



STATE MEDICAL BOARD OF OHIO

77 South High Street, 17th Floor • Columbus, Ohio 43266-0315 • (614)466-3934

June 16, 1995

James R. Holt, D.O.
816 E. Aurora Road
Macedonia, Ohio 44056

Dear Doctor Holt:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of Sharon W. Murphy, Esq., Attorney Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on June 14, 1995, including Motions approving and confirming the Findings of Fact and Conclusions of Law of the Hearing Examiner, and adopting an amended Order.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal may be taken to the Franklin County Court of Common Pleas only.

Such an appeal setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of a Notice of Appeal with the State Medical Board of Ohio and the Franklin County Court of Common Pleas within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO

Thomas E. Gretter, M.D.
Secretary

TEG:em
Enclosures

CERTIFIED MAIL RECEIPT NO.P 741 124 590
RETURN RECEIPT REQUESTED

cc: Kevin P. Byers, Esq.

CERTIFIED MAIL RECEIPT NO. 741 124 591
RETURN RECEIPT REQUESTED



STATE MEDICAL BOARD OF OHIO

77 South High Street, 17th Floor • Columbus, Ohio 43266-0315 • (614)466-3934

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

*

*

JAMES R. HOLT, D.O.

*

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on the 14th day of June, 1995.

Upon the Report and Recommendation of Sharon W. Murphy, Hearing Examiner, Medical Board, in this matter designated pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the modification, approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

1. The certificate of James R. Holt, D.O., to practice medicine and surgery in the State of Ohio, shall be REVOKED. Such revocation is stayed, provided that, within six (6) months of the effective date of this Order, Dr. Holt shall provide acceptable documentation of his successful completion of a minimum of ten (10) credit hours of Category I continuing medical education in medical recordkeeping. Such courses are to be approved in advance by the Board, and are to be in addition to continuing medical education requirements required by Section 4731.281, Ohio Revised Code.
2. Dr. Holt's certificate shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of two (2) years:
 - a. Dr. Holt shall obey all federal, state, and local laws, and all rules governing the practice of medicine in Ohio.
 - b. Dr. Holt shall submit quarterly declarations under penalty of perjury stating whether or not there has been compliance with all the provisions of probation.
 - c. Dr. Holt shall appear in person for interviews before the full Board, or its designated representative, at six (6) month intervals, or as otherwise requested by the Board.

- d. Dr. Holt shall not treat any patients for weight control problems utilizing controlled substances.
 - e. In the event that Dr. Holt should leave Ohio for three (3) consecutive months, or reside or practice outside the State of Ohio, Dr. Holt shall notify the Board in writing of the dates of departure and return. Periods of time spent outside the State of Ohio shall not apply to the reduction of the probationary period.
3. If Dr. Holt violates the probation in any respect, the Board, after giving Dr. Holt notice and the opportunity to be heard, may institute whatever disciplinary action it deems appropriate, up to and including the permanent revocation of Dr. Holt's certificate to practice medicine and surgery in Ohio.
 4. Upon successful completion of probation, Dr. Holt's certificate to practice medicine and surgery in Ohio shall be fully restored.

This Order shall become effective thirty (30) days from the date of mailing of notification of approval by the Board.

Thomas E. Gretter, M.D.
Secretary

(SEAL)

Date

STATE MEDICAL BOARD
OF OHIO

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**REPORT AND RECOMMENDATION
IN THE MATTER OF JAMES R. HOLT, D.O.**

The Matter of James R. Holt, D.O., was heard by Sharon W. Murphy, Esq., Hearing Examiner for the State Medical Board of Ohio, on March 22, 1995.

INTRODUCTION

I. Basis for Hearing

- A. The State Medical Board notified James R. Holt, D.O., by letter dated October 12, 1994, (State's Exhibit 1), that it proposed to take disciplinary action against his license to practice osteopathic medicine and surgery in Ohio because Dr. Holt failed to properly utilize controlled substances which he dispensed to Patients 1 through 3 for weight reduction. [Note: Patients 1 through 3 are identified in a patient key which is confidential and, thus, not for public disclosure).

The Board alleged that in his care and treatment of Patients 1 through 3, Dr. Holt: "failed to utilize the controlled substances as an adjunct in the treatment of obesity"; "failed to follow F.D.A. approved labeling for the products"; "failed to determine that the patient made a substantial good-faith effort to lose weight in a treatment program prior to the utilization of controlled substances"; "failed to obtain a thorough physical examination or rule out the existence of any recognized contraindications"; "failed to discontinue the controlled substances when the patient did not lose weight"; "failed to maintain medical records accurately reflecting an appropriate purpose for the utilization of controlled substance anorectics"; and/or "failed to consider the drug's potential for abuse, the possibility that the patients were using the drugs for non-therapeutic purposes, or the possibility that the drugs would be distributed to third parties."

