



STATE MEDICAL BOARD OF OHIO

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

October 13, 1995

Ernest A. Lewandowski, D.O.
5706 Turney Road - Room 103
Derby Professional Building
Garfield Heights, Ohio 44125

Dear Doctor Lewandowski:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of Suzanne E. Kelly, 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 October 11, 1995, including Motions approving and confirming the Finding 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. Greter, M.D.

Secretary

TEG:em
Enclosures

CERTIFIED MAIL RECEIPT NO. P 741 124 522
RETURN RECEIPT REQUESTED

cc: Jeffrey L. Kocian, Esq.

CERTIFIED MAIL RECEIPT NO. P 741 124 523
RETURN RECEIPT REQUESTED

Mailed 10-26-95



STATE MEDICAL BOARD OF OHIO

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

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; attached copy of the Report and Recommendation of Suzanne E. Kelly, Esq., Attorney Hearing Examiner, State Medical Board; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on October 11, 1995, including Motions approving and confirming the Finding of Fact and Conclusions of Law of the Hearing Examiner, and adopting an amended Order; constitute a true and complete copy of the Findings and Order of the State Medical Board in the Matter of Ernest A. Lewandowski, D.O., as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.

A handwritten signature in cursive script, which appears to read "Thomas E. Gretter, M.D.", is written over a horizontal line.

Thomas E. Gretter, M.D.
Secretary

(SEAL)

10/17/95
Date



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

*

*

ERNEST A. LEWANDOWSKI, D.O..

*

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on the 11th day of October, 1995.

Upon the Report and Recommendation of Suzanne E. Kelly, 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 the certificate of Ernest A. Lewandowski, D.O., to practice osteopathic medicine and surgery in the State of Ohio shall be permanently REVOKED.

This Order shall become effective immediately upon mailing of notification of approval by the State Medical Board of Ohio.

Thomas E. Gretter, M.D.
Secretary

(SEAL)

10/17/95

Date

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**REPORT AND RECOMMENDATION
IN THE MATTER OF ERNEST A. LEWANDOWSKI, D.O.**

The Matter of Ernest A. Lewandowski, D.O., came on for hearing before Suzanne E. Kelly, Esq., Hearing Examiner for the State Medical Board of Ohio, on July 17, 1995.

INTRODUCTION

I. Basis for Hearing

A. By letter dated April 12, 1995 (State's Exhibit 1), the State Medical Board of Ohio notified Ernest A. Lewandowski, D.O., that it intended to determine whether to take disciplinary action against his certificate to practice osteopathic medicine and surgery in the State of Ohio based upon the following factual allegations:

1. Dr. Lewandowski utilized controlled substance anorectics in his treatment of Patients 1-14, who are identified in a Patient Key which shall be treated confidentially, without indicating the diagnosis and purpose for which the controlled substances were utilized. Dr. Lewandowski: (1) failed to comply with state regulations concerning the proper procedure for prescribing controlled substance anorectics in his treatment of Patients 1 through 14; (2) prescribed controlled substance anorectics to Patients 1, 2, 5, 7, 9, 13, and 14 who exhibited contraindications for the use of these drugs; (3) prescribed controlled substance analgesics, anxiolytics, hypnotics and/or benzodiazepines to Patients 1, 2, 9, and 13 without indicating a diagnosis and/or purpose; (4) prescribed controlled substance anorectics for inappropriate purposes to Patients 1, 5, 7, 9, 13, and 14; (5) inappropriately administered Human Chorionic Gonadotropin (HCG) to Patients 3, 4, 6, 10, and 11; (6) administered monthly estrogen injections to Patient 7 for a twenty-three month period without conducting appropriate examinations; (7) administered monthly injections of B12 without indication to Patients 7 and 11; and (8) prescribed diuretics to Patient 8 without indication.

The Board alleged that Dr. Lewandowski's acts, conduct, and/or omissions as alleged, individually, and/or collectively, constituted "[f]ailure 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)(6), Ohio Revised Code"; "(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),

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Ohio Revised Code," "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: 4731-11-02(D), 4731-11-04(B), 4731-11-04(B)(1), (2), (3), (5)(a), (5)(b), and 4731-11-04(C), Ohio Administrative Code."

Dr. Lewandowski was advised of his right to request a hearing in this matter.

- B. Jeffrey L. Kocian, Esq., submitted a written hearing request on behalf of Dr. Lewandowski on May 1, 1995. (State's Exhibit 2)

II. Appearances

- A. On behalf of the State of Ohio: Betty D. Montgomery, Attorney General, by Lili C. Kaczmarek, Assistant Attorney General.
- B. On behalf of the Respondent: Jeffrey L. Kocian, Esq.

EVIDENCE EXAMINED

I. Testimony Heard

- A. Presented by the State
Daniel E. Konold, D.O.
- B. Presented by the Respondent
Ernest A. Lewandowski, D.O.

II. Exhibits Examined

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

- A. Presented by the State
1. State's Exhibit 3: May 5, 1995 letter to Dr. Lewandowski from the Board advising that a hearing had been set for May 18, 1995, and further advising that the hearing had been postponed pursuant to Section 119.09, Ohio Revised Code.
 2. State's Exhibit 4: May 10, 1995 letter to Dr. Lewandowski from the Board scheduling the hearing for July 17 through July 20, 1995. (2 pp.)

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3. State's Exhibit 5: Curriculum vitae of Daniel E. Konold, D.O. (3 pp.)
4. State's Exhibit 6: 4731-11-02, Ohio Administrative Code Section, General Provisions. (2 pp.)
5. State's Exhibit 7: 4731-11-04, Ohio Administrative Code Section, Controlled Substances: Utilization for Weight Reduction. (2 pp.)
- * 6. State's Exhibit 8A: Patient records for Patient 1. (108 pp.)
- * 7. State's Exhibit 8B: Patient records for Patient 2. (159 pp.)
- * 8. State's Exhibit 8C: Patient records for Patient 3. (39 pp.)
- * 9. State's Exhibit 8D: Patient records for Patient 4. (43 pp.)
- *10. State's Exhibit 8E: Patient records for Patient 5. (47 pp.)
- *11. State's Exhibit 8F: Patient records for Patient 6. (17 pp.)
- *12. State's Exhibit 8G: Patient records for Patient 7. (42 pp.)
- *13. State's Exhibit 9A: Patient records for Patient 8. (9 pp.).
- *14. State's Exhibit 9B: Patient records for Patient 9. (77 pp.)
- *15. State's Exhibit 9C: Patient records for Patient 10. (49 pp.)
- *16. State's Exhibit 9D: Patient records for Patient 11. (8 pp.)
- *17. State's Exhibit 9E: Patient records for Patient 12. (6 pp.)
- *18. State's Exhibit 9F: Patient records for Patient 13. (99 pp.)
- *19. State's Exhibit 9G: Patient records for Patient 14. (95 pp.)
20. State's Exhibit 10: Physicians' Desk Reference (PDR), 48th Ed., 1994, entries for: Adipex-P, Prelu-2, Ionamin, and Profasi. (8 pp.)

NOTE: THOSE EXHIBITS MARKED WITH AN ASTERISK (*) HAVE BEEN SEALED TO PROTECT PATIENT CONFIDENTIALITY AND IDENTITY.

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B. Presented by the Respondent

1. Respondent's Exhibit A: July 11, 1995 letter to the Assistant Attorney General from Jeffrey L. Kocian, Esq., regarding Dr. Lewandowski. Attached to this letter are: a statement from Dr. Lewandowski; an article by Bray, "Treatment For Obesity Must Be Continual," *Modern Medicine*, Vol. 63, April 1995; and an article by Tucker, "Fighting a Chronic Disease One Pound at a Time," *Family Practice News*, May 1, 1995. (18 pp.)

III. Post-Hearing Admissions to the Record

- A. The hearing record in this Matter closed on July 17, 1995. On August 3, 1995, Dr. Lewandowski submitted a letter with attachments. The Assistant Attorney General did not object to the admission of the documents, but did note that she had not had the opportunity to cross-examine the authors. Accordingly, this document is admitted as Respondent's Exhibit B.

Respondent's Exhibit B: July 27, 1995 letter to the Board from Dr. Lewandowski. Attached to this letter are articles by Browder, "Can Diet Pills Make You Thin?," *Woman's Day*, April 25, 1995; and by Weintraub, "Long Term Weight Control," *Clinical Pharmacol. Ther.*, May 1992. (16 pp.)

- B. Board Exhibit 1: Physicians' Desk Reference (PDR), 37th Ed., 1983, entry for: Profasi. (2 pp.)

PROCEDURAL MATTERS

1. All transcripts of testimony and exhibits, regardless of whether referred to in this Report and Recommendation, were thoroughly reviewed and considered by the Attorney Hearing Examiner prior to preparing this Report and Recommendation.
2. Dr. Lewandowski explained his notations in the medical records regarding prescriptions. A notation of one Phen-tab, one Ionamin or one Adipex means a two week supply of pills. Two of any kind of controlled substance anorectic means a four week supply. (Transcript [Tr.] 20-21, 64-65)
3. Although Dr. Lewandowski retained counsel, he appeared at the hearing alone. The Hearing Examiner explained Dr. Lewandowski's rights. After the state's expert reviewed two patients, Dr. Lewandowski requested that he be allowed to present his statement. The Assistant Attorney General did not object. After his statement, Dr. Lewandowski answered questions from the Assistant Attorney General and the Hearing Examiner. He then waived his

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right to continue listening to the state's case against him, and left the hearing.
(Tr. 56-71)

SUMMARY OF EVIDENCE

Ernest A. Lewandowski, D.O.

