted, a balloon is inserted and used to dilate the affected vein. In some cases, a stent may be placed to maintain widening of the veins. Though the invasive procedure is done on an outpatient basis without deep sedation, complications and risks exist.

1.8 Angioplasty and stenting of veins are long-standing and well-accepted therapies for venous blockages. Causes of these blockages include catheters, dialysis access, pacemaker leads, tumors, abnormal blood clotting, and bony compression. Complications and risks for CCSVI treatment and of angioplasty and stenting in general include: vein rupture; blood clotting and dissection within treated veins; need to surgically remove ruptured balloons; stent migration requiring surgical removal; stroke; nerve injury; paralysis; and death from bleeding. Both angioplasty and stent placement may also incite further narrowing of the treated vein or restenosis. These therapies are not recognized as standard or approved treatments for MS.

1.9 To date, there are no randomized, controlled, blinded studies proving the existence of CCSVI or the efficacy of treating it with angioplasty or stenting. On May 10, 2012, the FDA released a Safety Communication stating balloon angioplasty and stents are inefficacious in treating MS symptoms and pose risks to patients. Additionally, the FDA found no clear evidence that CCSVI exists or is linked to MS.

1.10 Respondent's reply letter to the Commission dated August 29, 2014, stated that as of May 2012, the scope of CCSVI practice is no longer listed on the VAC website and that VAC is not treating CCSVI patients. However, review of VAC's website reveals that CCSVI is still listed as a scope of venous practice.

Assessment and Treatment of Patients A, B, C, D, E, F, and G

1.11 Between March 2011 and September 2011, Respondent performed the CCSVI procedure at the Tukwila, Washington VAC facility on seven MS patients. In doing so, Respondent created an unreasonable risk of harm by conducting angioplasty and stent placement to treat a non-vascular disease. Respondent failed to meet the standard of care in performing an experimental treatment on MS patients. Respondent failed to adhere to the Bio-Med IRB protocol, failed to obtain an approved FDA Investigational Device Exemption (IDE), and misrepresented his findings in the patient

chart notes. Respondent's diagnosis and treatment documentation contained multiple discrepancies raising concerns about proper patient assessment and accurate procedure notes.

1.12 Respondent failed to adhere to the registry protocol in the following ways:

1.12.1 Only patients diagnosed with MS through proper neurologic examination are to be included in the registry. Respondent represented to the Commission that CCSVI patients are admitted after a comprehensive intake process. However, patient records indicate Respondent's failure to obtain or review MS examination records from the patients' neurologist. None of the patients have a recorded neurologic exam before or after the CCSVI procedure. There is no documentation that patients obtained a required Expanded Disability Status Scale rating before and after the procedure.

1.12.2 Respondent failed to obtain required magnetic resonance imaging or Doppler testing post-procedure as required for Patients A through G.

1.12.3 Respondent failed to conduct adequate physical evaluations, and he relied on patients' self-reporting of MS diagnosis and symptoms in determining whether or not patients met the inclusion criteria.

1.12.4 Respondent failed to properly include Patient D in the registry and performed CCSVI treatment on her before the Bio-Med IRB protocol was approved.

1.12.5 Before using the Bio-Med IRB protocol, VAC established its own protocol outlining exclusions. Respondent failed to follow VAC's protocol. The exclusions include any patient with "previous vascular interventional procedures." However, Patients A, B, E, F, and G, all had prior CCSVI treatments at other locations, yet Respondent included them in the registry and performed subsequent procedures. Between June 28 and July 26, 2011, Respondent performed two CCSVI procedures on Patient B.

1.12.6 The registry excludes patients with "abnormal kidney function." There is no documentation showing Patients A, C, and G underwent laboratory testing to assess kidney function prior to CCSVI treatment.

1.12.7 The registry lists Pregnancy as an exclusion. There is no documentation that Patients A, B, F, and G underwent laboratory testing to exclude pregnancy prior to the procedure.

1.12.8 Follow-up protocol states patients will be seen in the office and evaluated for complications and will undergo review of the procedure results. Respondent states that patients are typically seen the following day after the CCSVI procedure. However, Patients A through G's records do not indicate any office visit or physical evaluation by Respondent following treatment. Patient follow-up calls are noted as brief notations on a form by VAC staff. Respondent failed to conduct any physical evaluation of Patients A through G post-procedure.

1.13 Respondent diagnosed Patients A through G with CCSVI by listing chronic venous hypertension with complications, without corroborating reports or exams. Respondent failed to obtain Patient A, B, C, D, F, and G's MRI or magnetic resonance venography (MRV) reports identifying blood flow abnormalities. There are multiple discrepancies between the findings from the CCSVI procedure images and those Respondent noted in the procedure reports. Respondent inaccurately depicted the existence and/or severity of venous stenoses in Patients A through G.

