Final Order No. DOH-06-0006- FOF-MQA
FILED DATE - 1-9-06
Department of Health
By: Theresa McCown
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF OSTEOPATHIC MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2004-50384
LICENSE NO.: OS 007917

BACH MCCOMB, D.O.,

Respondent.
_____/

FINAL ORDER

THIS CAUSE came before the BOARD OF OSTEOPATHIC MEDICINE (Board) pursuant to Sections 120.569 and 120.57, Florida Statutes, on November 19, 2005, in Orlando, Florida, for consideration of the Administrative Complaint (attached hereto as Exhibit A) in the above-styled cause. Petitioner was represented by Diane Kiesling, Assistant General Counsel, and Respondent appeared pro se.

An Administrative Complaint was filed against the Respondent on Jan. 19, 2005. Attempts to serve the Respondent were made, but the mail was undeliverable. Respondent was in New Jersey being treated for botulism. Respondent returned to Florida for an appearance in Federal Court and service was made and accepted by Respondent's attorney on February 22, 2005.

On the 21st day after service, Respondent, through counsel, requested a thirty day extension of time to file his election of rights forms (EOR) and an extension of time was granted, in writing, giving Respondent until March 22, 2005, to file the EOR. Respondent did not file an EOR, but instead filed a motion to stay proceedings with the Department on March 23, 2005. The Department responded in opposition alleging that Respondent posed a serious danger to the community. It is alleged in the Administrative Complaint that Respondent, while already

under an emergency suspension order (ESO), injected himself and three other people with Botulium Neurotoxin type A at a level 10 times greater than the correct dose, thereby causing all four to contract a near fatal case botulism.

Respondent wanted to stay the proceedings until a criminal case was concluded which involved his relationship with a company called TRI that was supplying numerous health care practitioners with a form of Botulium Neurotoxin Type A that was not FDA approved. However, Petitioner found (as did the Board) that this matter had nothing to do with TRI and nothing to do with that criminal trial (TRI was not the source from which Respondent obtained the Botox he injected himself and three others). Furthermore, the pending criminal trial in no way impeded his ability to or preclude him from filing the ERO and then if need be, seeking an abeyance of the administrative proceedings until the criminal matter came to an end. The Department opposed any stay of proceedings because they were in no way related to those criminal proceedings or Respondent's 5th amendment rights related to those proceedings.

The Department denied Respondent's Motion to Stay Proceedings by order on June 30, 2005 and despite the denial, the Respondent never filed an EOR. Several telephone calls were placed to Respondent's counsels and a letter was sent, but no response was received, so the matter was set for a waiver hearing. Shortly thereafter, Respondent's counsel finally called Petitioner, at which time he was advised that a waiver hearing was scheduled because no EOR had ever been filed. Instead of filing an EOR or otherwise addressing the Department's Motion for Default, Respondent filed a Renewed Motion to Stay Proceedings.

Upon hearing argument and being duly advised on the premises, the Board hereby finds that Respondent was properly served with the Administrative Complaint and because Respondent failed to submit an Election of Rights or otherwise dispute any of the facts, he waived his right to a hearing pursuant to Section 120.57(1), Florida Statutes.

Upon further consideration, it is ORDERED:

1. The allegations of fact set forth in the Administrative Complaint are approved and adopted and incorporated herein by reference as the findings of fact by the Board.

2. The conclusions of law alleged and set forth in the Administrative Complaint are approved and adopted and incorporated herein by reference as the conclusions of law by the Board.

3. The violations set forth warrant disciplinary action by the Board. THEREFORE, IT IS HEREBY ORDERED AND ADJUDGED:

Respondent's license to practice osteopathic medicine in the State of Florida is hereby REVOKED and he order to pay an adminsitrative in the amount of $10,000.00 to the Department of Health within thirty (30) days of entry of this final order.

RULING ON MOTION TO ASSESS COSTS

The Board reviewed the Petitioner's Motion to Assess Costs and imposes the costs associated with this case in the amount of $4,750.06. Said costs are to be paid within thirty (30) days of entry of this final order.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 10 day of January, 2006 ~~2005~~.

BOARD OF OSTEOPATHIC MEDICINE

Pamela King
Executive Director

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to Bach McComb, D.O., 2545 East Sunrise Boulevard, Suite 202, Fort Lauderdale, Florida 33304; and by interoffice delivery to Diane Kiesling and Joy Tootle, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3265 this 9th day of January, 2006.