1. Ernest A. Lewandowski, D.O., graduated from Kansas City College of Osteopathic Medicine in 1953. He completed an internship at Cuyahoga Community Hospital in Akron, Ohio. Dr. Lewandowski earned his board certification in family practice in 1975. He maintained a family practice until he sold his practice and retired in July 1994. He currently treats only very close friends and his immediate family. (Tr. 62, 68-69)

Daniel E. Konold, D.O.

1. Daniel E. Konold, D.O., testified as an expert on behalf of the State. He graduated from the Ohio University College of Osteopathic Medicine. Dr. Konold completed an internship at Doctor's Hospital in June 1989, and a residency at the same hospital in July 1991. He works as a family physician at Whitehall-Bexley Family Medicine Inc. He earned his board certification from the American College of Osteopathic Family Physicians in 1991. Dr. Konold is a regional site instructor for the Ohio University College of Osteopathic Medicine in family practice, an air traffic medical examiner, and the team physician for a local high school. (State's Exhibit 5 [St. Ex.] Tr. 13-15)

Properties of Controlled Substances

1. The following controlled substance anorectics are sympathomimetic amines with pharmacological activity similar to the amphetamines: Adipex, phentermine hydrochloride; Prelu-2, phendimetrazine tartrate; and Ionamin, phentermine resin. They are schedule IV controlled substances, and are contraindicated for use in patients who have advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension or a history of drug abuse. Controlled substance anorectics are indicated in the management of exogenous obesity and as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restrictions. (St. Ex. 10)
2. Profasi (HCG) - chorionic gonadotropin is a polypeptide hormone produced by the human placenta. The Physician's Desk Reference states in bold type: "HCG HAS NOT BEEN DEMONSTRATED TO BE EFFECTIVE ADJUNCTIVE THERAPY IN THE TREATMENT OF OBESITY. THERE IS NO SUBSTANTIAL EVIDENCE THAT IT INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION. THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT

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ASSOCIATED WITH CALORIE-RESTRICTED DIETS." This warning appeared as early as 1983. (St. Ex. 10; Board Exhibit 1)

The Regulations

1. On November 17, 1986, regulations governing the prescription of controlled substances, including anorectics became effective. The regulations require a physician to complete and maintain accurate medical records which indicate the diagnosis and purpose for the use of the controlled substance. For controlled substance anorectics the regulations require the physician make an effort to determine if the patient made a good faith effort to lose weight before initiating treatment. The physician must obtain a thorough history, perform a physical examination and rule out the existence of any recognized contraindications before initiating treatment. The physician may not use a controlled substance when he knows or has reason to believe that a recognized contraindication to its use exists. Further, the physician shall not initiate or shall discontinue utilizing the controlled substances anorectics immediately if the patient has failed to lose weight over a period of fourteen days; if the patient has developed a tolerance; or if the patient has a history or propensity for alcohol or drug abuse. (St. Ex. 6 & 7)

Patient Summaries

Patient 1

1. Patient 1, a male born December 22, 1925, began seeing Dr. Lewandowski on May 4, 1973. (St. Ex., p. 3) On Patient 1's first visit, the records reflect no physical examination. Patient 1 developed systolic hypertension in February 1976. (St. Ex. 8A, p. 5, 101) A 1988 hospitalization discharge summary listed the following medical history for Patient 1: "Primary diagnosis: Ischemic ulcers of lower extremities. Secondary diagnosis: severe peripheral vascular disease; hypertension; and coronary artery disease." (St. Ex. 8A, p. 71; Tr. 41) In October 1988, Patient 1's right great toe was amputated due to arteriosclerosis obliterans and gangrene. (St. Ex. 8A, p 59, 62-63)
2. Although the medical records never indicated that Patient 1 was obese, or any other relevant diagnosis, Dr. Lewandowski prescribed controlled substance anorectics for Patient 1 from January 8, 1974 through July 1993. The records do not indicate Patient 1's height or dietary regime. The first time Dr. Lewandowski recorded Patient 1's weight is August 3, 1976, when Patient 1 weighed 162 pounds. Thereafter, Dr. Lewandowski weighed him only sporadically until April 12, 1983. (St. Ex. 8A, pp. 3-30)
3. From November 1986, Dr. Lewandowski did not document that he conducted a physical examination of Patient 1. (St. Ex. 8A, p. 20)

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4. Since November 1986 until August 1993, Patient 1 visited Dr. Lewandowski eighty-seven times for weight control. On fourteen visits Patient 1 failed to lose weight. (St. Ex. 8A, p. 21, 23-26, 27-29; Tr. 30-31)
5. Although Dr. Lewandowski did not keep an accurate record of Patient 1's weight, he regularly prescribed more than the recommended dosage of controlled substance anorectics to Patient 1. Dr. Lewandowski often prescribed a four, six, or eight week supply of controlled substance anorectics. (St. Ex. 8A, p. 21-26)
6. On March 1993, the last time a weight is recorded, Patient 1 weighed 163, 12 pounds less than he weighed the first time a weight was recorded. (St. Ex. 8A, p. 7, 29) However, Patient 1's weight fluctuated from 150 to 192 pounds throughout the time that he took controlled substance anorectics. (St. Ex. 8A, p. 18, 20)
7. The only indication that weight control advice was provided is a single conclusory note that a weight reduction sheet was given to Patient 1. (St. Ex. 8A, p. 21)
8. Dr. Lewandowski prescribed controlled substance anorectics to Patient 1 for inappropriate purposes and in the face of contraindications. In October 1992, June, July, and August 1993, Dr. Lewandowski prescribed "Phen-tabs" for "fatigue." (St. Ex. 8A, p. 28, 30) Fatigue is not an indicated usage for controlled substance anorectics. (St. Ex. 10; Tr. 36-37) In fact, "fatigue can be a side effect of rebound from the use of controlled substance anorectics." (Tr. 143)
9. From January 1974 through August 1993, Patient 1 consistently exhibited hypertension which is a contraindication for the use of controlled substance anorectics. (St. Ex. 8A, p. 5, 101; Tr. 24)
10. Beginning in March 1989, Dr. Lewandowski began prescribing Tylox, a schedule II controlled substance analgesic to Patient 1 without indicating the diagnosis or purpose for which the controlled substance was utilized. Dr. Konold testified that Tylox is typically prescribed for severe pain. (Tr. 33) However, his review of the records failed to reveal a contemporaneous injury or illness which would require Tylox. (Tr. 33) Dr. Lewandowski stated that he prescribed Tylox for great toe gangrene. (Respondent's Exhibit A [Res. Ex.], p. 5)

From March until October 1989, he prescribed 345 units of Tylox. In August and December 1990, Dr. Lewandowski prescribed a total of two hundred units of Tylox without indicating the purpose and diagnosis for it. Beginning in May 1991, Dr. Lewandowski began prescribing Tylox monthly to Patient 1. From May 1991 through June 1992, Dr. Lewandowski prescribed 1400 units of Tylox. On June 16, 1992, Patient 1's records note "No more Tylox!" Dr. Lewandowski

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stated that he decided to use a lower strength analgesic. (St. Ex. 8A, p. 22-27; Res. Ex. A, p. 5; Tr. 34-35)

9. In April 1993, Dr. Lewandowski prescribed Valium, a schedule IV controlled substance benzodiazepine, to Patient 1 without indicating the diagnosis and purpose for which it was used. (St. Ex. 8A, p. 29; Tr. 35-36)

Patient 2

1. Patient 2, a female born on July 9, 1937, began seeing Dr. Lewandowski on October 10, 1959. Her first recorded weight is 147 1/4 pounds on October 22, 1959. No height is indicated anywhere in the records. (St. Ex. 8B, p. 2)
2. Beginning in March 1973, Dr. Lewandowski prescribed Quaaludes. The records contain no indication of the purpose for this prescription. Over a period of three and a half years, Dr. Lewandowski prescribed Quaaludes twenty-eight times. (St. Ex. 8B, p. 9-13) On October 3, 1977, Patient 2 overdosed on Quaaludes. The emergency room indicated that she took nine pills prescribed by Dr. Lewandowski. (St. Ex. 8B, p. 124-130; Tr. 42-43) Her discharge summary directed Patient 2 to be seen in Dr. Lewandowski's office within one week. (St. Ex. 8B, p. 130; Tr. 43) However, the next appointment recorded is a month after the overdose and makes no mention of any treatment or investigation into the cause for the overdose. (St. Ex. 8B, p. 13) Dr. Lewandowski stated that Patient 2 was overwrought about her 1977 divorce and was making a call for help. (Res. Ex. A, p. 5; Tr. 63-64)

