verified/es

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF :

:

DONALD C. ATKINS, D.O. :

ENTRY OF ORDER

On March 9, 1994, the State Medical Board issued a citation letter to Donald C. Atkins, D.O., alleging that he had inappropriately used synthroid in the course of treatment rendered to twenty four specified patients. Dr. Atkins requested a hearing, and such hearing was scheduled to convene on August 2, 1994. The Medical Board was subsequently notified of Dr. Atkins' death on June 27, 1994.

As a result of the foregoing, it is hereby ORDERED that the action against Dr. Atkins be declared MOOT and that this matter be and is hereby DISMISSED.

So ORDERED this 12th day of July, 1994.

Carla S. O'Day

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

7/12/94

Date

(SEAL)

Raymond J. Albert

Raymond J. Albert
Supervising Member

7/12/94

Date

STATE MEDICAL BOARD OF OHIO

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

March 9, 1994

Donald C. Atkins, D.O.
225 W. Washington Row
Sandusky, OH 44870

Dear Doctor Atkins:

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) On or about April 5, 1978, Patient 1, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), was diagnosed by you as being hypometabolic.

Lab data reported on April 11, 1978, indicated that the patient was euthyroid. In spite of that, you prescribed 100 mcg/day of Synthroid beginning on April 12, 1978, and by May 12, 1978, you were prescribing 300 mcg/day of Synthroid for the patient. During your fourteen (14) year treatment of the patient, she complained regularly of hot flashes, decreased menstrual flow and increased bowel movements. Despite these complaints you continued to prescribe greater dosages, to a high of 700 mcg/day in June of 1987. As of 1987, the recommended replacement dose of Synthroid was 1.6 mcg/kg/day. From June of 1987 through summer of 1989, you were prescribing Patient 1 an average replacement dose of 9.4 mcg/kg/day, nearly six times the average replacement dose for truly hypothyroid patients. Blood tests during the same timeframe and patient complaints noted in your patient records during that time indicated that the patient was clinically and chemically hyperthyroid. Your use of Synthroid on this patient was inappropriate and not indicated.

Mailed March 10, 1994

(2) On or about October 9, 1989, you prescribed 100 mcg/day of Synthroid to Patient 2, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), in the absence of appropriate testing. An EKG done on October 9, 1989, showed low voltage (most probably secondary to the patient's obesity), but also aberrant intraventricular conduction with sinus arrhythmia. Despite this report, you prescribed Synthroid to this patient.

Further, on October 13, 1989, lab data indicated that the patient was euthyroid. Both her TSH and free T_4 were within normal limits. Again, despite the lab report, you continued to prescribe Synthroid to the patient, and, in fact, you increased her dosages. A lab report in June of 1990 indicated that the patient was now hyperthyroid with a free T_4 of 5.3 (normal 1 to 4.3) and a suppressed TSH of .25 (normal .3 to 5.0). Despite these test results, you continued to prescribe Synthroid to the patient in sporadically higher dosages. In the summer of 1991, you diagnosed the patient as hypothyroid without further testing. After you had placed her on supraphysiologic doses of Synthroid, the patient had a pulse of greater than 90 on multiple visits. A condition such as aberrant intraventricular conduction with sinus arrhythmia is a contraindication for such supraphysiologic doses of Synthroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(3) On or about December 24, 1991, you signed a physical exam form for Patient 3, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure). This exam form indicated that Patient 3 had a normal thyroid gland. At that time, Patient 3 was 5 years old and weighed 31 pounds. On January 10, 1992, you diagnosed her as hypothyroid and you prescribed 100 mcg/day of Synthroid. Lab data from January 18, 1992, indicated that she was euthyroid. You continued to prescribe Synthroid, despite the lab report, and by March of 1992 she was taking 200 mcg/day. On October 1, 1992, your records indicated, for the first time, a "goiterous enlargement of the neck". Your use of Synthroid on this patient was inappropriate and not indicated.