Cheryl Roberts

Deputy Agency Clerk

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2004-50384**

BACH McCOMB, D.O.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

COMES NOW the Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Osteopathic Medicine against Bach McComb, D.O., and alleges:

1. Petitioner is the state agency charged with regulating the practice of osteopathic medicine pursuant to section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 459, Florida Statutes.

2. Respondent is and has been at all times material hereto a licensed osteopathic physician in the state of Florida, having been issued license number OS 7917 on June 18, 1999.

3. Respondent's address of record is 2545 East Sunrise Boulevard, Suite 202, Ft. Lauderdale, Florida 33304.

4. On or about April 11, 2003, the Department issued an Order of Emergency Suspension of License (ESO) in case numbers 2002-28615, 2003-03247, 2003-03248, 2003-02806, and 2003-02808. The ESO suspended Respondent's license to practice osteopathic medicine in the State of Florida.

5. The ESO was personally served on Respondent and was in effect at all times material hereto.

6. On or about November 24, 2004, patients B.K. and E.K., husband and wife, presented to Advanced Integrated Medical Center (Advanced).

7. On or about November 24, 2004, Respondent administered a substance to B.K. and E.K. that Respondent represented as Botox treatment injections.

8. Botox, which contains Botulinum Toxin Type A, is a legend drug, which requires a physician's prescription for use or administration. It is indicated for the treatment of strabismus (a visual defect in which one eye cannot focus with the other on an objective because of imbalance of the eye muscles) and blepharospasm (spasmodic winking caused by the involuntary contraction of an eyelid muscle) associated with dystonia (abnormal tonicity of tissue), including benign essential blepharospasm or VII nerve disorders in patients 12 years of age or older. Botox is also indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia. On April 12, 2002, the federal Food and Drug Administration (FDA) approved use of this drug for the treatment of wrinkles.

9. On or about November 25, 2004, E.K. complained to his son, M.K., that he was feeling lightheaded and "spacey."

10. On or about November 25, 2004, E.K. received a telephone call from Respondent indicating that Respondent was experiencing similar symptoms and that they must have gotten a "bad batch" of Botox. Respondent advised E.K. not to worry,

that the symptoms would last a few days and that he would experience some headaches.

11. At all times material hereto, Dr. Thomas P. Toia (Dr. Toia) was a chiropractor and owner of Advanced.

12. On or about November 26, 2004, Dr. Toia arrived at the residence of E.K. and B.K. to provide treatment for a suspected reaction to the Botox treatment they had received from Respondent. Dr. Toia was accompanied by his son, Thomas M. Toia, a self-described "medical technician." Mr. Toia is not licensed by the Department.

13. On or about November 26, 2004 E.K. and B.K. were found to be very weak, had difficulty opening their eyes and were experiencing flu-like symptoms.

14. Mr. Toia, in the presence of Dr. Toia, administered an I.V. to E.K. and B.K. and prepared a "Myer's solution" by drawing into a syringe, approximately 12 units of ascorbic acid from a vial. Mr. Toia then used the same needle to draw five units from a vial of magnesium, one unit from a vial of vitamin C, one unit from a vial of vitamin B complex, and an unknown amount of saline solution.

15. Mr. Toia, in the presence of Dr. Toia, injected the solution into E.K.'s I.V.

16. Mr. Toia then repeated the procedure for B.K. Both E.K. and B.K. were given a 500 cc bag of "lactated ringers solution" via IV. The entire process took approximately 60 to 90 minutes.

FACTS RELATED TO PATIENT B.K.

17. On or about November 26, 2004, B.K. was examined in the emergency room by Dr. Dennis Egitto, M.D. ("Dr. Egitto"). B.K. exhibited the following symptoms:

progressive weakness, difficulty swallowing, blurred vision, shortness of breath and dry throat, difficulty clearing secretions, difficulty speaking, droopy eyelids, and flu-like feeling.