Seven years after Patient 2's overdose, Dr. Lewandowski again began prescribing controlled substances to Patient 2. These included: Demerol, a schedule II controlled substance analgesic; Fiorinal No. 3, a schedule IV controlled substance analgesic; Ativan, a schedule IV controlled substance anxiolytic; and Doral, a schedule IV controlled substance hypnotic. At no time did Dr. Lewandowski record a diagnosis to justify the use of these drugs. The only indication is a June 15, 1993, notation "for sleep." However, there is no information concerning the duration of Patient 2's problem, or a determination of the cause for her complaint. (St. Ex. 8B, pp. 20-22, 27, 33-34; Tr. 50-52)

3. Despite Patient 2's overdose, Dr. Lewandowski continued prescribing controlled substance anorectics to her through June 1993. Moreover, the only indication that Dr. Lewandowski discussed a weight reduction program with Patient 2 is a reference to a weight reduction sheet noted on June 28, 1988. The records are devoid of the results of a thorough physical and medical history for Patient 2. (St. Ex. 8B, pp. 9-34; Tr. 43, 45)
4. On eighteen separate occasions Patient 2 gained weight or failed to lose weight while taking controlled substance anorectics. On several of those occasions, Dr. Lewandowski prescribed more than the recommended dosage of controlled substance anorectics. (St. Ex. 8B, pp. 23-34; Tr. 45-48)

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5. After November 1986, Patient 2's weight fluctuated between 141 and 177 pounds. (St. Ex. 8B, pp. 23, 31)

Patient 3

1. Patient 3, a female, was 31 years old when she first visited Dr. Lewandowski in February, 1971. No date of birth or height appears in the record. She weighed 154 pounds, and her optimum weight is listed as 135 pounds. The records indicate that Patient 3 suffered from hypertension and asthma. (St. Ex. 8C, pp. 3, 12; Tr. 74-75)
2. From November 17, 1986 through August 1994, Dr. Lewandowski prescribed controlled substance anorectics in the treatment of Patient 3 without indicating the diagnosis and purpose for which they were utilized. There is no indication of the degree to which Patient 3 was overweight. There is no record of Patient 3 attempting weight reduction through means other than controlled substance anorectics. The records are devoid of the results of any thorough physical examination.
3. On thirty-eight separate occasions between March 1987 and August 1994, Patient 3 failed to lose weight. Throughout this period her weight fluctuated from 138 to 163 pounds. (St. Ex. 8C, pp. 22-38; Tr. 46-48) Nevertheless, Dr. Lewandowski continually prescribed controlled substance anorectics. In fact, Dr. Lewandowski often prescribed more than the recommended dosage. (St. Ex. 8C, pp. 21-23, 27, 30-31, 33, 36, 38-39; Tr. 46-48)
4. Beginning on or about October 24, 1989, when Patient 3 was 49 years old, Dr. Lewandowski administered HCG without indication. From August 17, 1993, through August 1994, Dr. Lewandowski administered HCG to Patient 3 on twenty-one visits. (St. Ex. 8C, pp. 26, 35-39)

In women, human chorionic gonadotropin (HCG) is indicated for the induction of ovulation or pregnancy. (St. Ex. 10; Tr. 79) Dr. Lewandowski asserted that: "I know that chorionic gonadotropin injections have not been demonstrated to have an effect on obesity, yet its alpha sub-unit resembles TSH and I know in my practice it has made a difference in reducing weight." In support of his defense, Dr. Lewandowski pointed out that amitriptyline, which is not "book indicated," is used for treating certain neuropathies. Therefore, although HCG is not indicated for weight loss, its use is not contraindicated. (Res. Ex. 8C, p. 4)

Dr. Konold testified that HCG was not indicated as an adjunct to weight loss. (Tr. 79-81) The PDR entry for HCG states unequivocally that HCG is not intended for weight loss: "HCG HAS NOT BEEN DEMONSTRATED TO BE EFFECTIVE ADJUNCTIVE THERAPY IN THE TREATMENT OF OBESITY. THERE IS NO SUBSTANTIAL EVIDENCE THAT IT INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION. THAT

IT CAUSES A MORE ATTRACTIVE OR 'NORMAL' DISTRIBUTION OF FAT,
OR THAT IT DECREASES THE HUNGER AND DISCOMFORT
ASSOCIATED WITH CALORIE-RESTRICTED DIETS." (St. Ex. 10; Tr. 79)
(emphasis in original)

Patient 4

1. Dr. Lewandowski saw Patient 4, a 38 year old female, for the first time on December 8, 1969. She weighed 136 pounds. No height is recorded. (St. Ex. 8D, p. 2-3) The significant medical history for Patient 4 includes obesity and menopausal syndrome. (St. Ex. 8D, p. 22) From on or about February 21, 1973 through July 1994, Dr. Lewandowski regularly utilized controlled substance anorectics in his treatment of Patient 4.
2. From November 1986 through July 1994, there is no indication of the purpose for the use of controlled substance anorectics. Because no height is noted in the patient records, it is impossible to determine if Patient 4 suffered from exogenous obesity. There is no evidence in the record that Patient 4 attempted to lose weight through other means prior to using controlled substance anorectics. Dr. Lewandowski did not perform a physical examination or order laboratory tests to determine whether Patient 4 exhibited any recognized contraindications before initiating treatment.
3. Out of 135 visits from November 1986 through July 1994, Patient 4 failed to lose weight on fifty-seven visits. Patient 4's weight fluctuated between 141 and 182 pounds. (St. Ex. 8D, p. 26, 37) During this period, Dr. Lewandowski's prescribing of controlled substance anorectics exceeded the recommended dosage of controlled substance anorectics by frequently prescribing a four week supply. (St. Ex. 8D, pp. 26-27, 31-37, 40-42).
4. Beginning on March 4, 1994, Dr. Lewandowski injected Patient 4 with HCG on six consecutive visits. At the time Patient 4 was 62 years old. The records contain no indication for the administration of HCG. (St. Ex. 8D, pp. 40-42)

Patient 5

1. Patient 5 visited Dr. Lewandowski for the first time in August 1973. She was 39 years old and weighed 137 1/2 pounds. No height is noted in the records. Patient 5's medical history includes elevated diastolic blood pressure, acute lumbosacral strain, nervousness, insomnia, and kidney stone. (St. Ex. 8E, p. 4; Tr. 89-90)
2. Since November 1986 there is no indication of the purpose for using controlled substance anorectics. Because no height is noted in the patient records, it is impossible to determine if Patient 5 suffered from exogenous obesity. There is no evidence in the record that Patient 5 attempted to lose weight through other means prior to using controlled substance anorectics. Dr. Lewandowski did not

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perform a physical examination or order laboratory tests to determine whether Patient 5 exhibited any recognized contraindications before initiating treatment. (St. Ex. 8E, p. 27; Tr. 90-91)

3. Dr. Lewandowski utilized controlled substance anorectics in his treatment of Patient 5 on a regular basis from on or about September 6, 1973, through August 1994. (St. Ex. 8E pp. 4-47) From December 1986 through August 1994, Patient 5 received controlled substance anorectics on ninety visits. Dr. Lewandowski prescribed more than the recommended dosage on sixty-one of those visits. Patient 5 failed to lose weight on thirty-three visits, and Dr. Lewandowski failed to weigh Patient 5 on thirteen visits. Patient 5's weight fluctuated between 134 and 167 pounds. In spite of Patient 5's failure to lose weight consistently, Dr. Lewandowski continued to prescribe controlled substance anorectics. (St. Ex. 8E, pp. 26-47)
4. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics. (St. Ex. 10; Tr. 92-93) Patient 5 initially presented in 1973 with elevated diastolic pressures. (Tr. 89) During January, March, June and November 1991, Patient 5's diastolic readings were elevated at 100. Despite such elevated readings Dr. Lewandowski continued to dispense controlled substance anorectics, and increased the dosage on October 3, 1991. (St. Ex. 8E, pp. 37-38; Tr. 92-93)
5. On May 24, 1994, Dr. Lewandowski prescribed "Adipex for energy." This is not an appropriate use for controlled substance anorectics. (St. Ex. 8E, p. 45; St. Ex. 10; Tr. 93, 95)

Patient 6

1. Patient 6 visited Dr. Lewandowski for the first time in April 1976. She was 21 years old and weighed 135 pounds. No height is noted in the records. Patient 6's records do not reflect that Dr. Lewandowski took a medical history or performed a physical examination. Dr. Konold described Patient 6's records as "scant at best." (St. Ex. 8E, p. 4; Tr. 96)
2. From April 6, 1976, through August 1994, Patient 6 received controlled substance anorectics on a regular basis. From November 1986 through August 1994, Patient 6 visited Dr. Lewandowski one hundred and seven times for weight control. Patient 6 failed to lose weight on forty-seven of those visits. (St. Ex. 8E, pp. 7-17) Although she was not always weighed, Patient 6's weight fluctuated between 135 and 170 pounds. (St. Ex. 8E, pp. 9, 16) Rather than discontinue the controlled substance anorectics, Dr. Lewandowski exceeded the recommended dosage on twelve occasions. (St. Ex. 8E, pp. 7, 13-14; St. Ex. 10; Tr. 96-99)

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3. On six occasions, Dr. Lewandowski injected Patient 6 with HCG. The records contain no indication for the administration of HCG. (St. Ex. 8E, pp. 13 16-17; Tr. 99)

