IN THE MATTER OF:
Michael Souza, D.O.
License No.: DO 00446
Case Nos.: C18-0288B, C19-0939, C21-0695

CONSENT ORDER

Michael Souza, D.O. ("Respondent") hereby agrees to the entry of the following Consent Order by the Board of Medical Licensure and Discipline ("Board") in the above-referenced pending matters.

FINDINGS OF FACT

1. Respondent has been a licensed physician in the State of Rhode Island since June 8, 1994.

2. Respondent's medical practice, East Bay Innovative Medicine ("Innovative Medicine"), is located at 1278 Wampanoag Trail, Riverside, Rhode Island.

3. In the matter of C18-0288B, the Board's Investigative Committee reviewed a complaint alleging that Respondent engaged in deceptive advertising on his Respondent's website.

4. The Investigative Committee reviewed various intravenous (I.V.) treatments offered through Respondent's 2018 website under, "I.M. Drip Bar." The treatments involve inserting an intravenous catheter into a patient and infusing these fluids over various durations of time. These I.V. fluids are offered to address a specific health condition, disease or are intended to prevent a medical condition.

5. At the time of the filing of the 2018 Complaint, Respondent's website referenced

various I.V. products, including "Pre-op," "Post-op," "Time-Machine," and "Flu-Fighter." with claims of health improvement from various ailments and diseases, including cancer. The website also referenced an I.V. product called, "Wing-man," which claimed to reduce the effects of excessive alcohol consumption. A copy of the 2018 version of Respondent's former website is attached hereto as Exhibit A.

6. At his September 25, 2018 appearance before the Investigative Committee, Respondent explained that the I.V. treatments consist of vitamins, minerals and antioxidants that enhance the body's natural healing process. The Board received a written submission from an expert who is: board certified in internal medicine, with a palliative care certification; board certified in integrative medicine; the Medical Director for the Center for Integrative Medicine at a major teaching hospital; and an Assistant Professor of Medicine at the medical school affiliated with that hospital. In his written submission, that expert reviewed the website statements concerning the I.V. infusions, explained that they accurately described the effects those infusions will have on patients and their symptoms, explained the basis for those statements and concluded that they "were entirely accurate and appropriate and consistent with the applicable standard of care."

7. Respondent subsequently amended statements on his website to address the concerns expressed by the Investigative Committee.

8. The Investigative Committee determined that there was probable cause for a finding that certain claims and assurances of health benefits advertised in the 2018 version of Respondent's website were misleading and were not supported by adequate clinical data and therefore, there was probable cause for a finding of unprofessional conduct in violation of R.I. Gen. Laws § 5-37-5.1(2).

9. In the matter of C19-0939, the Complaint alleged a pattern of prescribing both phentermine and phendimetrazine. Both medications carry a warning about using the medication with another anorexiant agent. These medications have not been approved to be used together for weight loss.

10. A review of the Rhode Island Prescription Drug Monitoring Program ("PDMP") revealed 15 patients who were prescribed a combination of phentermine and phendimetrazine by Respondent. The Board subpoenaed the medical records for four of the 15 patients for review.

11. The Respondent appeared before the Investigative Committee on November 27, 2019 and addressed the concerns of the Investigative Committee.

12. A review of the PDMP and the four subpoenaed medical records—those of Patients A, B, C and D (aliases)—was completed. Based upon a review of the PDMP, the Investigative Committee concluded that Respondent had 15 patients in his care on this combination of medication with a clear contraindication. The medical records did not reveal any documentation that these medications were contraindicated.

13. Had this matter gone to hearing, Respondent would have presented an expert witness, who is board certified in internal medicine, cardiology and obesity medicine, who stated that the warnings and contraindications referenced by the Board with respect to the combination of phentermine and phendimetrazine and other anorectic agents are based upon labeling approved by the FDA when both medications were first approved for weight loss treatment approximately 50 years ago and were not based upon studies that actually evaluated the combined use of those medications.

14. In addition, Respondent and the expert stated that no studies of phentermine subsequent to its initial approval by the FDA some 50 years ago bore out the label warnings and

contraindications over length of use or use with other anorectic agents. This is exemplified by the FDA's 2012 approval of the package insert and labelling for Qysimia, a component of which is phentermine. The warnings and contraindications for phentermine and its use with phendimetrazine referenced by the Investigative Committee are not contained in the FDA approved package insert and labeling for Qysimia, evidencing that the clinical trials upon which the FDA approved Qysimia in 2012 did not support those warnings and contributions. Thus, Respondent and his expert do not believe the most recent studies and literature support the warnings and contraindications referenced by the Investigative Committee in the FDA approved labeling and package inserts for phentermine and phendimetrazine.