18. Dr. Egitto referred B.K. for neurovascular consultation.

19. On or around November 26, 2004, B.K. was evaluated by Dr. Charles Schallop, M.D.

20. Dr. Schallop recorded the following impression:

> [B.K.] underwent a botulinum toxin A procedure, periorbital, on November 24, 2004, by Dr. Bach in Fort Lauderdale. She underwent similar procedure approximately 6 to 8 months ago. Since the procedure, she has been experiencing progressive weakness, dysphagia, blurred vision, difficulty clearing her secretions. The patient's husband underwent the same procedure the same day by the same doctor, and he is experiencing similar symptoms. They spoke to their doctor and were told that both he and his wife are experiencing similar symptoms as well. The etiology needs to be better defined, whether this is an adverse reaction or spread of toxin. The patient has not been taking any other medication at this time. They have no fever, no chills. There is no history of neuromuscular disorder.

21. Dr. Schallop considered B.K. critically ill. Dr. Schallop odered intravenous fluids, pulmonary and E.N.T. evaluation, and swallow evaluation for B.K. Dr. Schallop also notified the Centers for Disease Control and Florida Poison Control.

21. On or about November 27, 2004, Dr. Richard Weinstock, D.O. ("Dr. Weinstock"), evaluated B.K. pursuant to Dr. Egitto's referral. At this time, B.K. had been placed on a respirator due to her inability to breathe on her own. Dr. Weinstock noted that B.K. had received nearly three times the amount of botulinum toxin A as had E.K. Dr. Weinstock's impression was respiratory failure, and possibly botulism reaction

to Botox. Dr. Weinstock recommended antitoxin and continued ventilatory support. Dr. Weinstock also recommended a tracheostomy tube if B.K. continued on the respirator to prevent vocal chord damage.

22. To date, B.K. remains hospitalized in a similar condition.

FACTS RELATED TO PATIENT E.K.

23. On or about November 26, 2004, Dr. Charles Schallop, M.D., performed a neurovascular evaluation on E.K. pursuant to a referral from emergency room physician, Dr. Dennis Egitto, M.D.

24. E.K. exhibited the following symptoms: generalized weakness, dysarthric speech, dysphagia, blurred vision, shortness of breath and dry throat, and difficulty clearing secretions.

25. Dr. Schallop had the following impression:

> [E.K.] underwent chemodenervation with botulinum toxin A in the periorbital muscles for cosmetic reasons on Wednesday, November 24, 2004. He has experienced since Thursday progressive weakness, dysphagia, difficulty clearing secretions, shortness of breath, cystharic speech, and blurred vision. He has no history of neuromuscular disorder. He underwent a similar procedure 6 to 8 months ago with no adverse effects. Patient states that the physician at the clinic injected himself and his significant other, and they are experiencing similar symptoms. The etiology needs to be better defined, adverse reaction/extensive diffusion of the botulinum toxin A.

26. Dr. Schallop considered E.K. critically ill. Dr. Schallop ordered intravenous fluids, pulmonary and E.N.T. evaluation, swallow evaluation, and close assessment of E.K.'s neuromuscular status. Dr. Schallop also notified the hospital pharmacy, Advanced, and Florida Poison Control.

27. On or about November 27, 2004, Dr. Richard Weinstock, D.O. ("Dr. Weinstock"), evaluated E.K. pursuant to Dr. Egitto's referral. At this time, E.K. was being intubated and placed on a respirator due to his worsening condition. Dr. Weinstock's impression was Botox reaction causing respiratory failure, aspiration, and dysphagia. Dr. Weinstock also recommended a tracheostomy tube if E.K. continued on the respirator to prevent vocal chord damage.

28. As of this date, E.K. remains hospitalized in a similar condition.

29. According to an affidavit in support of a search warrant signed by a Special Agent with the Office of Criminal Investigations of the U.S. Food and Drug Administration, dated December 9, 2004, and filed in the United States District Court for the Northern District of California ("the FDA affidavit"), the Centers for Disease Control ("CDC") has confirmed that B.K. and E.K. both suffer from botulism type A.

30. Botulism is a muscle-paralyzing disease caused by a toxin made by a bacterium called Clostridium botulinum. Once in the body, the toxin binds to nerve endings at the point where the nerves join muscles. This prevents the nerves from signaling the muscles to contract. The result is weakness and paralysis that descends from the cranium down, affecting, among other things, the muscles that regulate breathing. Recovery can be extremely slow. Assuming the patient receives proper care to ensure continued breathing, recovery occurs only when the affected nerves grow new endings, a process that can take several months, although the length of time varies greatly from case to case.