Patient 7

1. Patient 7, a female aged 48, visited Dr. Lewandowski for the first time in January 1973. (St. Ex. 8G, p. 4) Patient 7 received controlled substance anorectics on a regular basis from October 16, 1973 through August 1994. (St. Ex. 8G, pp. 3-40) Nevertheless no weight is recorded for Patient 7 until August 3, 1976 at which time she weighed 134 1/2 pounds. (St. Ex. 8G, p. 6; Tr. 102-03) The first recorded height is 5'3 1/2" on October 6, 1992. (St. Ex. 8G, p. 34) Patient 7's records do not reflect that Dr. Lewandowski conducted a physical examination or medical history prior to prescribing controlled substance anorectics. (Tr. 104) Dr. Konold identified the following significant medical history for Patient 7: significant hypertension, menopause, arthritis and fatigue. (Tr. 101) There is no evidence in the record that Patient 7 attempted to lose weight through any other method than controlled substance anorectics. The chart contains bare references to diet sheets, weight reduction sheets and "exercise stressed." (St. Ex. 8G, pp. 20, 23, 40)
2. From November 1986 through August 1994, Patient 7 visited Dr. Lewandowski 183 times for controlled substance anorectics. (St. Ex. 8G, pp. 20-40) Patient 7 failed to lose weight on seventy-four of those visits. On nineteen visits she was not weighed. Rather than discontinue the controlled substance anorectics, Dr. Lewandowski exceeded the recommended dosage on twenty-three occasions. (St. Ex. 8G, pp. 20-36, 38-40; St. Ex. 10; Tr. 103-105; 108)
3. Dr. Lewandowski prescribed controlled substance anorectics even though Patient 7's records reflect evidence of and treatment for hypertension. (St. Ex. 8G, pp. 29, 32, 34; Tr. 105-106) Dr. Lewandowski also prescribed controlled substance anorectics for fatigue. (St. Ex. 8G, pp. 33, 38) Fatigue is not a recognized indication. (St. Ex. 10; Tr. 106)
4. Dr. Lewandowski administered monthly estrogen injections to Patient 7 from July 16, 1991 through May 25, 1993 without conducting appropriate examinations such as breast exams, mammograms, pap smears, pelvic exams, or screening for possible estrogen sensitive tumors. There is no documentation of a purpose for estrogen injections. The records indicate that Patient 7 was menopausal, but do not note symptoms or problems related to her status. (St. Ex. 8G, pp. 30-35; Tr. 106-07) Dr. Lewandowski asserted that Patient 7 saw another doctor for gynecological examinations. (Res. Ex. A, p. 8) However, there is no documentation that Dr. Lewandowski received test results from the other doctor.
5. Dr. Lewandowski also administered monthly injections of B12 to Patient 7 without indication. Dr. Konold stated that B12 should be administered only to

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patients who cannot absorb vitamin B or who have megaloblastic anemia. (Tr. 108) There is no indication in the record that Patient 7 suffered from either of these conditions. Dr. Lewandowski gave the following explanation for prescribing B12: "I have been using vitamin B12 since 1954 with good results I'm looking for. I explain to each pt. to whom I give B12, that it is not truly indicated for their specific problem, but I have had good results in its use." (Res. Ex. A, p. 8)

Patient 8

1. Patient 8, a female aged 33, visited Dr. Lewandowski for the first time in May 2, 1988, and received controlled substance anorectics. Patient 8 weighed 130 1/2 pounds and stood 5'5" tall. (St. Ex. 9A, p. 2; Tr. 109) Dr. Konold stated that if Patient 8 had a medium frame then she was only five pounds overweight. Controlled substance anorectics are not indicated for a patient who was only five pounds overweight. (St. Ex. 10; Tr. 110) Dr. Lewandowski stated "People today for many various reasons are weight conscious even if they are only 10 pounds overweight. If they say all else has failed and request medication, I give them some, but with the same admonishment concerning diet, etc." (Res. Ex. A, pp. 8-9)

Patient 8's records do not reflect that Dr. Lewandowski conducted a physical examination or took a medical history prior to prescribing controlled substance anorectics. There is no evidence in the record that Patient 8 attempted to lose weight through any other method than controlled substance anorectics. Dr. Konold identified no significant medical history for Patient 8. (Tr. 110)

2. Patient 8 received controlled substances anorectics on a regular basis from May 2, 1988, through April, 1989, and from April, 1990, through July, 1993. From May 2, 1988 through April 1989, Patient 8's weight fluctuated between 116 and 128 1/4 pounds. (St. Ex. 8A, p. 3) Patient 8 did not visit Dr. Lewandowski from April 1989 through April 1990, and weighed 184 1/2 pounds when she returned. Dr. Lewandowski resumed prescribing controlled substance anorectics and continued through July 1993. (St. Ex. 9A, pp. 4-9) During this time, Patient 8's weight fluctuated between 125 and 139 pounds. (St. Ex. 9A, pp. 6, 8) Although from April 1990 through January 1991, Patient 8's weight dropped steadily, Dr. Lewandowski began prescribing two kinds of controlled substance anorectics in April 1990 through March 1992. (St. Ex. 9A, pp. 4-7)
3. On April 10, 1990, with a blood pressure reading of 122/70, Dr. Lewandowski prescribed Lozol, a diuretic, to Patient 8. (St. Ex. 9A, p. 4) On July 17, October 9, 1990, April 9, 1991, and October 29, 1991, Patient 8 received HydroDIURIL, another diuretic. (St. Ex. 9A, pp. 4, 5 6) On April 26, 1992, and April 13, 1993, Dr. Lewandowski prescribed Hydrochlorothiazide, yet another diuretic, to Patient 8. (St. Ex. 9A, pp. 7, 8) Dr. Konold testified that Patient 8 had normal blood pressure and that he found nothing in the records to justify the prescription of diuretics. (Tr. 112-115) Dr. Lewandowski asserted

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that he prescribed the diuretics to alleviate premenstrual water retention.
(Res. Ex. A, p. 9)

Patient 9

1. Patient 9, was 35 years old when she began seeing Dr. Lewandowski on August 12, 1957. (St. Ex. 9B, p. 4) On November 1, 1958, Patient 9 was 5'4" tall and weighed 137 1/2 pounds. (St. Ex. 9B, p. 4) Dr. Konold detailed her medical history from Patient 9's initial visit through August 1994: significant pharyngitis, interstitial disease, vulvar mass, urinary tract infection, arthritis, bursitis, osteopenia, anemia, COPD, pneumonia, and hypertension. (St. Ex. 9B, pp. 4-31, 62; Tr. 116-117)
2. Patient 9 received controlled substance anorectics on a regular basis from April 10, 1989 through June 1994. (St. Ex. 9B, p. 16-30) There is no notation that Dr. Lewandowski conducted a physical examination or reviewed her medical history to ascertain whether contraindications to the use of controlled substance anorectics existed. (Tr. 118) The records contain no information concerning Patient 9's efforts to lose weight by other means. From April 10, 1989 through June 1994, Patient 9 visited Dr. Lewandowski forty-four times for controlled substance anorectics. Patient 9 failed to lose weight on twelve of those visits, and was not weighed on seven visits. Rather than discontinue the controlled substance anorectics, Dr. Lewandowski exceeded the recommended dosage on thirty-five occasions. (St. Ex. 9B, p. 17-26, 29-30; St. Ex. 10; Tr. 119, 122) Patient 9's weight fluctuated from 134 to 155 pounds throughout the time she took controlled substance anorectics.
3. Dr. Lewandowski prescribed controlled substance anorectics even though Patient 9's records reflect evidence of and treatment for hypertension. (St. Ex. 9B, p. 14, 59, 62; Tr. 117, 120, 122) Dr. Lewandowski also prescribed controlled substance anorectics for fatigue. (St. Ex. 9B, p. 23) Fatigue is not a recognized indication. (St. Ex. 10; Tr. 121-122)
4. Dr. Lewandowski prescribed controlled substances without indicating the diagnosis and purpose for which they were used. On seven occasions Dr. Lewandowski prescribed Darvocet N 100, often with five refills. On five occasions, Dr. Lewandowski prescribed Valium 5 mg. with five refills. (St. Ex. 9B, p. 13-23; Tr. 120, 122). The only notes in the records which explain this prescribing are a note on May 26, 1992 which states "sore back (low) Darvocet not helping," and a note on the following visit, "also c/o vaginal pain that goes away (with) Valium." (St. Ex. 9B, p. 21; Tr. 120, 122)

Patient 10

1. Patient 10 was 41 years old at the time of her first visit to Dr. Lewandowski on February 5, 1968. She weighed 121 1/2 pounds. There is no indication of her height. (St. Ex. 9C, p. 4) Dr. Konold described Patient 10's medical history:

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three pregnancies with three children, anxiety, depression, cystocele and hyperlipemia. (Tr. 123)

2. Patient 10 began taking controlled substance anorectics on a regular basis from February 12, 1973, through July 1994. (St. Ex. 9C, pp. 10-42) Patient 10 took controlled substance anorectics on a monthly basis for the next five years, and then intermittently through her last visit in July 1994. (St. Ex. 9C, p. 10-42; Tr. 123-24) Throughout her treatment with controlled substance anorectics, Patient 10's weight fluctuated between 101 pounds and 126 1/2 pounds. (St. Ex. 9C, p. 13, 38)
3. Dr. Lewandowski did not document a physical examination or a medical history for Patient 10. The records contain no information concerning Patient 10's efforts to lose weight by other means. (St. Ex. 9C, p. 28) There is no indication in the record why Dr. Lewandowski prescribed controlled substance anorectics to Patient 10.