15. The Investigative Committee reviewed a consent form, found in the medical records for Patients A, B and D, relative to the combined use of phentermine or phendimetrazine; Patient C's medical record contained no consent form. The Investigative Committee determined that the consent form for phentermine or phendimetrazine was misleading and deceptive. Specifically, the form is clearly indicated "Phentermine (Adipex) or Phendimetrazine (Bontril)." The consent form is for the use of one or the other drugs, not for their use in combination. Relative to decreased body weight, the form states, "When the drug is effective the weight loss tends to occur within the first 1-2 weeks," yet Respondent's patients were on these drugs far longer. Relative to "Off Label" use, the form states, "This is a schedule IV substance," when, in fact, only phentermine is a schedule IV substance; phendimetrazine is a schedule III substance, which is not specified in the consent form. Also related to "Off Label" use, the form continues, "There is a rare condition known as 'Primary Pulmonary Hypertension' (PPH) that has been associated with some weight loss medications, including Phentermine." There was no mention of phendimetrazine, even though the FDA approved package insert for phendimetrazine states, "In a case-control

epidemiological study, the use of anorectic agents, including Phendimetrazine tartrate, was associated with an increased risk of developing pulmonary hypertension."

16. Respondent's consent form incorrectly defines PPH as an "irreversible stiffening of the lung tissue that leads to permanent shortness of breath," when PPH actually refers to high blood pressure in the lungs because the pulmonary artery narrows and raises blood pressure.

17. Respondent's consent form states, "We at Intellectual Medicine 120 do not believe that the medications cause PPH and to date no one in our practice has had this diagnosis. However, we want to be aware of any possible concerns regarding your treatment." The consent form does not disclose that PPH is untreatable, incurable, and fatal. The consent form does not disclose that prolonged usage of the drugs increases the risk as indicated in the package inserts. The consent form does not contain the word "contraindication" or any synonym thereof in layman's terms or a warning about the contraindications. The consent form also does not indicate that the combination of these medications is, at all, contraindicated. The consent form does not explain that the risk of these life-threatening complications increases the longer the patient is on the medications. The consent form also does not disclose that there are other contraindications, such as history of cardiovascular disease (e.g., coronary artery disease, stroke, arrythmias, congestive heart failure, or uncontrolled hypertension). The consent form goes further and implies that the risk to the patient is minimal or non-existent, when the actual risks to the patient are potentially fatal.

18. Upon review of the medical records for Patients A, B, C and D, there was no clear documentation of patient goals, no dietary histories and no history of patient exercise habits. The standard of care requires the inclusion of medical history information concerning a patient's nutrition intake, fluids intake, and exercise habits. There were incomplete or absent vital signs, which is significant since hypertension is a side effect of both medications.

19. The Investigative Committee determined that the facts described above, relating to C19-0939, provided probable cause for a finding of a violation of R.I. Gen. Laws § 5-37-5.1(19) and Section 1.5.12 of the Rules and Regulations for the Licensure and Discipline of Physicians (216-RICR-40-05-1).

20. The matter of C21-0695 concerns the enforcement of a consent order entered on June 9, 2020, in a previous complaint, C19-0652, relating to the compounding of sterile products (2020 Consent Order).

21. Under the terms of the 2020 Consent Order, Respondent was required to retain, at his own expense, a Board-approved monitor to conduct inspections of Respondent's practice on a quarterly basis and prepare related reports to ensure compliance with applicable laws and regulation on the compounding of sterile products. Respondent was also required to pay an administrative fee of $4252.87.

22. On May 24, 2021, during a routine compliance check, it was determined that Respondent failed to timely pay the administrative fee and submit quarterly monitoring reports to the Board. Respondent later paid the administrative fee in full on June 7, 2021. Respondent explained that while he believed the administrative fee had been paid, a review of his records revealed that through an oversight in his office, the payment had not been issued. He also explained that he had entered into a written contract with a pharmacy consulting firm to provide the required monitoring reports. The consultant provided by that firm submitted an initial report to the Board, indicating that Respondent's practice was in compliance with applicable sterile compounding standards. The Respondent understood that the continued quarterly monitoring and reporting would continue to be performed pursuant to his contract with the pharmacy consulting firm and expected to be notified if those efforts raised any issues that needed to be addressed.

However, after providing that initial report, that consultant left the pharmacy consulting firm and did not understand that he was to continue to perform the additional quarterly monitoring reports. The firm did not send another consultant. When Respondent learned that that the quarterly monitoring and reporting to the Board was not being performed, the consultant who provided the initial report to the Board was contacted and reengaged. On June 18, 2021, that consultant submitted a report to the Board confirming that the Respondent's practice met or exceeded applicable sterile compounding standards.