The Board further alleged that Dr. Holt's conduct after November 17, 1986, constituted "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board,' as that clause is used in Section 4731.22(B)(20), Ohio Revised Code." The Board claimed that the conduct of Dr. Holt violated Rules 4731-11-02(A), (C), and (D), and 4731-11-04(A) and (B), Ohio Administrative Code. The Board further claimed that pursuant to paragraph (F) of Rule 4731-11-02, Ohio Administrative Code, a violation of any provision of Rule 4731-11-02 would also constitute violations of Sections 4731.22(B)(2) and (B)(6), Ohio Revised Code. Moreover, a violation of Rule 4731-11-02(C), if committed purposely, knowingly, or recklessly, would also constitute a violation of Section 4731.22(B)(3), Ohio Revised Code. Finally, the Board alleged that pursuant to Rule 4731-11-04(C), Ohio Administrative Code, a violation of any provision of Rule 4731-11-04 would

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also constitute violations of Sections 4731.22(B)(2), (B)(3), and (B)(6), Ohio Revised Code.

The Board advised Dr. Holt of his right to request a hearing.

B. On November 10, 1994, Kevin P. Byers, Esq., filed a written hearing request on behalf of Dr. Holt. (State's Exhibit 2).

II. Appearances

A. On behalf of the State of Ohio: Betty D. Montgomery, Attorney General, by Anne B. Strait, Assistant Attorney General

B. On behalf of the Respondent: Kevin P. Byers, Esq.

III. Testimony Heard

A. Presented by the State

James R. Holt, D.O.

B. Presented by the Respondent

James R. Holt, D.O.

IV. Exhibits Examined

In addition to State's Exhibits 1 and 2, noted above, the following exhibits were identified and admitted into evidence:

A. Presented by the State

1. State's Exhibit 3: Respondent's Notice of Appearance, filed November 10, 1994.
2. State's Exhibit 4: Respondent's Request for List of Witnesses and Documents filed November 10, 1994.
3. State's Exhibit 5: November 14, 1994, letter to Mr. Byers from the Board, advising him that a hearing had been initially scheduled for November 23, 1994, and further advising that the hearing had been postponed pursuant to Section 119.09, Ohio Revised Code.
4. State's Exhibit 6: November 21, 1994, letter to Mr. Byers from the Board scheduling the hearing for January 15, 1995. (2 pp.)

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5. State's Exhibit 7: Respondent's Unopposed Motion for Continuance, filed December 20, 1994. (3 pp.)
6. State's Exhibit 8: State's Motion for Continuance filed December 21, 1994. (4 pp.)
7. State's Exhibit 9: December 28, 1994, Entry granting the parties' motions for continuance.
8. State's Exhibit 10: February 21, 1995, Entry granting State's Motion for Continuance. (Note: corresponding State's Motion for Continuance not submitted for admission into evidence).
9. State's Exhibit 11: State's Request for List of Witnesses and Documents filed March 2, 1995. (2 pp.)
10. State's Exhibit 12: State's Motion for Continuance filed March 10, 1995. (3 pp.)
11. State's Exhibit 13: March 13, 1995, Entry granting State's Motion for Continuance.
12. State's Exhibit 14: Copy of Section 4731-11-01, Ohio Administrative Code.
13. State's Exhibit 15: Copy of Section 4731-11-02, Ohio Administrative Code. (2 pp.)
14. State's Exhibit 16: Copy of Section 2901.22, Ohio Revised Code.
15. State's Exhibit 17: Copy of Section 4731-11-04, Ohio Administrative Code. (2 pp.)
16. State's Exhibit 18: Copy of Physician's Desk Reference (PDR) excerpt for Fastin. (2 pp.)
17. State's Exhibit 19: Copy of PDR excerpt for Tenuate. (2 pp.)
18. State's Exhibit 20: Copy of PDR excerpt for Ionamin.
19. State's Exhibit 24: Copies of Dr. Holt's medical records for Patient 1. (58 pp.) (Note: These records have been sealed to protect patient confidentiality.)
20. State's Exhibit 25: Copies of Dr. Holt's medical records for Patient 2. (54 pp.) (Note: These records have been sealed to protect patient confidentiality.)

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21. State's Exhibit 26: Copies of Dr. Holt's medical records for Patient 3. (27 pp.) (Note: These records have been sealed to protect patient confidentiality.)