Dr. Konold found no justification for prescribing these drugs to Patient 10 who weighed 109 pounds in August 1986. (Tr. 125) Dr. Lewandowski prescribed a ten week supply to her at that time. (St. Ex. 9C, p. 28) Dr. Lewandowski again prescribed a ten week supply in December 1986. (St. Ex. 9C, p. 28; Tr. 125) From December 1986 through July, 1994, Patient 10 visited Dr. Lewandowski ninety-seven times for controlled substance anorectics. (St. Ex. 9C, p. 10-41) Patient 10 failed to lose weight on forty-nine of those visits, (St. Ex. 9C, p. 28-30, 31-42; Tr. 125-26), and was not weighed on three visits, (St. Ex. 9C, p. 30, 37). Rather than discontinue the controlled substance anorectics, Dr. Lewandowski exceeded the recommended dosage on thirty occasions. (St. Ex. 9C, p. 35-38, 40-42; St. Ex. 10; Tr. 125-126)

4. On November 16, 1993, Dr. Lewandowski injected Patient 10 with HCG. (St. Ex. 9C, p. 40) Dr. Lewandowski subsequently injected Patient 10 with HCG on six visits. (St. Ex. 9C, p. 40-42) At that time, Patient 10 was 67 years old. The records contain no indication for the administration of HCG. (Tr. 126-27)

Patient 11

1. Patient 11 began seeing Dr. Lewandowski on April 14, 1987. She weighed 147 pounds. There is no notation of height, date of birth or age in her records. (St. Ex. 9D, p. 2) Dr. Lewandowski did not document a physical examination or a medical history for Patient 11. The records contain no information concerning Patient 11's efforts to lose weight by other means. (St. Ex. 9D, p. 2; Tr. 129) At her first visit, Dr. Lewandowski prescribed controlled substance anorectics. (St. Ex. 9D, p. 2) Patient 11 continued to receive controlled substance anorectics through April 1994, and made seventy-six visits for controlled substance anorectics. (St. Ex. 9D, p. 2-9) On thirty visits Patient 11 failed to lose weight. (St. Ex. 9D, p. 2-8; Tr. 130-31) During that time her weight fluctuated between 141 and 167 pounds. (St. Ex. 9D, p. 6, 7) Rather than

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discontinue the controlled substance anorectics, Dr. Lewandowski exceeded the recommended dosage on forty-seven occasions. (St. Ex. 9D, p. 2-3, 5-8; Tr. 130, 132) On her last visit, Patient 11 weighed 158 pounds, nine pounds more than on her first visit. (St. Ex. 9D, p. 8; Tr. 130)

2. On January 4, 1994, Dr. Lewandowski injected Patient 11 with HCG and B12. (St. Ex. 9D, p. 8) Dr. Lewandowski subsequently injected Patient 11 with that combination again. (St. Ex. 9D, p. 8) The records contain no indication for the administration of HCG or B12. (Tr. 131-32)

Patient 12

1. Patient 12 visited Dr. Lewandowski on March 17, 1974. No date of birth or height is noted in her records. Her age at the first visit was 22 and she weighed 141 pounds. On her first visit, Dr. Lewandowski prescribed controlled substance anorectics. Thereafter, Patient 12 visited Dr. Lewandowski sporadically. (St. Ex. 9E, p. 2-4; Tr. 134-35) Patient 12 saw Dr. Lewandowski three times between November 1986 and January 1987. (St. Ex. 9E, p. 4) At that time Dr. Lewandowski did not document a physical examination or a medical history for Patient 12. The records contain no information concerning Patient 12's efforts to lose weight by other means.

Over four years later on October 25, 1991, Patient 12, weighing 194 pounds, returned to Dr. Lewandowski who prescribed controlled substance anorectics. He again did not document a physical examination or a medical history, nor did he investigate any other means Patient 12 had used to lose weight. (St. Ex. 9E, p. 4)

Patient 12 made 12 visits. On five of those visits, Patient 12 failed to lose weight. Her weight fluctuated between 185 1/2 and 172 pounds. Rather than discontinue prescribing controlled substance anorectics, Dr. Lewandowski used a combination of two different controlled substance anorectics in amounts that exceeded the recommended dosage. (St. Ex. 9E, p. 4; Tr. 135-137)

Patient 13

1. Patient 13 first visited Dr. Lewandowski on August 25, 1959, when she was 34 years old. (St. Ex. 9F, p. 4) Patient 13's first recorded weight was 98 pounds in 1968. (St. Ex. 9F, p. 48) The next time a weight is recorded is 103 pounds on February 9, 1976. (St. Ex. 9F, p. 19) Dr. Konold gleaned the following medical history from hospital records included in Patient 13's file: hypertension, degenerative joint disease, nicotine use, mild cardiomegaly, cardiac surgery, electrolyte imbalance, dizziness, cholecystectomy and hysterectomy. (Tr. 137-38) Dr. Lewandowski did not document a thorough medical history or physical examination.

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2. Patient 13 received controlled substance anorectics on a regular basis from November 1972 through June 1993. Her weight is recorded only four times in that time period and it fluctuated between 103 and 110 pounds. (St. Ex. 9F, p. 19, 32, 41) Dr. Konold stated that it was inappropriate to prescribe controlled substance anorectics to this patient. (Tr. 143) Nevertheless, Dr. Lewandowski prescribed more than the recommended dosage of controlled substance anorectics on thirty visits between December 6, 1988 through November 12, 1991. (St. Ex. 9F, p. 32-38) In Dr. Lewandowski's response, he stated that obesity was the indication for the prescription of controlled substance anorectics. (Res. Ex. A, p. 10)
3. Dr. Lewandowski prescribed controlled substance anorectics even though Patient 13's records reflect evidence of and treatment for hypertension. (St. Ex. 9F, pp. 24-25, 28, 30-32, 36-37, 42-43; Tr. 138, 142, 144-45, 147) Dr. Lewandowski also prescribed controlled substance anorectics for fatigue on fourteen occasions. (St. Ex. 9F, pp. 29, 40-43, 46) Fatigue is not a recognized indication. (St. Ex. 10; Tr. 143, 147)
4. Dr. Lewandowski prescribed controlled substances to Patient 13 without indicating the diagnosis and purpose for which the controlled substances were utilized. Dr. Lewandowski prescribed Ativan, a schedule IV controlled substance anxiolytic, on three occasions without indication. (St. Ex. 9F, pp. 32-33; Tr. 145-46, 147) Dr. Lewandowski also prescribed Darvocet N-100, a schedule IV controlled substance analgesic, on five occasions. (St. Ex. 9F, pp. 34-37, 39, 42; Tr. 146-47)

Patient 14

1. Patient 14, a female born June 4, 1930, became Dr. Lewandowski's patient on April 6, 1967. She weighed 149 pounds. (St. Ex. 9G, pp. 2-3) Dr. Konold described Patient 14's medical history: pulmonary fibrosis, pneumothorax, cardiomegaly, hyperlipemia, cirrhosis, carpal tunnel syndrome, hypertension, fibrocystic breast disease, chronic low back pain, and total abdominal hysterectomy. (Tr. 148)
2. Patient 14 received controlled substances anorectics on a regular basis from April 3, 1973, through February 10, 1987, and from November 27, 1989, through July, 1994. (St. Ex. 9G, pp. 17-42) Dr. Lewandowski did not document the results of any physical examination or medical history for Patient 14. The records contain no information concerning Patient 14's efforts to lose weight by other means. (St. Ex. 9G, pp. 17, 33; Tr. 152) Dr. Lewandowski failed to weigh Patient 14 on twenty-eight visits on which he prescribed controlled substance anorectics. Patient 14's weight fluctuated between 145 and 160 pounds. (St. Ex. 9G, pp. 33, 42) From March 17, 1987, Patient 14 visited Dr. Lewandowski for controlled substance anorectics thirty-five times. (St. Ex. 9G, pp. 33-42) Even though Dr. Lewandowski had an inadequate record of Patient 14's

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progress on weight loss, he prescribed more than the recommended dosage of controlled substance anorectics on twelve visits. (St. Ex. 9G, pp. 33, 35-41)

3. Dr. Lewandowski prescribed controlled substance anorectics even though Patient 14's records reflect evidence of and treatment for hypertension. (St. Ex. 9G, p. 22, 33, 43-44, 58; Tr. 148-49, 151) Dr. Lewandowski also prescribed controlled substance anorectics for fatigue on two occasions. (St. Ex. 9G, p. 40-41) Fatigue is not a recognized indication. (St. Ex. 10; Tr. 143, 147) In fact, "fatigue can be a side effect of rebound from the use of controlled substance anorectics." (Tr. 150)