(4) On or about February 11, 1992, Patient 4, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office with a history of heart disease and high blood pressure. Lab data reported on February 21, 1992, indicated that the patient was euthyroid with normal free T_4 index and normal TSH. At the time, Patient 4 was a 70 year old

female who weighed 213 pounds and was 5' 3 1/2" tall. On May 14, 1992, you noted that the patient was "losing weight too slowly", then you increased her dosage of Synthroid to 250 mcg per day and it was noted, "reason to lose weight". You again increased her dosage to 275 mcg/day and on June 12, 1992, it was noted, "lost weight with effort". The patient was on 3 mcg/kg/day of Synthroid, well above the 1.6 mcg/kg/day average replacement dose for truly hypothyroid patients. A compromised cardiac status is a contraindication for such supraphysiologic doses of Synthroid. On June 29, 1992, the patient suffered a myocardial infarction, cause and effect could not be ascertained. Your use of Synthroid on this patient was inappropriate and not indicated.

(5) On or about October 21, 1991, Patient 5, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented himself to your office with a basketball injury. On October 31, 1991, you diagnosed this 15 year old as hypometabolic. On December 12, 1991, you diagnosed him as hypothyroid and prescribed Synthroid. However, lab data from December 19, 1991, indicated that he was euthyroid. Despite that data, you increased his prescription to 250 mcg of Synthroid per day on January 10, 1992 and to 300 mcg/day on February 17, 1992. Your records indicated that the patient's stepfather thought the boy had become "hyper", and that the pharmacist at Wal-Mart had questioned the dosage. On February 26, 1992, the patient was receiving 5.5 mcg/kg/day which is approximately 3 to 4 times the replacement dose for truly hypothyroid patients. Your use of Synthroid on this patient was inappropriate and not indicated.

(6) On or about August 15, 1978, Patient 6, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office as a 58 year old female, 5'4" tall, and weighing 164 pounds. Lab data obtained at that time indicated that the patient was hypothyroid. Her TSH was 50 (normal 0 to 10) and her T_4 1.6 (normal 5.4 to 13.0). You began prescribing Synthroid to Patient 6. Based upon her weight, her recommended replacement dose of Synthroid in 1978 would have been between 150 mcg and 175 mcg daily. However, by September 26, 1978, you increased her dosage to 250 mcg/day. At that time, she indicated that she was having trouble writing. Despite this, you increased her dose on November 14, 1978, to 400 mcg/day, a dose which was clearly more than twice the replacement dose. You fluctuated her dosage between 300 and 350 mcg/day for a number of

months in 1979. Your records indicated that in August of 1979 the patient stated that her fingernails were weak and that her hair was falling out. In December of 1979 it was noted that she was "too shaky to write Christmas cards." These were signs consistent with chronic hyperthyrodism. Despite this, you continued her dosage and, in fact, you slowly increased it over the years, to 450 mcg/day in August of 1982. You continued this prescribing through 1986. During these years she complained of insomnia and problems dealing with heat. Also, lab data indicated that her T4 levels were now clearly hyperthyroid. Her prescription was decreased to 300 mcg/day, but by July 1990, you had her back up to 450 mcg of Synthroid per day. Despite patient complaints of chest fullness and pressure, you failed to treat her condition or refer her to another physician. Lab data from July of 1987, January of 1988, October of 1988, January of 1991 and September of 1992 indicated that the Patient's TSH was suppressed and her T4 levels were well above the normal range. At a dose of 450 mcg of Synthroid, she was on 3 to 4 times the normal replacement dose of Synthroid. Your use of Synthroid on this patient was inappropriate and excessive.

(7) On or about October 11, 1988, Patient 7, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office. At that time, Patient 7 was a 34 year old male, stood 5'9" and weighed 147 pounds. On October 18, 1988, you began prescribing Synthroid to the patient with no clinical correlation and no lab data. Lab data reported on October 23, 1988, indicated that the patient was euthyroid. Despite these test results, you continued prescribing Synthroid to the patient and by December of 1988 the dosage was up to 300 mcg of Synthroid per day. During this time, the patient had hallucinations, a symptom consistent with psychoses. Despite the fact that it is well known that hyperthyroidism may allow the development or expression of subclinical psychotic state, you continued to increase the patient's dosage of Synthroid into 1989. You began prescribing Haldol to the patient on December 16, 1988. Following the January 16, 1989, office visit there were no notes of any other office visits or prescriptions until July 20, 1989. It is noted that the patient was in the Toledo Mental Health Center for a portion of that time.

