

BEFORE THE NEVADA STATE BOARD OF OSTEOPATHIC MEDICINE

1
2 IN THE MATTER OF THE COMPLAINT)
3 AGAINST)
4 EDWARD HOFFMAN, D.O.)
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RESPONDENT.

Case No.: AD-04-68-229
Filed: 12-22-04


Executive Director

AMENDED COMPLAINT

Pursuant to the provisions of Chapter 633 of the Nevada Revised Statutes, and by virtue of the authority vested in it by said chapter, the Investigative Board Member of the Nevada Board of Osteopathic Medicine, having a reasonable basis to believe that EDWARD HOFFMAN, D.O., hereinafter referred to as "RESPONDENT," has violated the provisions of said chapter, hereby issues its formal Complaint, stating the Investigative Board Member's charges and allegations, as follows:

1. That RESPONDENT is licensed in active status to practice medicine in the state of Nevada, and at all times alleged herein, was so licensed by the Board of Osteopathic Medicine of the State of Nevada pursuant to the provisions of Chapter 633 of the Nevada Revised Statutes.

2. That NRS 633.511(1) provides that unprofessional conduct is grounds for initiating disciplinary proceedings.

3. NRS 633.131(1) provides "Unprofessional conduct" includes:

(f) Engaging in any:

(2 Medical practice harmful to the public or any conduct detrimental to the public health, safety, or morals which does not constitute gross or repeated malpractice or professional incompetence.

4. NAC 633.350 provides in pertinent part as follows:

For purposes of this chapter and chapter 633 of NRS, a licensee engages in unethical conduct if he:

8. Fails to comply with an order of the board;

5. NRS 633.131(k) provides "Unprofessional conduct" includes:

1 (k) Willful disobedience of the regulations of the state board of
2 health, the state board of pharmacy or the state board of
3 osteopathic medicine.

4 **COUNT ONE**
5 **(NRS 633.131(1)(f)(1))**
6 **(Failure to Comply with a Board Order)**

7 6. The allegations set forth in paragraphs 1 through 5 are incorporated herein as if
8 set out in full.

9 6. On or about May 15, 2004, RESPONDENT voluntarily entered into a Settlement
10 Agreement with the Investigating Board Member to settle the Complaint filed against
11 RESPONDENT in Case No. SE-02-04-229. The Settlement Agreement was approved and
12 ordered by the Board on May 15, 2004.

13 7. Pursuant to Section A, page 4, Dr. Hoffman was ordered to engage in an
14 intensive in-patient multi-modal treatment program for professionals at one of the designated
15 treatment facilities. RESPONDENT was ordered to begin his treatment within 30 days from
16 the date of acceptance of the Settlement Agreement, May 15, 2004. Accordingly, treatment
17 was required to begin by June 15, 2004, (hereinafter referred to as "effective date").

18 8. Pursuant to Section B, page 5, of the Settlement Agreement and Order,
19 Respondent "voluntarily agree[d] not to engage in the practice of osteopathic medicine while
20 Respondent is engaged in the treatment program and until the Board meets to review the
21 recommendations of the treatment facility upon completion of Respondent's treatment and a
22 determination is made by the Board regarding any license conditions to be imposed, if any."
23 The Board has not held said hearing as of the date of this complaint.

24 9. Pursuant to Section D, page 5, the Settlement Agreement and Order provided
25 that "[u]pon successful completion of the treatment program, Respondent shall notify the
26 Board and upon receipt of the treatment facility's report to the Board, the Board will hold a
27 hearing to consider any recommendations made by the treatment facility within 30 days of
28 receipt of the report regarding possible conditions to the practice of osteopathic medicine by
Edward Hoffman. The Board may condition Respondent's license in accordance with the
recommendations made by the treating physicians."

1 10. The treatment facility discharged RESPONDENT prior to completion of
2 treatment due to RESPONDENT'S failure to participate in treatment.

3 11. RESPONDENT failed and continues to fail to successfully complete treatment
4 for the issues presented in the evaluation of Professional Renewal Center for boundary and
5 ethical issues relating to sexual misconduct about which the original complaint was brought.
6 The treating facility refuses to advocate for RESPONDENT'S return to practice of osteopathic
7 medicine as RESPONDENT remains a risk to his patients and cannot safely practice
8 osteopathic medicine.

9 12. That RESPONDENT's failure to successfully complete treatment and failure to
10 be rehabilitated so as to safely return to the practice of osteopathic medicine is a failure to
11 comply with an Order of the Board. The failure of RESPONDENT to comply with a Board
12 Order constitutes unprofessional conduct pursuant to NRS 633.131(f) and (k) and is grounds
13 for disciplinary action pursuant to NRS 633.511(1).

14 13. The Board Order required RESPONDENT to begin treatment and cease
15 practicing osteopathic medicine by June 15, 2004. Subsequent to June 15, 2004, when
16 RESPONDENT was required to cease the practice of medicine, RESPONDENT wrote
17 numerous prescriptions for controlled substances to patients.

18 14. Subsequent to the effective date of the Board's Order whereby RESPONDENT
19 was required to cease practicing medicine and at all times relevant hereto, RESPONDENT
20 engaged in the practice of osteopathic medicine by acquiring and/or administering Botox to
21 patients and treating patients for weight loss.

22 15. RESPONDENT'S conduct constitutes the practice of medicine in violation of the
23 Board's Order entered May 15, 2004. Such conduct is a violation of NAC 633.250 and
24 grounds for disciplinary action pursuant to NRS 633.511(1).