Dr. Lewandowski's Response

1. Dr. Lewandowski asserted that his treatment of patients met minimal standards of care. He denied that phentermine was addictive. (Res. Ex. A, p. 2; Tr. 61, 66) In support of this statement, he cited two articles and a recent study. (Res. Ex. A, pp. 11-14; Res. Ex. B; Tr. 61-62, 66-68) He stated that he prescribed phentermine in one month doses to assist patients who could not afford to pay for an office visit every two weeks. (Res. Ex. A, pp. 2-3; Tr. 61) Dr. Lewandowski offered weight control to his patients to provide complete health program. (Tr. 60) His practice was large. (Tr. 60, 70) Many of his patients were with him for years. "So, I grew up with their history." (Res. Ex. A, p. 2; Tr. 60) Dr. Lewandowski asserted that he did physicals and histories. However, if there was no significant change, he did not record his findings. (Res. Ex. A, p. 2; Tr. 61) He included an affidavit from his office assistant as evidence of this practice. (Res. Ex. A)

Dr. Lewandowski explained his approach to weight loss: "The patients, at intervals, need a crutch, be that a stimulant or a tranquilizer. What I am being accused of is the use or abuse of Phenteramine in all these cases. In all my years of practice, I have never seen a case of addiction or even dependence on this medication. Remember we're not talking about amphetamine, we're not talking about Dilaudid, we're talking about Phenteramine....When I use them in chronic fatigue or even depression I so noted it. More often than not in those cases I used them as a placebo....In helping [patients] I was very aware of the hypertension, the arteriosclerosis, the addiction potential but at all times I felt that I was controlling the dosage and monitoring the pt." (Res. Ex. A, p. 2-3)

FINDINGS OF FACT

1. Dr. Lewandowski failed to comply with state regulations concerning the proper procedure for prescribing controlled substance anorectics in his treatment of Patients 1 through 14. Dr. Lewandowski documented no physical examinations, detailed no medical history, did not determine whether his patients attempted unsuccessfully to lose weight through other means, and did not rule out contraindications. Dr. Lewandowski continued to prescribe

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- controlled substance anorectics when the patients failed to lose weight, and he failed to weigh the patients every fourteen days.
2. Dr. Lewandowski utilized controlled substance anorectics in his treatment of Patients 1-14 without indicating the diagnosis and purpose for which they were utilized.
 3. Dr. Lewandowski prescribed more than the recommended dosages of controlled substance anorectics to Patients 1-14.
 4. Dr. Lewandowski prescribed controlled substance anorectics to Patients 1, 2, 5, 7, 9, 13, and 14 who exhibited contraindications for the use of these drugs. Patients 1, 5, 7, 9, 13, and 14 exhibited hypertension. Patient 2 had a history of untreated drug abuse.
 5. Dr. Lewandowski prescribed controlled substance analgesics, anxiolytics, hypnotics and/or benzodiazepines to Patients 1, 2, 9, and 13 without indicating a diagnosis or a purpose.
 6. Dr. Lewandowski prescribed controlled substance anorectics for inappropriate purposes to Patients 1, 5, 7, 9, 13, and 14.
 7. Dr. Lewandowski inappropriately administered Human Chorionic Gonadotropin (HCG) to Patients 3, 4, 6, 10, and 11.
 8. Dr. Lewandowski administered monthly estrogen injections to Patient 7 for a twenty-three month period without conducting appropriate examinations.
 9. Dr. Lewandowski administered monthly injections of B12 without indication to Patients 7 and 11.
 10. Dr. Lewandowski prescribed diuretics to Patient 8 without indication.

CONCLUSIONS

1. Dr. Lewandowski's conduct as set forth in Findings of Fact 2-5 constitutes "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: 4731-11-02(D)."
2. Dr. Lewandowski's conduct as set forth in Findings of Fact 1, 3, 4 constitutes "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: 4731-11-04(B)(1), (2), (3), (5)(a), and (5)(b), Ohio Administrative Code."

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3. Dr. Lewandowski's conduct as set forth in Findings of Fact 1, 3, and 4 constitutes "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: 4731-11-04(C), Ohio Administrative Code."
4. Dr. Lewandowski's conduct as set forth in Findings of Fact 1-10 constitutes "failure to use reasonable care discrimination in the administration of drugs," and "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.
5. Findings of Fact 1-10 also support a conclusion that Dr. Lewandowski's conduct constitutes "(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.

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Dr. Lewandowski failed to monitor his patient's weight loss programs. He relied on his anecdotal experience in administering controlled substances rather than complying with the Board's regulations. As a result, he maintained his patients on controlled substance anorectics for years without consistent weight loss and in the face of contraindications. Dr. Lewandowski protested that these fourteen patients represented only a fraction of the thousands of patients he treated over his career. However, the uniformity of the charts and treatment present a clear picture of his practice habits. Scant records, absence of physical examination results, and inappropriate prescribing fall below the minimal standards of care.

PROPOSED ORDER

It is hereby ORDERED that:

1. The certificate of Ernest A. Lewandowski, D.O., to practice osteopathic medicine and surgery in the State of Ohio shall be permanently REVOKED. Such revocation is STAYED, and Dr. Lewandowski's certificate is hereby SUSPENDED for an indefinite period of time, but not less than two years. The State Medical Board shall not consider reinstatement of Dr. Lewandowski's certificate unless and until all of the following minimum requirements are met:
 - a. Dr. Lewandowski shall submit an application for reinstatement, accompanied by appropriate fees;

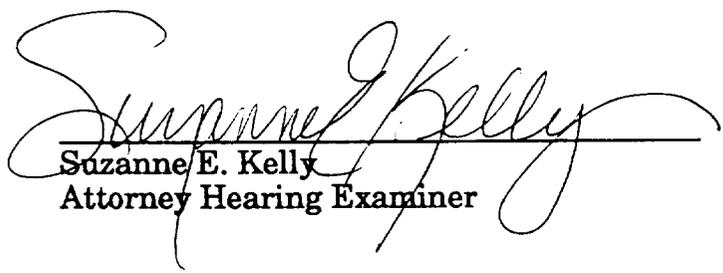
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- b. Dr. Lewandowski shall provide acceptable documentation of successful completion of 100 hours of Category I, Continuing Medical Education ("CME") dealing with the prescribing of controlled substances, including diagnostic testing and methods of evaluating patient symptoms and complaints. Such CME is to be approved in advance by the Board or its designee, and shall be in addition to the regular Category I CME requirements for relicensure under Section 4731.281, Ohio Revised Code;
 - c. Dr. Lewandowski shall provide acceptable documentation of successful completion of a minimum of fifty hours of medical record-keeping CME. Such CME shall be approved in advance by the Board or its designee, and shall be in addition to the regular Category I CME requirements for relicensure under Section 4731.281, Ohio Revised Code;
 - d. In the event that Dr. Lewandowski has not been engaged in the active practice of osteopathic medicine and surgery for a period in excess of two year prior to application for reinstatement, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Dr. Lewandowski's fitness to resume practice.
2. Upon reinstatement and commencement of practice in Ohio, Dr. Lewandowski's certificate shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least five years.
- a. Dr. Lewandowski shall obey all federal, state and local law, and all rules governing the practice of osteopathic medicine in Ohio.
 - b. Dr. Lewandowski shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution stating whether there has been compliance with all the conditions of this probation.
 - c. Dr. Lewandowski shall appear in person for interviews before the full Board or its designated representative at three month intervals, or as otherwise requested by the Board.
 - d. In the event that Dr. Lewandowski should leave Ohio for three consecutive months, or reside or practice outside the State, Dr. Lewandowski must notify the State Medical Board in writing of the dates of departure and return. Periods of time spent outside of Ohio will not apply to the reduction of this probationary period, unless otherwise determined by the Board in instances where the Board can be assured that probationary monitoring is otherwise being performed.
 - e. In the event Dr. Lewandowski is found by the Secretary of the Board to have failed to comply with any provision of this agreement, and is so

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notified of that deficiency in writing, such period of non-compliance will not apply to the reduction of the probationary period under this Order.

- f. Dr. Lewandowski shall keep a log of all controlled substances purchased, prescribed, dispensed, or administered. Such log shall be submitted in the format approved by the Board thirty days prior to Dr. Lewandowski's personal appearances before the Board or its designated representative, or as otherwise directed by the Board. Further, Dr. Lewandowski shall make his patient records with regard to such prescribing available for review by an agent of the State Medical Board upon request.
 - g. If Dr. Lewandowski violates probation in any respect, the Board, after giving Dr. Lewandowski notice and the opportunity to be heard, may institute whatever disciplinary action it deems appropriate, up to and including the permanent revocation of Dr. Lewandowski's certificate to practice osteopathic medicine and surgery in Ohio.
 - h. Upon successful completion of probation, as evidenced by a written release from the Board, Dr. Lewandowski's certificate will be fully restored.
3. This Order shall become effective thirty days from the date of mailing of notification of approval by the State Medical Board of Ohio. In the thirty (30) day interim, Dr. Lewandowski shall not undertake the care of any patient not already under his care and shall not undertake treatment of any individual not already under his care.