On September 1, 1989, you diagnosed the patient as hypothyroid, and began Synthroid treatment again. Lab data available September 8, 1989, indicated the patient was euthyroid. Despite the data, you continued prescribing Synthroid to the patient. By January of 1990 you had increased this prescription to 500 mcg/day. In 1990 when a

diagnosis of seminoma was made you lowered his dose to 150 mcg, prior to surgery in September 1990. Following surgery you again increased his dosage to a high of 450 mcg of Synthroid per day. Your use of Synthroid on this patient was inappropriate and not indicated.

(8) On or about January 11, 1990, Patient 8, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office with complaints of arthritis and hypertension. At the time, the patient was 64 years old, stood 5' 8", and weighed 198 pounds. You prescribed Synthroid to the patient despite laboratory tests which indicated normal thyroid function. His dosage was 150 mcg/day on March 1, 1990, when he was diagnosed with autoimmune thyroiditis and as hypothyroid. You continued the patient on Synthroid. Lab tests done in February of 1991 demonstrated that the patient was now hyperthyroid with a TSH of 0.1 (normal 0.5 to 6.0). A test done in October of 1991 indicated a TSH of 0.2 (normal 0.5 to 6.0). By July of 1992 you were prescribing 550 mcg/day of Synthroid to Patient 8, an average replacement dose of 6 mcg/kg/day, approximately 4 times the recommended dose for truly hypothyroid patients. Your use of Synthroid on this patient was inappropriate and not indicated.

(9) On or about October 9, 1987, Patient 9, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office complaining of stomach problems. At the time, the patient was 74 years old, 5' 8" tall and weighed 132 pounds. In January of 1989 you began prescribing Synthroid to the patient without making a diagnosis, and despite laboratory data which indicated that he was euthyroid. On October 20, 1989, Patient 9 complained of palpitations. In January of 1990 the diagnosis of hypothyroidism was noted. You decreased the dosage prior to the patient's surgery at Firelands Community Hospital in February of 1990. Records indicated that he was on no medications and was euthyroid at the time of his surgery.

Following surgery you again prescribed Synthroid at dosages reaching 300 mcg/day. Your records indicated that the patient developed heat intolerence, but you continued the medication. Laboratory data from November of 1991 indicated that the patient was chemically hyperthyroid with a free T_4 index of 5.1 (normal 1.3 to 4.7) and an undetectable TSH. A dose of 300 mcg/day is 4.9 mcg/kg/day, or 3 times the recommended replacement dose for truly hypothyroid patients. Your use of Synthroid on this patient was inappropriate and not indicated.

(10) On or about September 22, 1987, Patient 10, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office complaining of back pain. At that time, the patient was a 26 year old, stood 5' 4 1/2", and weighed 224 1/2 pounds. Your physical exam showed no evidence of hypothyroidism. Further, lab work done at that time indicated that the patient was euthyroid. Despite this, you diagnosed the patient as hypothyroid and you prescribed 100 mcg of Synthroid per day. Your patient records indicated that from April of 1989 to May of 1989 the patient complained of shaking, difficulty sleeping, sweats, feeling jumpy and scared, and of an inability to concentrate. During that time you increased her dosage of Synthroid to 400 mcg/day. By August of 1990, the patient was taking 500 mcg/day, 3 times the average replacement dose that is recommended for a truly hypothyroid person of her weight. Your use of Synthroid on this patient was inappropriate and not indicated.

(11) On or about September 30, 1976, Patient 11, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), first came to your office. At that time, Patient 11 was a 34 year old female, stood 5' 6", and weighed 182 pounds. Lab data available at that time indicated that the patient was euthyroid. On October 14, 1976, it was noted in your records that the patient "needs appetite suppressant". On October 28, 1976, it is noted "on 1 1/2 yellow Syn. for 1 week" and she was instructed to increase the dose to 2 and then 2 1/2, and to return in two weeks.

Patient 11 returned two years later, and, on October 19, 1978, you diagnosed her as hypometabolic. You again prescribed Synthroid to the patient despite lab data which indicated that she was euthyroid. On November 30, 1978, it was noted "needs hormone" and "thinks gaining weight" and you increased the dosage to 300 mcg of Synthroid per day. It was noted on December 18, 1978, that the patient couldn't sleep. On December 30, 1978, you increased the dosage to 500 mcg/day. By March of 1979 you had increased her dosage to 600 mcg of Synthroid per day, approximately three times the recommended replacement dose for truly hypothyroid patients. Your use of Synthroid on this patient was inappropriate and not indicated.