B. Presented by Respondent

1. Respondent's Exhibit A: Dr. Holt's curriculum vitae.
2. Respondent's Exhibit B: March 15, 1995, letter to the Board members from Mark P. Pace, D.O., commending Dr. Holt.
3. Respondent's Exhibit C: Undated letter to the Board members from Frank A. Labagnara, D.O., commending Dr. Holt.
4. Respondent's Exhibit D: Undated letter to the Board members from Richard P. DeBlander, D.O., commending Dr. Holt.
5. Respondent's Exhibit E: March 24, 1995, letter to the Board members from Charles V. Gemma, D.O., FACOS, commending Dr. Holt.
6. Respondent's Exhibit F: March 20, 1995, letter to the Board members from John G. Chase, patient of Dr. Holt, commending Dr. Holt.
7. Respondent's Exhibit G: Undated letter to the Board members from Robert F. and Mary I. Hudecek, patients of Dr. Holt, commending Dr. Holt.
8. Respondent's Exhibit H: Undated letter to the Board members from JoAnn Floyd, patient of Dr. Holt, commending Dr. Holt.
9. Respondent's Exhibit I: (proffered).

PROCEDURAL MATTERS

Although the October 12, 1994, citation letter alleged conduct which had occurred prior to November 17, 1986, the State advised at hearing that evidence of this conduct was presented for historical perspective only. The State further advised that only evidence of Dr. Holt's conduct occurring after November 17, 1986, was being to prove the alleged violations.

SUMMARY OF THE EVIDENCE

The complete transcript of testimony and all exhibits, regardless of whether specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparation of this Report and Recommendation.

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1. Chapter 4731-11, Ohio Administrative Code, became effective November 17, 1986. This Chapter contains rules promulgated by the State Medical Board with regard to the utilization of controlled substances.

Rule 4731-11-02(C), Ohio Administrative Code, requires that a physician consider "the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a non therapeutic use or to distribute to others, and the possibility of an illicit market for the drug." Paragraph (D) also mandates that the physician keep accurate records, which shall include documentation of physical examination and a patient diagnosis. (See State's Exhibit [St. Ex.] 15).

When using a controlled substance specifically for the purpose of weight reduction, a physician must also comply with Rule 4731-11-04, Ohio Administrative Code. Paragraph (A) allows a physician to use a schedule III or IV controlled substance for purposes of weight reduction only when the F.D.A. has approved that drug for the purpose of weight reduction. Moreover, the physician may use the schedule III or IV controlled substance only in the treatment of obesity, only as a supplement to a dietary plan, only in accordance with strict guidelines, and only in compliance with the following requirements set forth in paragraph (B):

- (1) Before initiating treatment utilizing a schedule III or IV controlled substance, the physician determines through review of his own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.
- (2) Before initiating treatment utilizing a schedule III or IV controlled substance, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized.

* * *

- (5) The physician shall not initiate or shall discontinue utilizing all schedule III or IV controlled substances immediately upon ascertaining or having reason to believe:
 - (a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of fourteen days, which determination shall be made by weighing the patient at least every fourteenth day, except that a patient who has never before received

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treatment for obesity utilizing any controlled substance who fails to lose weight during his first such treatment attempt may be treated with a different controlled substance for an additional fourteen days, or

- (b) That the patient has developed tolerance (a decreasing contribution of the drug toward further weight loss) to the anorectic effects of the controlled substance being utilized.

(St. Ex. 17).

2. Ionamin, Fastin and Tenuate are sympathomimetic amines with pharmacologic action similar to amphetamine. All are schedule IV controlled substances, "indicated in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction." Contraindications include "[a]dvanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity, or idiosyncrasy, to the sympathomimetic amines, glaucoma. . . . agitated states. . . . [p]atients with a history of drug abuse." (St. Exs. 18, 19, 20).
3. James R. Holt, D.O., received an undergraduate degree in Pharmacy in 1953. He worked as a Pharmacist in the Army until 1955, at which time he worked as a civilian pharmacist until he graduated from medical school in 1961. (Respondent's Exhibit [Resp. Ex.] A; Hearing Transcripts [Tr.] at 46-47).

Dr. Holt received a Doctor of Osteopathy degree from the Chicago College of Osteopathy in 1961. He completed a one year internship at the Brentwood Hospital in Warrensville Heights, Ohio. In 1962, Dr. Holt opened an office in family practice/primary care. He has maintained that practice for thirty-four years. (Resp. Ex. A; Tr. at 17-18, 61-62). He testified that he has been board certified in family practice since 1974. (Tr. at 19-20).

4. Patient 1 was a patient of Dr. Holt for 14 years. When Patient 1 first presented to Dr. Holt on November 16, 1978, she was 42 years old and weighed 121½ pounds. She informed Dr. Holt that her ideal weight was 115 pounds and that she had previously received Biphedamine for weight loss from another physician. There is no documentation of a physical examination other than a blood pressure of 130/80 and a pulse rate of 96 with a notation for regular rhythm and rate. Nevertheless, Dr. Holt prescribed Biphedamine '20', one tablet every morning. (St. Ex. 24 at 33).