Suzanne E. Kelly
Attorney Hearing Examiner



STATE MEDICAL BOARD OF OHIO

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EXCERPT FROM THE DRAFT MINUTES OF OCTOBER 11, 1995

REPORTS AND RECOMMENDATIONS

Dr. Garg announced that the Board would now consider the findings and orders appearing on the Board's agenda.

Dr. Garg asked whether each member of the Board had received, read, and considered the hearing record, the proposed findings, conclusions, and orders, and any objections filed in the matters of: Donald R. Bernat, M.D.; Ahmet Helvaciolglu, M.D.; William John Jenkins, M.T.; Robert D. Kukla, M.D.; Ernest A. Lewandowski, D.O.; James Miller, D.O.; Ajay H. Parghi, M.D.; Heimo W. Reckmann, M.D.; and Harry A. Schutte, D.O. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Bhati	- aye
	Dr. Stienecker	- aye
	Dr. Gretter	- aye
	Dr. Egner	- aye
	Dr. Agresta	- aye
	Dr. Buchan	- aye
	Ms. Noble	- aye
	Mr. Sinnott	- aye
	Dr. Heidt	- aye
	Dr. Steinbergh	- aye
	Dr. Garg	- aye

Dr. Garg asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Bhati	- aye
	Dr. Stienecker	- aye
	Dr. Gretter	- aye
	Dr. Egner	- aye
	Dr. Agresta	- aye
	Dr. Buchan	- aye

Ms. Noble	- aye
Mr. Sinnott	- aye
Dr. Heidt	- aye
Dr. Steinbergh	- aye
Dr. Garg	- aye

In accordance with the provision in Section 4731.22(C)(1), Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of this matter. Dr. Gretter did not serve as Secretary in the above-named cases.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

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All Assistant Attorneys General and All Enforcement Coordinators left the meeting at this time.

REPORT AND RECOMMENDATION IN THE MATTER OF ERNEST A. LEWANDOWSKI, D.O.

Dr. Garg stated that if there were no objections, the Chair would dispense with the reading of the proposed findings of fact, conclusions and order in the above matter. No objections were voiced by Board members present.

DR. STEINBERGH MOVED TO APPROVE AND CONFIRM MS. KELLY'S PROPOSED FINDINGS OF FACT, CONCLUSIONS, AND ORDER IN THE MATTER OF ERNEST A. LEWANDOWSKI, D.O. DR. BHATI SECONDED THE MOTION.

Dr. Garg asked whether there were any questions concerning the proposed findings of fact, conclusions and order in the above matter.

Dr. Agresta stated that Dr. Lewandowski's use of medications was just unbelievable. It shows a total lack of knowledge of pharmacology. Dr. Agresta stated that he doesn't know what Dr. Lewandowski did with the rest of his practice, but this is appalling. This is the kind of individual the Board does not want taking care of patients.

Mr. Sinnott agreed, and added that he had an amendment to offer.

MR. SINNOTT MOVED THAT THE PROPOSED ORDER IN THE MATTER OF ERNEST A. LEWANDOWSKI, D.O., BE AMENDED BY SUBSTITUTING THE FOLLOWING:

The certificate of Ernest A. Lewandowski, D.O., to practice osteopathic medicine and surgery in the State of Ohio shall be permanently REVOKED.

This Order shall become effective immediately upon mailing of notification of approval by the State Medical Board of Ohio.

Mr. Sinnott stated that he feels this was an egregious prescribing case, and he can't draw a distinction between this case and other cases where the Board has revoked licenses based on records very much like this.

DR. BUCHAN SECONDED THE MOTION.

Dr. Buchan stated that he came today prepared to offer the same amendment. It was fortunate that no one died based on Dr. Lewandowski's prescribing practices.

Dr. Stienecker agreed that permanent revocation is appropriate in this case. Not only doesn't Dr. Lewandowski know anything about pharmacology, he rejects any suggestion of a need for training in the use of addictive drugs. Dr. Stienecker stated that this suggests that Dr. Lewandowski can't recognize addiction problems.

Dr. Heidt commented that Dr. Lewandowski retired from practice a year ago. Revoking his license now is like closing the barn door after the horse is gone.

Dr. Buchan stated that Dr. Lewandowski is still treating family members and friends.

Dr. Steinbergh spoke in support of the proposed amendment, adding that the Board has revoked the licenses of other retired physicians.

A vote was taken on Mr. Sinnott's motion to amend:

VOTE:	Mr. Albert	- abstain
	Dr. Bhati	- aye
	Dr. Stienecker	- aye
	Dr. Gretter	- abstain
	Dr. Egner	- aye
	Dr. Agresta	- aye
	Dr. Buchan	- aye
	Ms. Noble	- aye
	Mr. Sinnott	- aye
	Dr. Heidt	- aye
	Dr. Steinbergh	- aye

The motion carried.

DR. BUCHAN MOVED TO APPROVE AND CONFIRM MS. KELLY'S PROPOSED FINDINGS OF FACT, CONCLUSIONS, AND ORDER, AS AMENDED IN THE MATTER OF ERNEST A. LEWANDOWSKI, D.O. DR. AGRESTA SECONDED THE MOTION. A vote was taken:

VOTE:	Mr. Albert	- abstain
	Dr. Bhati	- aye
	Dr. Stienecker	- aye
	Dr. Gretter	- abstain
	Dr. Egner	- aye
	Dr. Agresta	- aye
	Dr. Buchan	- aye
	Ms. Noble	- aye
	Mr. Sinnott	- aye
	Dr. Heidt	- aye
	Dr. Steinbergh	- aye

The motion carried.



STATE MEDICAL BOARD OF OHIO

77 South High Street, 17th Floor # Columbus, Ohio 43215-2001

April 12, 1995

Ernest A. Lewandowski, D.O.
Derby Professional Building
5706 Turney Road - Room 103
Garfield Heights, OH 44125

Dear Dr. Lewandowski:

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 March 7, 1974, you began utilizing controlled substance anorectics in your treatment of Patient 1 (as identified on the attached Patient Key - Key confidential: to be withheld from public disclosure), a 47-year-old man. Patient 1 received controlled substance anorectics on a regular basis since on or about September 18, 1973, through in or about July 1993.
 - a) Your records reveal that this patient developed systolic hypertension in February 1976. The patient later had multiple hospital admissions related to coronary artery disease and peripheral vascular disease necessitating ischemic ulcer debridements and amputations of toes. Patient 1 also had a long standing history of hypertension and was on multiple antihypertensive medications. Despite this medical history, you dispensed controlled substance anorectics to Patient 1 on almost every office visit. Advanced arteriosclerosis, symptomatic cardiovascular disease and moderate to severe hypertension are contraindications for the use of controlled substance anorectics.
 - b) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 1 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - c) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment. In addition, on 16

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visits from on or about July 30, 1991, through on or about April 21, 1992, you routinely failed to weigh the patient.

- d) Also, you routinely utilized controlled substance anorectics when Patient 1 failed to lose weight.
 - e) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics to Patient 1. For example, see 7 visits from on or about August 21, 1990, through on or about February 12, 1991, and see 14 visits from on or about July 2, 1991, through on or about March 24, 1992. In addition, you utilized the controlled substance anorectics on a long-term basis, which deviated from the recommended usage.
 - f) On or about March 13, 1989, you began prescribing Tylox, a schedule II controlled substance analgesic, to Patient 1, without indicating the diagnosis and purpose for which the controlled substance was utilized. You continued to prescribe Tylox until on or about June 16, 1992, when your records note "no more Tylox!" During or about April 1993, you prescribed Valium, a schedule IV controlled substance benzodiazepine, to Patient 1, without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - g) Your records also reveal that in or about June and July 1993, you utilized "Phen-tabs" for "fatigue." Dispensing of a controlled substance anorectic for the indication of "fatigue" is inappropriate.
- 2) On or about February 19, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 2 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 37-year-old woman. Patient 2 received controlled substance anorectics on a regular basis from on or about February 19, 1973, through in or about June 1993.
- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 2 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 2 failed to lose weight.

- d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics to Patient 2. For example, see 8 visits from on or about December 1, 1987, through on or about May 31, 1988, 8 visits from on or about May 2, 1991, through on or about February 11, 1992, and 9 visits from on or about October 27, 1992, through June 15, 1993. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Your records also revealed that Patient 2 had a history of drug abuse. In 1977, Patient 2 was admitted to Brentwood Hospital following a Quaalude overdose. Despite this history of drug abuse, you prescribed Demerol, a Schedule II controlled substance analgesic, on or about June 3, and November 21, 1985, without indicating the diagnosis and/or purpose for which the controlled substance was utilized. On or about June 30, 1986, you prescribed Fiorinal No. 3, a Schedule IV controlled substance analgesic without indicating the diagnosis and purpose for which the controlled substance was utilized. On or about November 16, 1989, you prescribed Ativan, a Schedule IV controlled substance anxiolytic without indicating the diagnosis and purpose for which the controlled substance was utilized. You also prescribed Doral, a Schedule IV controlled substance hypnotic, on or about January 19, April 26, and June 15, 1993, without indicating the diagnosis and/or purpose for which the controlled substance was utilized.
 - f) Additionally, despite the patient's history of drug abuse, you continued to dispense controlled substance anorectics to the patient.
- 3) On or about April 5, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 3 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 33-year-old woman. Patient 3 received controlled substance anorectics on a regular basis from on or about April 5, 1973, through in or about August 1994.
- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 3 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.