(12) On or about October 24, 1980, you diagnosed Patient 12, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), as hypothyroid and began prescribing Synthroid. However, lab data indicated that the patient was euthyroid. At that time, Patient 12 was 16 years old, stood 6' 2", weighed 304 pounds, and was diabetic. You increased his dosage of Synthroid through March 26, 1981, to 400 mcg/day. You conducted no follow-up lab data and no assessment of his thyroidal status. You fluctuated his daily dose of Synthroid between 250 mcg and 450 mcg over the next year. During 1984, you were constantly altering his dose of thyroid medication between a high of 500 mcg/day (January 5, 1984) and a low of 200 mcg/day (February 2, 1984). Your use of Synthroid on this patient was inappropriate and not indicated.

(13) On or about August 5, 1985, Patient 13, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office with a chief complaint of obesity. At that time the patient was 33 years old, 5' 2" and weighed 234 pounds. A lab report done at that time indicated that the patient was euthyroid. Despite this lab report, you prescribed Synthroid to the patient. By the end of September of 1985 you were prescribing 300 mcg/day of Synthroid. In October of 1992, without biochemical data, your records indicated that, for the first time, you diagnosed the patient's condition as "Hypothyroidism, Acq. - Clinical". Your use of Synthroid on this patient was inappropriate and not indicated.

(14) On or about January 7, 1987, Patient 14, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office as a 72 year old female, 4' 10" tall and weighing 127 pounds. Laboratory tests done in January of 1988 indicated that the patient was euthyroid. In spite of that, you prescribed and continued to prescribe Synthroid to Patient 14. By July 7, 1988, you were prescribing 300 mcg of Snythroid per day. On November 21, 1988, you diagnosed her as hypothyroid. You continued to prescribe 300 mcg/day of Synthroid to Patient 14 from 1989 through 1991. A lab report done on November 5, 1991, indicated that the patient had a suppressed TSH of 0.2 (normal 0.5 to 6.0), she was now hyperthyroid. Despite the lab report, you again diagnosed the patient as hypothyroid on November 14, 1991, December 17, 1991, and January 2, 1992. Your use of Synthroid on this patient was inappropriate and not indicated.

(15) On or about March 27, 1990, you diagnosed Patient 15, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), as being in a hypometabolic state. You then prescribed and continued to prescribe Synthroid to Patient 15 despite laboratory data which indicated that she was euthyroid. A blood test done in February of 1991 indicated that she was chemically hyperthyroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(16) On or about May 30, 1990, Patient 16, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office with complaints of nervousness and of weight gain of 30 pounds. At that time, Patient 16 was a 37 year old female, stood 5' 1 1/2", and weighed 142 pounds. You diagnosed her as hypothyroid on the first visit despite the lack of clinical evidence and laboratory data. You prescribed Synthroid to the patient on July 19, 1990. Lab data available a few days later indicated that the patient was euthyroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(17) On or about October 19, 1990, Patient 17, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office as a 59 year old female, standing 5 feet tall and weighing 235 pounds. Lab data done at that time indicated that she was euthyroid and your notes contained no evidence that she was hypothyroid. Nevertheless, you began prescribing Synthroid to Patient 17. On December 13, 1990, the patient was diagnosed as hypothyroid. On January 7, 1991, you increased her prescription to 250 mcg/day. On January 8, 1991, Patient 17 was seen in the emergency room for chest pain. On January 11, 1991, a 24 hour holter monitor was performed that showed sinus bradycardia and tachycardia. Four days later, you increased her dosage to 300 mcg of Synthroid per day and to 450 mcg on May 21, 1992. Your use of Synthroid on this patient was inappropriate and not indicated.