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COUNT TWO
(NRS 633.131(1)(f)2)

(Administering to patients a dangerous drug, botulinum neurotoxin type A, not FDA approved is conduct detrimental to the public health)

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4 16. The allegations set forth in paragraphs 1 through 5 are incorporated herein as if
5 set out in full.

6 17. On or about September 20, 2004, Dr. Hoffman purchased four vials of
7 Stabilized Botulinum Neurotoxin type A: 500 IU (5.0 ng.) from a company called Toxin
8 Research International, Inc., P.O. Box 89357, Tucson, Arizona 85752 (hereinafter TRI). On
9 the invoice and the vials was printed "For research purposes only, not for human use."

10 18. On or about October 14, 2004, Dr. Hoffman purchased two vials of Stabilized
11 Botulinum Neurotoxin type A: 500 IU (5.0 ng.) from TRI. On the invoice and the vials was
12 printed "For research purposes only, not for human use."

13 19. Even though the invoice and vials bore clear warnings that the botulinum toxin
14 type A obtained from TRI was for research purposes only and was not for human use, Dr.
15 Hoffman personally and through his staff administered the botulinum toxin type A obtained
16 from TRI to his various patients.

17 20. The Board Staff of the Nevada Board of Pharmacy audited Dr. Hoffman's
18 inventory of drugs and other substances. Board Staff found only one partial vial of botulinum
19 toxin type A in Dr. Hoffman's inventory.

20 21. TRI is not an FDA approved manufacturer of botulinum toxin type A because
21 TRI's botulinum toxin type A is not intended for and is not approved for human use. TRI is not
22 licensed in Nevada as a wholesaler or manufacturer authorized to provide drugs into Nevada.

23 22. Dr. Hoffman or his agent, at Dr. Hoffman's direction, administered the botulinum
24 toxin type A, obtained from TRI, to his patients.

25 23. Botulinum toxin type A has been approved by the FDA for human use as an
26 orphan drug. Approved orphan drug manufacturers include Allergan (brand name Botox),
27 Ipsen Limited (brand name Dysport), and Botulinum Toxin Research Associates (no brand
28 ...

1 name). The botulinum toxin type A obtained by Dr. Hoffman from TRI was not manufactured
2 by any of the three approved manufacturers of botulinum toxin type A.

3 24. In obtaining and administering to patients a substance, namely botulinum toxin
4 type A obtained from TRI, that was not approved for human use, Dr. Hoffman or his staff,
5 through his direction, violated NRS 633.131(f). Such conduct was harmful to the public and
6 detrimental to the public health, safety, and morals, and is grounds for disciplinary action
7 pursuant to NRS 633.511(1).

8 **COUNT THREE**
9 **(NRS 633.131(1)(f)(2))**
10 **(Administering a flu vaccine not FDA approved is conduct**
11 **detrimental to the public health**

11 25. The allegations set forth in paragraphs 1 through 5 are incorporated herein as if
12 set out in full.

13 26. On or about November 11, 2004, Dr. Hoffman ordered and received several
14 vials of a product that bore the label of Fluviral 5 ml., manufactured by a company called
15 Shire Biologics, a division of Shire Biochem, Inc. Shire Biochem, Inc. is a Canadian
16 manufacturer of drugs based in Laval, Quebec and is a division of Shire Pharmaceuticals
17 Groups plc., which is based in the United Kingdom.

18 27. Upon receiving the Fluviral vials, Dr. Hoffman began advertising that he would
19 provide injections of flu vaccine to the public. Dr. Hoffman and his staff, at this direction,
20 provided flu vaccinations to the public, until the Fluviral supply was exhausted on November
21 17, 2004. Based upon Dr. Hoffman's records, it appears that he and his staff administered
22 from his office more than 36 injections of Fluviral to various patients.

23 28. In obtaining and administering to patients a substance, namely Fluviral, that was
24 not approved for use in the United States by the FDA, either by himself or his staff, through
25 his direction, such conduct was harmful to his patients or detrimental to the public health and
26 safety. Dr. Hoffman violated NRS 633.131(f)(2) which is grounds for disciplinary action
27 pursuant to NRS 633.511(1).

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COUNT SIX
(NRS 233.127 and NAC 633.450)
(Emergency Suspension)

35. The allegations set forth in paragraphs 1 through 30 are incorporated herein as if set out in full.

36. That EDWARD HOFFMAN, D.O. has violated Chapter 633 and a summary suspension is necessary to prevent further violations of Chapter 633.

37. That the public health, safety, and welfare imperatively require action and summary suspension of EDWARD HOFFMAN, D.O.'s, license to practice medicine in the state of Nevada pending a hearing on the Amended Complaint. That the continuing practice of medicine or the continuing ability to practice medicine by EDWARD HOFFMAN, D.O., during the pendency of the time necessary for a hearing on this Amended Complaint would endanger the health, safety, and welfare of his patients. An emergency suspension is proper pursuant to NRS 233B.127, NRS 633.591 and NAC 633.450.

WHEREFORE, the Investigative Member of the Board of Osteopathic Medicine prays as follows:

1. That the Nevada State Board of Osteopathic Medicine schedule an emergency hearing and affirmatively find that the public health, safety, and welfare imperatively require emergency action and summarily suspend Respondent's license to practice Osteopathic Medicine in the state of Nevada pending a hearing on the Complaint pursuant to NRS 633.591.

2. That the Nevada State Board of Osteopathic Medicine conduct a hearing on this Amended Complaint as provided by statute and regulation.

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