31. Botulinum Toxin Type A is a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 321(g), intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, or to affect the structure or the function of the body of man, and biologic, as defined in section 361(i) of the Public Health Service Act, 42 U.S.C. s. 262.

32. On December 9, 1991, the Food and Drug Administration (FDA) approved BOTOX®, a Botulinum Toxin Type A drug manufactured by Allergan of Irvine, California, for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia and the treatment of strabismus and blepharospasm associated with dystonia.

33. On April 12, 2002, FDA approved a supplement to the Botulinum Toxin Type A license application for treatment of glabellular lines, commonly referred to as wrinkles. Under this approval, Botulinum Toxin Type A is marketed and labeled for this new indication as BOTOX® and BOTOX®COSMETIC manufactured by Allergan, and MYOBLOC®, manufactured by Elan Pharmaceuticals. No other manufacturers have been approved by the FDA to produce or distribute Botulinum Toxin Type A as a drug in the United States.

34. On or about November 30, 2004, the FDA interviewed M.K., the son of B.K. and E.K. M.K. advised he was present when Respondent injected his parents with "Botox" on November 24, 2004, at Advanced. Respondent told M.K. he had just received a vial of 100 units of "Botox," which costs $500, and that he had injected himself and another person on or about November 23, 2004. Respondent indicated that

the vials he was using on B.K. and E.K. were left over from the vial of "Botox" he had used on himself and the other person.

35. On or about December 1, 2004, a Department investigator interviewed Neil Garfield, an attorney representing Advanced. Mr. Garfield indicated that he thought Advanced Integrated had received a batch of "Botox" with a higher dose from a source other than Allergan, and it was used on all of the four individuals that had been hospitalized.

36. According to the FDA affidavit, a federal search warrant was served at Advanced on or about December 1, 2004. Records reviewed and seized from Advanced did not disclose any purchases of botulinum toxin from a source other than Allergan.

37. In the course of the search, and pursuant to the warrant, a three-page document from Toxin Research International, also designated as TRI ("TRI"), P.O. Box 89357, Tuscon, Arizona, was seized. The first two pages of the document are a "Material Safety Data Sheet" ("MSDS") regarding Botulinum Neurotoxin A. This document states in pertinent part, "Botulinum neurotoxin type A from Clostridium botulinum is a 150,000 dalton protein and is one of the most potent toxins known." The third page of the document, labeled "Product Detail," offers 500 units per vial for $1,250 and two (2) vials for $2,000. It also includes a notation under the company logo which states: "For Research Purposes Only Not For Human Use."

38. Further according to the FDA affidavit, shipping information obtained from United Parcel Service ("UPS") indicates that, on or about October 5, 2004, TRI shipped a two-pound package to Dr. Al Boyce, at Advanced, 1655 East Oakland Park Boulevard,

Fort Lauderdale, Florida. According to UPS records, Advanced also received packages from TRI on or about August 26, 2004, and March 12, 2004.

39. A Department investigator interviewed Dr. Boyce. Dr. Boyce indicated he was a 75 year-old osteopathic physician at Advanced Integrated, but since approximately February 2004, he has only worked there on Monday of each week. He said he is not involved in ordering any medications. He further indicated that he was not aware that Respondent's license had been suspended.

40. On or about December 6, 2004, an FDA agent interviewed Thomas M. Toia, whose father, Thomas P. Toia, D.C., owns Advanced. Mr. Toia indicated he had been employed at Advanced Integrated since September 2003, when his father acquired the clinic. Mr. Toia was responsible for ordering medical supplies for the clinic, including drugs, at the direction of the doctors.

41. Mr. Toia ordered the drugs under the license of Dr. Boyce, and the drugs were addressed to Dr. Boyce when delivered to Advanced. In the interview with the FDA agent, Thomas M. Toia indicated that he had, on two to four occasions, ordered vials of botulinum toxin from TRI for Advanced Integrated.

42. Mr. Toia further indicated to the FDA agent that, prior to Respondent administering the injections to B.K. and E.K., Respondent had instructed Thomas M. Toia to order the botulinum toxin from List Biological Laboratories, Inc. ("List"), via the internet. At Respondent's request, Mr. Toia purchased a single 100 microgram vial from List via the internet.

43. Botulinum toxin from List is not an FDA approved drug.

44. According to the FDA affidavit, Mr. Toia provided to the FDA a copy of the transaction detail for the corporate Visa debit card account he used to purchase the botulinum toxin from List. The statement reflected the transaction with List, in the amount of $571.33.