Dr. Holt continued to prescribe Biphedamine '20', 30 tablets, approximately monthly for almost seven years. (St. Ex. 24 at 20-33). On July 12, 1985, Dr. Holt discontinued Biphedamine and, instead, prescribed Tepanil. (St. Ex. 24 at 20). Tepanil is very similar to Tenuate. (Tr. at 28). For the next sixteen months, Dr. Holt prescribed either Tepanil, DAS 15 mg. or Fastin 30 mg., to be

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taken daily. Patient 1's weight fluctuated between 149 and 140 pounds. (St. Ex. 24 at 20).

The Board's rules for use of controlled substances became effective on November 17, 1986. (St. Exs. 12, 13, 15). On Patient 1's next visit, on December 12, 1986, Dr. Holt prescribed Ionamin 30 mg., 30 tablets, one daily. He recorded a blood pressure of 120/80, a pulse of 84, and a temperature of 98°. He noted that her lungs were clear and heart rate and rhythm regular. Patient 1 weighed 139 pounds. No other physical examination was noted.

Dr. Holt testified that he became aware of the newly enacted rules during the first week of January, 1987. Dr. Holt testified that a pharmacist called regarding a different patient, to inform him that he could only prescribe controlled substances for weight reduction in fourteen day amounts. He was told that after fourteen days, the patient would have to be reevaluated by the physician. (St. Ex. 25 at 17, Tr. at 21).

On January 15, 1987, Patient 1 saw Dr. Holt for the first time since he had been notified of the new rules for prescribing anorectic medications. On that visit, Patient 1 had gained 4 1/2 pounds. Dr. Holt prescribed Fastin, 30 mg., but only 14 tablets. Thereafter, he consistently prescribed 14 tablets of whichever Schedule IV anorectic medication he prescribed.

Patient 1 kept her appointments with Dr. Holt sporadically, and appeared at one to five month intervals. Dr. Holt continued to prescribe either Fastin, Tenuate, or Ionamin, 14 tablets per visit, to Patient 1, regardless of the frequency of her visits or of her weight gain or loss. (St. Ex. 24 at 10-14). During that period, her weight fluctuated between 139 and 145 pounds. There are occasional references to a 1000 calorie diet, clear lungs and regular heart rhythm. (St. Ex. 24 at 14-16).

Dr. Holt briefly ceased prescribing anorectic medications in January of 1990, when he noted that Patient 1 had an irregular heartbeat. He ordered an electrocardiogram, a chest x-ray, a Holter monitor, a complete blood count and a chemistry panel. (St. Ex. 24 at 10). The laboratory studies were within normal limits except that cholesterol and triglyceride levels were elevated. (St. Ex. 24 at 43-44). The Holter monitor studies revealed frequent premature contractions, probably of junctional origin. (St. Ex. 24 at 40).

Dr. Holt resumed prescribing Tenuate on May 3, 1990. Regardless of Patient 1's weight loss or the frequency of her visits, Dr. Holt continued to prescribe Tenuate or Fastin through April 1992, with one exception. (St. Ex. 24 at 1-9). On January 13, 1992, Patient 1 had gained 2 pounds. Dr. Holt noted "no weight loss . . . see one week," and withheld the anorectic medication. One week later, when Patient 1 had lost two pounds, Dr. Holt again prescribed Fastin, 30 mg. (St. Ex. 24 at 2).

5. When Patient 2 first presented to Dr. Holt on February 1, 1972, she was 47 years old and weighed 122 pounds. Dr. Holt prescribed a 1000 calorie diet and 454 ACN. (St. Ex. 25 at 47). Dr. Holt testified that 454 ACN was a diet pill which contained amphetamines. (Tr. at 26). Physical examination revealed two previous childbirths, a past appendectomy, and no allergy to medications. (One other entry is illegible.) He also noted that her lungs were clear and that he heard no murmurs. (St. Ex. 25 at 47).

From 1972 through 1992, Dr. Holt prescribed Patient 2 various anorectic medications which included Fastin, Tenuate, and Ionamin. During that time, her weight fluctuated between 104½ and 126½ pounds. (St. Ex. 25 at 1-48).

On January 2, 1987, Dr. Holt noted that "Druggist called, she can only have 14 day supply, then has to see Dr." (St. Ex. 25 at 17). At this point, Patient 2 weighed 119 pounds. (Tr. at 30). Dr. Holt began prescribing 14 tablets of anorectic medication per visit, rather than 30 tablets. (St. Ex. 25 at 17).

Findings from physical examination were rarely noted. In October of 1985, Dr. Holt noted that Patient 2's heart sounds were "OK." (St. Ex. 25 at 20). On July 14, 1987, Dr. Holt noted that her lungs were clear. (St. Ex. 25 at 16). On March 3, 1989, Dr. Holt noted that Patient 2 had a runny nose, but no cough; her heart was "OK" and her lungs were clear; she had "no ST." (One entry was illegible.) (St. Ex. 25 at 9). There are a few random notations that Patient 2 was feeling well. (St. Ex. 25 at 4, 8, 14, 18).