(18) On or about August 12, 1991, you prescribed 100 mcg/day of Synthroid to Patient 18, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), though laboratory data at that time indicated that she was euthyroid. At the time, Patient 18 was a 37 year old female, standing 5' 6", and weighing 234 pounds. You diagnosed this patient in September of 1991 as hypothyroid without clinical data to support that diagnosis. By November 9, 1991, you had increased her dosage to 400 mcg/day

with no follow-up laboratory work. It is noted in your records that her pulse was greater than 90 on multiple visits and that the patient complained that she did not sleep well at night. Despite this, you maintained the patient on Synthroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(19) On or about August 15, 1991, Patient 19, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office with a medical history of epilepsy. At that time, Patient 19 was a 31 year old female, stood 5' 4", and weighed 202 pounds. Lab data reported on August 29, 1991, indicated that she was euthyroid. On September 3, 1991, you prescribed 100 mcg/day of Synthroid to the patient despite this lab data. On September 13, 1991, you increased her dosage to 150 mcg of Synthroid per day. The patient complained of increased seizure activity on October 8, 1991, and you stopped prescribing Synthroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(20) On or about September 24, 1991, Patient 20, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), an 18 year old female, initially presented to your office. On September 30, 1991, you diagnosed the patient as hypothyroid and started her on Synthroid without correlation with clinical data. Laboratory data received shortly thereafter indicated that the patient was euthyroid. Despite these test results, you continued to prescribe Synthroid and, in fact, you increased the dosage. On January 2, 1992, your records indicated that the patient had stopped taking Synthroid because of a rash, and you advisedher to "get back on Synthroid today!!!". By February 12, 1992, you indicated that you were not sure if the patient was taking her medications. On June 15, 1992, you noted that she has an endocrine imbalance and that she was hypothyroid. Again, blood work done at that time indicated that the patient was euthyroid. For the first time, on September 23, 1992, you noted that the patient had a goitrous enlargement of the neck. Your use of Synthroid on this patient was inappropriate and not indicated.

(21) On or about December 4, 1991, Patient 21, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), presented to your office with the complaint of back pain. At that time, Patient 21 was a 43 year old male, stood 6' 4", and weighed 245 pounds. On December 6, 1991, you diagnosed him as hypothyroid without clinical correlation. Laboratory data available at the time indicated that he was euthyroid. Despite this lab data,

you began prescribing Synthroid to the patient on December 6, 1991. Your use of Synthroid on this patient was inappropriate and not indicated.

(22) On or about February 22, 1992, Patient 22, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office because of recurrent Bell's Palsy. At that time, Patient 22 was a 57 year old male, stood 5' 8", and weighed 208 pounds. You began prescribing Synthroid to the patient on April 18, 1992, despite lab data which indicated that the patient was euthyroid. On April 28, 1992, you diagnosed him as hypothyroid. Despite patient complaints, you told the patient that [he] "should stay on Synthroid". By July of 1992 you had increased his dosage to 550 mcg/day. Lab data from October of 1992 indicated that the patient was now hyperthyroid. Your use of Synthroid on this patient was inappropriate and not indicated.

(23) On or about February 25, 1992, Patient 23, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), initially presented to your office and you diagnosed her as hypothyroid. At that time Patient 23 was a 29 year old female, was 5' 1", and weighed 250 pounds. Laboratory data reported on March 3, 1992, indicated that the patient was euthyroid. Despite the lab data you prescribed Synthroid to the patient on March 10, 1992. By April 21, 1992, you were prescribing 200 mcg of Synthroid per day to the patient in the absence of appropriate data and the presence of complaints that the patient was not sleeping well. Your use of Synthroid on this patient was inappropriate and not indicated.

(24) On or about March 23, 1992, you prescribed Synthroid to Patient 24, who is identified on the attached Patient Key (Key Confidential--to be withheld from public disclosure), and, on March 26, 1992, you diagnosed this 66 year old female as hypothyroid. Her medical history included myocardial infarction and stable angina. A lab report issued on April 8, 1992, indicated that the patient was euthyroid. Despite the report, you continued to prescribe Synthroid and, in fact, you increased her dosage. Your use of Synthroid on this patient was inappropriate and not indicated.

Your acts, conduct, and/or omissions as alleged in paragraph (1) above, individually and/or collectively, constitute "failure to use reasonable care discrimination in the administration of drugs," and/or "failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraphs (1) through (24) above, individually and/or collectively constitute "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code, as in effect prior to March 15, 1993.

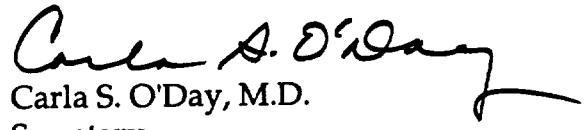
Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty (30) days of the time of mailing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

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 348 885 347
RETURN RECEIPT REQUESTED