45. Mr. Toia told the FDA agent that he accepted delivery of the toxin from List, which was addressed to him, on or about November 23, 2004. Mr. Toia placed the box on a table at Advanced and watched as Respondent prepared to reconstitute the toxin. Toia did not witness Respondent reconstitute the toxin, but saw Respondent bring out some empty bottles and saline in preparation to do so.

46. Mr. Toia indicated that, by his calculation, the 100 microgram vial of botulinum toxin from List was the equivalent of 20,000 international units of botox. Mr. Toia suggested to Respondent that he needed to use 100 milliliters of saline to reconstitute this dosage, rather than the 10 milliliters of saline Respondent had set aside. Respondent did not agree and advised Mr. Toia that he was off by a factor of ten.

47. The next day, on or about November 24, 2004, Respondent administered the purported "botox" to B.K. and E.K.

48. Respondent did not administer the FDA approved BOTOX® drug, but, rather, administered the unapproved botulinum toxin that he had purchased from an unlicensed source.

49. As a direct result of Respondent's administering an adulterated drug, B.K. suffered a life-threatening condition.

50. As a direct result of Respondent's administering an adulterated drug, E.K. suffered a life-threatening condition.

51. Respondent practiced osteopathic medicine subsequent to the Order of Emergency of Suspension of License dated April 11, 2003, while the order was still in effect.

52. Respondent injected the botulinum toxin into B.K. in a manner that was outside the course of Respondent's professional practice.

53. Respondent injected the botulinum toxin into E.K. in a manner that was outside the course of Respondent's professional practice.

COUNT ONE

54. Petitioner re-alleges and incorporates paragraphs 1-53 as if fully set forth in this count.

55. Section 456.072(1)(q), Florida Statutes (2004), provides that violating a lawful order of the Department or Board is an act for which disciplinary action may be taken.

56. Respondent violated a lawful order of the Department or Board by practicing osteopathic medicine subsequent to, and in violation of, the ESO filed April 11, 2003, in case numbers 2002-28615, 2003-03247, 2003-03248, 2003-02806, and 2003-02808.

57. Based on the foregoing, Respondent violated Section 456.072(1)(q), Florida Statutes (2004), by practicing Osteopathic Medicine subsequent to, and in

violation of, the ESO filed April 11, 2003 in case numbers 2002-28615, 2003-03247, 2003-03248, 2003-02806, and 2003-02808.

COUNT TWO

58. Petitioner re-alleges and incorporates paragraphs 1-53 and 59 as if fully set forth in this count.

59. Section 459.015(1)(t), Florida Statutes (2004), provides that prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing a legend drug, other than in the course of an osteopathic physician's professional practice, is an act for which disciplinary action may be taken.

60. Respondent prescribed, dispensed, administered, supplied, sold, gave, mixed or otherwise prepared a legend drug other than in the course of Respondent's professional practice, by injecting the botulinum toxin into B.K. in a manner that was outside the course of Respondent's professional practice.

61. Based on the foregoing, Respondent violated Section 459.015(1)(t), Florida Statutes (2004), by injecting the botulinim toxin into B.K. in a manner that was outside the course of Respondent's professional practice.

COUNT THREE

62. Petitioner re-alleges and incorporates paragraphs 1-50 and 56 as if fully set forth in this count.

63. Respondent prescribed, dispensed, administered, supplied, sold, gave, mixed or otherwise prepared a legend drug other than in the course of Respondent's

professional practice, by injecting the botulinum toxin into E.K. in a manner that was outside the course of Respondent's professional practice.

64. Based on the foregoing, Respondent violated Section 459.015(1)(t), Florida Statutes (2004), by injecting the botulinim toxin into E.K. in a manner that was outside the course of Respondent's professional practice.

WHEREFORE, the Petitioner respectfully requests that the Board of Osteopathic Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 11th **day of** January, **200**5

John O. Agwunobi, M.D., M.B.A., M.P.H.
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FILED
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DEPUTY CLERK
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1-19-05

Reviewed and approved by: DKK Date 12/30/04
PCP: Jan. 6, 2005
PCP Members: Hand + Kaufman

DOH v. Bach McComb, D.O., Case Number 2004-50416

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.