6. Patient 3 first presented to Dr. Holt on April 11, 1972, for complaints unrelated to weight. (St. Ex. 26 at 27). Dr. Holt testified that Patient 2 wanted to lose weight to see if it would alleviate a hemorrhoid problem. (Tr. at 35). On August 14, 1973, when she weighed 140 pounds, Dr. Holt began prescribing Spasatal and a 1000 calorie diet. (St. Ex. 26 at 21). He continued prescribing Spasatal or Deleo, both anorectic drugs, at intervals, over the next several years. (St. Ex. 26 at 11-21; Tr. at 34, 36).

On April 11, 1983, Dr. Holt prescribed Ionamin 30 mg, 30 tablets, one tablet daily. (St. Ex. 26 at 10). Patient 3 weighed 136 pounds. He continued prescribing Ionamin or Tenuate, with intermittent breaks, until July 2, 1991. (St. Ex. 26 at 1-17). In response to the information he received from the pharmacist, in early 1987, Dr. Holt began prescribing 14, rather than 30, tablets per visit. (St. Ex. 26 at 7).

Patient 3 used anorectic medications sporadically over the years. Generally, when she was taking the medications, Patient 3's weight decreased with each visit. Patient 3 only demonstrated weight gains when she had ceased taking the medications for a period of time. (St. Ex. 26 at 1-11). For example, on May 28, 1987, after a period of consistent weight loss while taking anorectic medication, Patient 3 weighed 150 pounds, a gain of two pounds. Dr. Holt did not give her a prescription for anorectic medication. Patient 3 returned two years later,

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weighing 173 pounds. Dr. Holt prescribed Ionamin 30 mg. (St. Ex. 26 at 6). Patient 3 displayed consistent weight loss every two weeks until August 7, 1989, when she weighed 157½ pounds, a gain of three pounds. Again, Dr. Holt withheld the Ionamin. This time, Patient 3 returned one week later and received a prescription for Ionamin. (St. Ex. 26 at 5). A few weeks later, Patient stopped coming to Dr. Holt. She did not return until April 2, 1990, at 177 pounds. Dr. Holt prescribed Ionamin for three months as Patient 3 demonstrated consistent weight loss. When she presented with a gain of 2½ pounds, Dr. Holt refused her prescription. (St. Ex. 26 at 3-4).

Dr. Holt rarely documented the results of any physical examination.

From 1983 through 1991, Patient 3's weight ranged from 118 to 179½ pounds. (St. Ex. 26 at 1-11). At the time of her final visit, Patient 3 weighed 154½ pounds. (St. Ex. 26 at 1).

7. Dr. Holt testified that all three of these patients were local people and he knew them well. (Tr. at 43, 61). He also treated family members of each patient. He testified that he prescribed the anorectic medications to each patient only as "an adjunct to help suppress their appetite." (Tr. at 43-44). He further testified that his instructions to each patient included compliance with a 1000 calorie diet, three meals a day, no snacks, no salt, and exercise. He recommended swimming or walking. (Tr. at 43).
8. When asked his definition of obesity, Dr. Holt stated that it is "a gray area." By his definition, obesity is a weight ranging from ten to fifty percent more than normal weight. For some people it can be ten pounds and for others forty pounds. Everybody has their own standard. (Tr. at 63).
9. Dr. Holt testified that he was familiar with the contraindications for the use of anorectic medications, which include hyperthyroid disease, heart or coronary disease, and pregnancy. (Tr. at 45, 50). He stated that he examined the patients on each visit. The examination would include a manual examination for thyroid enlargement, examination of the heart, pulse rate and lungs. He also weighed the patients and monitored their blood pressure. He did not record results of an examination if the results were negative. (Tr. at 44).

Dr. Holt also testified that he considered the possibility of dependence. (Tr. at 49). He did not believe that any of these patients had become dependent on the anorectic medications because the patients did not request refills on a regular basis. The patients would often be without the medications for periods from two weeks up to many months. (Tr. at 50). He also denied seeing any signs of tolerance. Moreover, knowing these three patients as well as he did, he did not believe that any of them would be diverting their medications to an illicit market. He believed he was prescribing the medications for therapeutic use. (Tr. at 49). Finally, Dr. Holt did not think that any of the three ignored his

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instructions regarding the medications. He did think, however, that they didn't stick to their diets as well as they should. (Tr. at 52).