23. Following the determination that the monitoring of the sterile compounding practices had not been performed, the Board Pharmacy Investigator conducted an inspection and discovered several deficiencies relating to the compounding practices, in violation of the standards set forth under USP 797, a federal standard which addresses sterile compounding protocol and the Rules and Regulation for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216 RICR 40-15-1). The Respondent submitted further information to Board refuting those deficiencies, and from June 18, 2021 through the present, the Board approved monitor has continuously reported that the compounding practices in the Respondent's office met the standard set forth in USP 797.

24. The violation of the terms of the 2020 Consent Order constitutes a violation of R.I. Gen. Laws § 5-37-5.1(24).

Based on the foregoing, the parties agree as follows:

1. Respondent admits to and agrees to remain under the jurisdiction of the Board.

2. Respondent has agreed to this Consent Order and understands that it is subject to final approval by the Board and is not binding on Respondent until final ratification by the Board.

3. If ratified by the Board, Respondent hereby acknowledges and waives:

a. The right to appear personally or by counsel or both before the Board;

b. The right to produce witnesses and evidence on his behalf at a hearing;

c. The right to cross examine witnesses;

d. The right to have subpoenas issued by the Board;

e. The right to further procedural steps except for those specifically contained herein;

f. Any and all rights of appeal of this Consent Order;

g. Any objection to the fact that this Consent Order will be presented to the Board for consideration and review; and

h. Any objection that this Consent Order will be reported to the National Practitioner Data Bank and Federation of State Medical Boards and posted to the RIDOH public website.

4. This Consent Order does not represent an admission of any kind by either party and instead, results from an agreement between the parties to resolve the above referenced Complaints and avoid further litigation.

5. Respondent agrees to pay an administrative fee of $15,589.00 for costs associated with investigating and prosecuting the above-referenced complaints in four (4) installments of $3897.25. The first installment shall be paid within sixty (60) days of the approval and ratification of this Consent Order. The subsequent installments shall be paid three (3), six (6) and nine (9) months from the date of payment of the initial installment. Such payments shall be made by certified check, made payable to the "**Rhode Island General Treasurer**," and sent to Rhode Island Department of Health, 3 Capitol Hill, Room 205, Providence, RI 02908, Attn: Jessica

DiSanto. Respondent will send notice of compliance with this condition to DOH.PRCompliance@health.ri.gov within 5 days of submitting the above-referenced payment.

6. Respondent agrees to the Board's sanction of a reprimand.

7. Respondent shall not prescribe, or cause to be prescribed by others, the combination of phentermine and phendimetrazine to the same patient.

8. Respondent has ceased offering the I.V. product, "Wing-man" and Respondent shall not offer it or any other product that promotes a treatment for excessive alcohol consumption.

9. Respondent's license is on probation for three (3) years from ratification of this Consent Order.

10. For period of three (3) years from the ratification of this Consent Order, Respondent will make no substantive change to the descriptions of treatments and/or products on his website without first having that change reviewed and approved by a Board approved monitor, at Respondent's own expense, who will report the results of that review to the Board at DOH.PRCompliance@health.ri.gov at least 30 days' in advance of any such change being made.

11. Respondent shall continue the quarterly monitoring required by the June 2020 Consent Order through June 2024.

12. In the event that any term of this Consent Order in paragraphs 1-11 immediately above is violated, after ratified and approved, the Director shall have the discretion to impose further disciplinary action pursuant to R.I. Gen. Laws §§ 5-37-5.1 through 5-37-6.3, including immediate suspension of his medical license pursuant to and as permitted by R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c). If the Director imposes further disciplinary action, Respondent shall be given notice and shall have the right to request an administrative hearing within twenty (20) days of the suspension and/or further discipline period permitted by law or regulation. The Director

shall also have the discretion to request an administrative hearing after notice to Respondent of a violation of any term of this Consent Order. The Board may suspend Respondent's license or impose further discipline as described above if any alleged violation is proven by a preponderance of evidence. Any administrative hearings, whether initiated by the Director or the Respondent, shall be conducted in accordance with R.I.Gen.Laws §§ 5-37-5.1 through 5-37-6.3 or R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c) , the Rules and Regulations for the Licensure and Discipline of Physicians (216-RICR-40-05-1), the Rules and Regulations for Practices and Procedures Before the Rhode Island Department of Health (216-RICR-10-05-4), and applicable provisions of R.I. Gen. Laws Chapter 42-35 and § 42-35-9 through 42-35-13. Any discipline ultimately imposed pursuant to this paragraph is appealable pursuant to Rhode Island Gen. Laws §§ 5-37-37 et seq. and 42-35-15 et seq.

Signed this 9th day of April 2024.

Michael Souza D.O.

Ratified by the Board of Medical Licensure and Discipline on the 8th day of May 2024.

Staci A. Fischer, MD.

Name

Chief Administrative Officer, BMD

Title