1.13.1 In his procedure reports, Respondent reported stenoses to be more severe than those seen on the radiologic images. Review of patients' images demonstrated abnormalities that would not be considered significant or justified in requiring endovascular treatment.

1.13.1.1 For Patients A, B, C, D, and G, Respondent documented degrees of left common iliac vein stenosis ranging from 50% to 80%. Respondent performed left common iliac vein angioplasty on these patients and reported the treatment successful. Review of the patients' radiologic images revealed Patients A, B, C, D, and G had no significant left common iliac vein abnormality and no significant change following angioplasty. In fact, mild narrowing of the left common iliac vein from extrinsic effect of the overlying right common iliac artery is a frequent normal finding in asymptomatic patients. In rare cases, severe stenosis may cause symptoms such as leg swelling and pain, and in these cases the narrowings are not treated by angioplasty alone, but by stent placement, since the vein

narrowings are caused by extrinsic pressure. Patients A, B, C, D, and G did not present with or complain of iliac vein compression symptoms.

1.13.1.2 Respondent documented that Patients B, E, and F had left renal vein stenoses of 50% to 70%. Respondent performed left renal vein angioplasty on these patients and reported the treatment successful. Review of the images revealed Patient B, E, and F had no significant left renal vein stenosis and no change following angioplasty.

1.13.1.3 Respondent documented that Patients A, B, and F had azygos vein stenoses of 30% to 70%. Respondent performed azygos vein angioplasty on Patients A and B, and included stent placement in Patient F. Respondent reported the treatment successful. However, review of images revealed Patients A and B had no stenosis of the azygos vein, and Patient F had minimal irregularity but no significant stenosis.

1.14 Respondent required patients to pay for the procedure in full or obtain insurance payment approval prior to any treatment. Respondent billed Patients B, C, D, F, and G's insurance companies for the CCSVI procedure with billing codes typical for endovascular conditions even though Respondent was treating a neurologic disease. It is not evident that Respondent forwarded his procedure notes to Patients A through G's neurologist or primary care provider, or if Respondent ever established any post-procedure medical evaluation of patients to determine the efficacy or benefits of CCSVI treatment.

1.15 Between calendar years 2010 and 2013, Respondent performed CCSVI treatment on 233 patients, including Patients A through G, at the Tukwila facility. Only two patients had a physician referral for CCSVI, and none of the patients had a neurologist referral.

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2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, Respondent has committed unprofessional conduct in violation of RCW 18.130.180(4), (7), (13), (16), (22), and 21 CFR § 56.103, 21 CFR § 812.100, and 21 CFR § 812.110(a), which provide in part:

> **RCW 18.130.180 Unprofessional conduct.** The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:
>
> ...
>
> (4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;
>
> (7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;
>
> ...
>
> (13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;
>
> ...
>
> (16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;
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> ...
>
> (22) Interference with an investigation or disciplinary proceeding by willful misrepresentation of facts before the disciplining authority or its authorized representative, or by the use of threats or harassment against any patient or witness to prevent them from providing evidence in a disciplinary proceeding or any other legal action, or by the use of financial inducements to any patient or witnesses to prevent or attempt to prevent him or her from providing evidence in a disciplinary proceeding;
>
> ...
>
> **21 C.F.R. § 56.103 Circumstances in which IRB review is required.**
>
> (a) Except as provided in §§ 56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.
>
> (b) Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived

from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

21 CFR § 812.100 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with part 50 of this chapter. Additional responsibilities of investigators are described in subpart G.

21 C.F.R. § 812.110 Specific responsibilities of investigators.

(a) *Awaiting approval.* An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval.

. . . .

2.2 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

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3. NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Executive Director of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline and the imposition of sanctions under Chapter 18.130 RCW.

DATED: November 25, 2014.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

MELANIE DE LEON
EXECUTIVE DIRECTOR

KRISTIN G. BREWER, WSBA # 38494
ASSISTANT ATTORNEY GENERAL

I declare that this is a true and accurate copy of the original on file with the Washington State Department of Health, Medical Quality Assurance Commission

Michael J. Kramer

10-22-15
Date

STATE OF WASHINGTON * OFFICIAL SEAL * DEPARTMENT OF HEALTH

CONFIDENTIAL SCHEDULE

This information is confidential and is NOT to be released without the consent of the individual or individuals named below. RCW 42.56.240(1)

Patient A

Patient B

Patient C

Patient D

Patient E

Patient F

Patient G