10. Dr. Holt testified that when the pharmacist notified him of the new rules in January of 1972, the pharmacist also sent him a copy of the rules. That copy did not include the last page which, Dr. Holt testified, contained the specific provisions for prescription of controlled substances for weight reduction. Dr. Holt testified that he complied with the instructions of the pharmacist, even though he did not see those specific instructions in the rules. (Tr. at 20).

Dr. Holt stated that he received an official copy of the rules in 1991 or 1992. He stopped prescribing controlled substances for weight loss at that time. When he understood the Board's rules, he decided it was too difficult to utilize the medications and abide by the rules. (Tr. at 20).

11. Dr. Holt submitted letters of support from colleagues and patients. Mark P. Pace, D.O., F.A.C.C., wrote that Dr. Holt is "a leader in the medical community," and has served as Chairman of the Utilization Review Committee at Brentwood Hospital for many years. He further wrote: "In light of his knowledge, his kind, compassionate and caring approach in the management of his patients and his understanding of the standards of practice, I have no question or reservation about his capabilities of making sound medical judgments." (Resp. Ex. B). Frank Labagnara, D.O., Richard DeBlander, D.O., and Charles V. Gemma, D.O., FACOS, all peers and colleagues of Dr. Holt, wrote similar letters of support and commendation. (Resp. Exs. C-E). Dr. Holt also submitted letters of confidence from patients to whom he has provided care for decades. (Resp. Ex. F-H).

FINDINGS OF FACT

1. Dr. Holt prescribed Fastin and Tenuate, both schedule IV controlled substance stimulants, to Patient 1 from 1985 through 1992. He prescribed Ionamin, Tenuate and Fastin, all schedule IV controlled substance stimulants, to Patient 2 from 1977 through 1992. Dr. Holt prescribed Ionamin and Tenuate, both schedule IV controlled substance stimulants, to Patient 3 from 1983 through 1991. His purpose in prescribing these controlled substance stimulants to Patients 1 through 3 was weight reduction.
2. Dr. Holt's medical records for Patient's 1 through 3 do not indicate a diagnosis of obesity or the basis upon which such diagnosis could be made. The records do not reflect a thorough history review or physical examination, nor do they indicate any examination performed to rule out the contraindications to the use of these medications. The medical records do not indicate that Dr. Holt made a review of his or a prior treating physician's records to determine that any of the patients made "a substantial good-faith effort" to lose weight prior to Dr. Holt's prescribing controlled substances for that purpose.

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3. Dr. Holt did not consistently discontinue the use of controlled substances when the patients failed to lose weight over a period of fourteen days. Although the records and Dr. Holt's testimony indicated that he did, on some occasions, refuse to prescribe controlled substances when the patient returned with a weight gain, this behavior is inconsistent. For the most part, Dr. Holt did continue to prescribe controlled substances regardless of weight gain. Moreover, when he did refuse to prescribe a controlled substance because the patient had gained weight, he would resume prescribing the controlled substance on the patient's following visit, whether it occurred in two weeks or a few months.
4. When Dr. Holt used controlled substances for weight loss purposes, he did not do so "in accordance with the F.D.A. approved labeling for the product." Ionamin, Tenuate, and Fastin are all indicated in "the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction." (St. Exs. 18, 19, 20). Dr. Holt never diagnosed these patients as suffering from "exogenous obesity." Moreover, he utilized these agents for many years, in clear violation of the short-term stipulation.
5. The evidence sufficiently demonstrated that Dr. Holt "failed to utilize the controlled substances as an adjunct in the treatment of obesity." Dr. Holt testified that obesity can be defined as additional weight in a range of ten to fifty percent of the normal weight. The State provided no contrary definition of obesity. However, even using Dr. Holt's definition of obesity, Patient 1 fails to fall within its parameters. Patient 1 weighed 121½ pounds when she came to see Dr. Holt, and stated that her ideal weight was 115 pounds. Dr. Holt did not dispute this fact. An increase of even ten percent over her ideal weight would be 126½ pounds. Patient 1 weighed five pounds less than Dr. Holt's lower limit for obesity.
6. The evidence did not show that Dr. Holt "failed to consider the drugs' potential for abuse, the possibility that the patients were using the drugs for non-therapeutic purposes, or the possibility that the drugs would be distributed to third parties." Although the medical records do not indicate his specific considerations, Dr. Holt testified that he knew these three patients well and did not consider them to be persons who would either sell or abuse the medications. He also testified that he had considered the possibility that Patients 1 through 3 could become dependent on the anorexic medications, but found it unlikely because each of the patient frequently discontinued their use of the medications without ill effects. Alternatively, the State presented no evidence to support its contention that Dr. Holt failed to consider these matters.

CONCLUSIONS

1. Dr. Holt's conduct in prescribing controlled substances to Patients 1 through 3, after November 17, 1986, constituted "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate,

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any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code. The evidence presented supports a conclusion that the conduct of Dr. Holt violated Rules 4731-11-02(D) and 4731-11-04(A) and (B), Ohio Administrative Code."

2. Accordingly, pursuant to paragraph (F) of Rule 4731-11-02, Ohio Administrative Code, Dr. Holt's violations of Rule 4731-11-02 (D), Ohio Administrative Code, further constitute violations of Sections 4731.22(B)(2), (B)(3), and (B)(6), Ohio Revised Code.
3. Moreover, pursuant to Rule 4731-11-04(C), Ohio Administrative Code, Dr. Holt's violations of Rule 4731-11-04(A) and (B), Ohio Administrative Code, constitute violations of Sections 4731.22(B)(2) and (B)(6), Ohio Revised Code.

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The conduct of Dr. Holt in prescribing controlled substance anorectic medications to Patients 1 through 3 clearly constituted violations of Ohio's statutes and rules. He prescribed these medications for many years, without proper documentation in the patient's medical records, and with insufficient physical examination. None of these patients was severely obese. Most significantly, when he obtained copies of the rules which did not duplicate what the pharmacist had advised him, Dr. Holt made no attempt to reconcile the conflict. He continued to prescribe the medications from 1987 through 1992 without fully understanding the Board's regulations.

Nevertheless, the conduct of Dr. Holt was not heinous. He provided controlled substance anorectic medications to three middle aged women who he knew well and who requested his assistance with weight loss. There was no evidence of drug seeking behavior by any of these three patients, other than their desire for assistance with weight loss. Moreover, there was no indication of patient harm. Each of the patients frequently discontinued the use of the medications, making it unlikely that dependence was developing.

Finally, there is no evidence of a dishonest or selfish motive on the part of Dr. Holt. His colleagues, peers and patients all support his integrity and commitment to quality medical care. He fully admitted his error, and ceased prescribing all anorectic controlled substances when he realized his mistake in 1992. Considering all the evidence, it is unlikely that Dr. Holt presents a danger to the public as it is improbable that he will commit any similar violations in the future.

PROPOSED ORDER

It is hereby ORDERED that:

1. The certificate of James R. Holt, D.O., to practice medicine and surgery in the State of Ohio, shall be REVOKED. Such revocation is stayed, and Dr. Holt's

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certificate is **SUSPENDED** for an indefinite period of time, but not less than thirty (30) days. The State Medical Board shall not consider reinstatement of Dr. Holt's certificate to practice medicine and surgery in Ohio, unless and until all of the following minimum requirements are met:

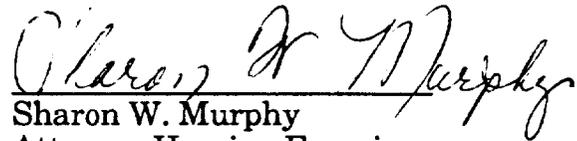
- a. Dr. Holt shall submit an application for reinstatement, accompanied by appropriate fees. The Board shall not act upon such application until the thirty day suspension period has expired.
 - b. Dr. Holt shall provide acceptable documentation of his successful completion of a minimum of ten (10) credit hours of Category I continuing medical education in prescribing of controlled substances. Such courses are to be approved in advance by the Board, and are to be in addition to continuing medical education requirements required by Section 4731.281, Ohio Revised Code.
 - c. In the event that Dr. Holt has not been engaged in the active practice of medicine and surgery for a period in excess of two (2) years prior to his application for reinstatement, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Dr. Holt's fitness to resume practice.
2. Upon reinstatement, Dr. Holt's certificate shall be subject to the following probationary terms, conditions, and limitations for a period of two (2) years:
- a. Dr. Holt shall obey all federal, state, and local laws, and all rules governing the practice of medicine in Ohio.
 - b. Dr. Holt shall submit quarterly declarations under penalty of perjury stating whether or not there has been compliance with all the provisions of probation.
 - c. Dr. Holt shall appear in person for interviews before the full Board, or its designated representative, at six (6) month intervals, or as otherwise requested by the Board.
 - d. Dr. Holt shall not treat any patients for weight control problems utilizing controlled substances.
 - e. In the event that Dr. Holt should leave Ohio for three (3) consecutive months, or reside or practice outside the State of Ohio, Dr. Holt shall notify the Board in writing of the dates of departure and return. Periods of time spent outside the State of Ohio shall not apply to the reduction of the probationary period.
3. If Dr. Holt violates the probation in any respect, the Board, after giving Dr. Holt notice and the opportunity to be heard, may institute whatever

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disciplinary action it deems appropriate, up to and including the permanent revocation of Dr. Holt's certificate to practice medicine and surgery in Ohio.

4. Upon successful completion of probation, Dr. Holt's certificate to practice medicine and surgery in Ohio shall be fully restored.

This Order shall become effective thirty (30) days from the date of mailing of notification of approval by the Board. In the thirty (30) day interim, Dr. Holt shall not undertake the care of any patient not already under his care.


Sharon W. Murphy
Attorney Hearing Examiner



STATE MEDICAL BOARD OF OHIO

77 South High Street, 17th Floor • Columbus, Ohio 43266-0315 • (614) 466-3934

October 12, 1994

James Holt, D.O.
816 E. Aurora Road
Macedonia, OH 44056

Dear Doctor Holt:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio intends to determine whether or not to limit, revoke, suspend, refuse to register or reinstate your certificate to practice osteopathic medicine and surgery, or to reprimand or place you on probation for one or more of the following reasons:

- (1) You dispensed controlled substances for Patients indicated in paragraphs (1)(a) through (c) identified in the attached Patient Key (Key Confidential -- not for public disclosure) for weight loss. You failed to utilize the controlled substances as an adjunct in the treatment of obesity, failed to follow F.D.A. approved labeling for the products, failed to determine that the patient made a substantial good-faith effort to lose weight in a treatment program prior to the utilization of controlled substances, failed to obtain a thorough physical examination or rule out the existence of any recognized contraindications, and/or failed to discontinue the controlled substances when the patient did not lose weight.

Further, you failed to maintain medical records accurately reflecting an appropriate purpose for the utilization of controlled substance anorectics. You failed to consider the drugs' potential for abuse, the possibility that the patients were using the drugs for nontherapeutic purposes or the possibility that the drugs would be distributed to third parties.

- a) From 1978 until at least 1992 a physician/patient relationship existed between you and Patient 1 identified in the attached Patient Key (Key Confidential -- not for public disclosure). You prescribed Biphentamine, a schedule II controlled substance stimulant, to Patient 1 from 1978 until 1984. In 1985, you began prescribing Fastin and Tenuate, both schedule IV controlled substance stimulants, to Patient 1; this prescribing continued until at least 1992. At the time of her first visit in 1978, Patient 1 weighed one hundred twenty-one and one half pounds. At the time of her last recorded visit in 1992, she weighed one hundred thirty-seven pounds.

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- b) In or about 1977 you began prescribing Ionamin, Tenuate and Fastin, all schedule IV controlled substance stimulants, to Patient 2, identified in the attached Patient Key (Key Confidential – not for public disclosure). This prescribing continued until at least April 1992. In 1977 Patient 2 weighed one hundred eight pounds; at the time of her last recorded visit, April 23, 1992, she weighed one hundred twenty pounds.
- c) In or about 1983 you began prescribing Ionamin and Tenuate, both schedule IV controlled substance stimulants, to Patient 3, identified in the attached Patient Key (Key Confidential – not for public disclosure). This prescribing continued until at least July, 1991. In 1983 the patient weighed one hundred eighteen pounds; at the time of her last recorded visit, July 2, 1991, she weighed one hundred fifty-four and one-half pounds.

Your acts, conduct, and/or omissions committed after November 17, 1986 as alleged in paragraph (1) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: Rules 4731-11-02(A), (C) and (D), Ohio Administrative Code. Pursuant to paragraph (F) of Rule 4731-11-02, Ohio Administrative Code, a violation of any provision of this rule, as determined by the board, shall also constitute a violation of Sections 4731.22(B)(2) and (B)(6), Ohio Revised Code. A violation of paragraph (C) of this rule, if committed purposely, knowingly, or recklessly, as those words are defined in Section 2901.22 of the Revised Code, shall also constitute a violation of Section 4731.22(B)(3), Ohio Revised Code.

Further, your acts, conduct, and/or omissions committed after November 17, 1986 as alleged in paragraph (1) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: Rules 4731-11-04(A) and (B), Ohio Administrative Code. Pursuant to paragraph (C) of Rule 4731-11-04, Ohio Administrative Code, a violation of any provision of this rule, as determined by the board, shall also constitute a violation of Sections 4731.22(B)(2), (B)(3) and (B)(6), Ohio Revised Code.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty (30) days of the time of mailing of this notice.

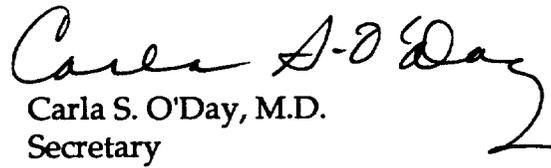
October 12, 1994

You are further advised that you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty (30) days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, suspend, refuse to register or reinstate your certificate to practice osteopathic medicine and surgery or to reprimand or place you on probation.

Copies of the applicable sections are enclosed for your information.

Very truly yours,


Carla S. O'Day, M.D.
Secretary

CSO:jmb

Enclosures:

CERTIFIED MAIL #P 348 885 470
RETURN RECEIPT REQUESTED