- c) Also, you routinely utilized controlled substance anorectics when Patient 3 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics. For example, see 7 visits from on or about December 15, 1987, through on or about May 24, 1988, and 10 visits from on or about August 6, 1991, through on or about March 31, 1992. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Also, beginning on or about August 17, 1993, you administered human chorionic gonadotropin (HCG) to Patient 3, who was approximately 53 years old, without indication. In women, HCG is indicated for the induction of ovulation or pregnancy. Such inappropriate administration occurred on 21 subsequent visits through on or about August 2, 1994.
- 4) On or about February 21, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 4 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 41-year-old woman. Patient 4 received controlled substance anorectics on a regular basis from on or about February 21, 1973, through in or about July 1994.
- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 4 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 4 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics to Patient 4. For example, see 8 visits from on or about November 20, 1987, through on or about June 2, 1988, 23 visits from on or about February 21, 1991, through on or about March 3, 1992, 9 visits from on or about November 12, 1992, through on or about July 9, 1993, and 7 visits from on or about February 10, 1994, through on or about July 29, 1994. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.

- e) Beginning on or about March 4, 1994, you administered human chorionic gonadotropin (HCG) to Patient 4, a 62-year-old woman, without indication. In women, HCG is indicated for the induction of ovulation or pregnancy. Such inappropriate administration occurred on all six subsequent visits through July 29, 1994.
- 5) On or about September 6, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 5 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 39-year-old woman. Patient 5 received controlled substance anorectics on a regular basis from on or about September 6, 1973, through in or about August 1994.
- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 5 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 5 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics for Patient 5. For example, see 5 visits from on or about May 16, 1989, through on or about August 29, 1989, and 24 visits from during or about January 1990 through on or about January 9, 1992. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Further, during or about January, March, June, and November 1991, Patient 5's blood pressure readings were elevated with diastolics of 100. Despite such elevated readings, your dispensing of controlled substance anorectics did not change and, in fact, you increased the dosage on or about October 3, 1991. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics.
 - f) Your records reveal that on or about May 24, 1994, you utilized "Adipex" "for energy." Dispensing of a controlled substance anorectic for the indication of "energy" is inappropriate.

- 6) On or about April 6, 1976, Patient 6 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), first presented to your office and you began utilizing controlled substance anorectics in your treatment of Patient 6, a 21-year-old woman. Patient 6 received controlled substance anorectics on a regular basis from on or about April 6, 1976, through in or about August 1994.
 - a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 6 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 6 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics for Patient 6. For example, see 10 visits from on or about May 23, 1991, through on or about March 10, 1992. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) On or about November 29, and December 17, 1991, you administered human chorionic gonadotropin (HCG) to Patient 6, a 37 year old woman, without indication. In women, HCG is indicated for the induction of ovulation or pregnancy. You again administered HCG to Patient 6 without indication on or about June 16, 1994, and on all four subsequent visits through on or about August 1, 1994.

- 7) On or about October 16, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 7 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 41-year-old woman. Patient 7 received controlled substance anorectics on a regular basis from on or about October 16, 1973, through in or about August 1994.
 - a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 7 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose

weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.

- c) Also, you routinely utilized controlled substance anorectics when Patient 7 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics for Patient 7. For example, see 13 visits from on or about December 15, 1987, through on or about March 31, 1988, and visits on or about April 9, June 18, August 13, and September 24, 1991. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) During or about February or March 1991, Patient 7 was prescribed Procardia XL for her blood pressure which was elevated to 160/100. On or about April 21, 1992, her blood pressure was elevated to 180/100. On January 5, 1993, it was 160/100. Despite such elevated readings, your dispensing habits did not change and you maintained the patient on the controlled substance anorectics on a regular basis through on or about August 8, 1994. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics.
 - f) Your records reveal that on or about June 16, and August 25, 1992, you dispensed to Patient 7 "phen tab for fatigue." Dispensing of a controlled substance anorectic for treatment of "fatigue" is inappropriate.
 - g) Your records also reveal that you administered monthly estrogen injections to Patient 7 from on or about June 16, 1991, through on or about May 25, 1993, without conducting appropriate exams, such as breast exams, mammograms, pap smears, pelvic exams, or screening for possible estrogen sensitive tumors.
 - h) Additionally, your records reveal that you administered to Patient 7 monthly injections of B12 without indication. See, for example, in or about April 1988 through in or about January 1989 and in or about March 1989 through in or about January 1991.
- 8) On or about May 2, 1988, Patient 8 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 33-year-old woman, first presented to your office. Patient 8 was 5' 5'' in height and weighed 130 1/2 pounds. You began dispensing controlled substance anorectics to her on this first visit.

- a) Since November 15, 1988, you utilized controlled substance anorectics in your treatment of Patient 8 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 8 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of more than one controlled substance anorectic to Patient 8. For example, see 5 visits from on or about January 15, 1991, through on or about March 12, 1991, and also the 372 day period of March 26, 1991, through March 31, 1992. During this period you dispensed 812 daily doses of controlled substance anorectics and Patient 8 gained two (2) pounds. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) On at least six occasions you prescribed diuretics to Patient 8 without indication. On or about April 10, 1990, with a blood pressure reading of 122/70, you prescribed Lozol to her. On or about July 17, October 9, 1990, and October 29, 1991, with no evidence of hypertension or other indication, you prescribed HydroDIURIL to Patient 8. On or about April 26, 1992, and on or about April 13, 1993, with no evidence of hypertension or other indication, you prescribed Hydrochlorothiazide to her.
- 9) On or about April 10, 1989, you began utilizing controlled substance anorectics in your treatment of Patient 9 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 67-year-old woman. Patient 9 received controlled substance anorectics on a regular basis from on or about April 10, 1989, through in or about June 1994.
- a) Since April 10, 1989, you utilized controlled substance anorectics in your treatment of Patient 9 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough

history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment. In addition, on 4 visits from on or about November 18, 1991, through on or about February 10, 1992, and visits on or about March 1, 1993, and on or about June 6, 1994, you failed to weigh the patient.

- c) Also, you routinely utilized controlled substance anorectics when Patient 9 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics. For example, see, among others, 12 visits from on or about August 28, 1989, through on or about July 2, 1990, and 3 visits from in or about April 1993 through on or about June 7, 1993. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Your records reveal that on or about May 12, 1988, Patient 9's blood pressure was elevated to 160/92. Additionally, a discharge summary from Brentwood Hospital dated February 22, 1989, includes hypertension among the discharge diagnoses. Despite the patient's history of hypertension, you utilized controlled substance anorectics on or about April 10, 1989, and continued to do so through or about June 1994. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics.
 - f) Your records reveal that on or about June 29, and July 27, 1992, you dispensed to Patient 9 "phen tab for fatigue." Dispensing of a controlled substance anorectic for the treatment of "fatigue" is inappropriate.
 - g) Further, your records reveal that on many occasions you prescribed controlled substances without indicating the diagnosis and purpose for which they were being utilized. For example, you prescribed Valium, a schedule IV controlled substance benzodiazapine, on or about May 12, 1988, January 15, 1990, and May 28, 1991, among others. Also, you prescribed Darvocet N-100, a schedule IV controlled substance analgesic, on or about October 24, 1988, April 10, 1989, and August 8, 1991, among others.
- 10) On or about February 12, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 10 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 46-year-old woman. Patient 10 received controlled substance anorectics on a regular basis from on or about February 12, 1973, through in or about July 1994.

April 12, 1995

- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 10 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 10 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics. For example, see 7 visits from on or about September 24, 1991, through on or about March 10, 1992, and 6 visits from on or about August 25, 1992, through on or about January 12, 1993. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Also, beginning on or about November 16, 1993, you began administering human chorionic gonadotropin (HCG) to Patient 10, a 67 year old woman, without indication. In women, HCG is indicated for the induction of ovulation or pregnancy. Such inappropriate administration occurred on an additional five visits subsequent to November 16, 1993.
- 11) On or about April 14, 1987, Patient 11 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), of unknown age, first presented to your office. On this first visit you began utilizing controlled substance anorectics in your treatment of Patient 11, without indication. You utilized such controlled substance anorectics in your treatment of Patient 11 on a regular basis from on or about April 14, 1987, through in or about April 1994.
- a) Since April 14, 1987, you utilized controlled substance anorectics in your treatment of Patient 11 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.

- c) Also, you routinely utilized controlled substance anorectics when Patient 11 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of the controlled substance anorectics. For example, see 14 visits from on or about May 12, 1987, through on or about May 17, 1988, and 33 visits from on or about May 31, 1990, through on or about April 27, 1994. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) On or about January 4, 1994, and March 1, 1994, you administered human chorionic gonadotropin (HCG) to Patient 11, without indication. In women, HCG is indicated for the induction of ovulation or pregnancy.
 - f) Also, on or about January 4, 1994, and March 1, 1994, you administered Vitamin B12 to Patient 11, without indication.
- 12) On or about October 25, 1991, you began utilizing controlled substance anorectics in your treatment of Patient 12 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 38-year-old woman.
- a) Such utilization was done without indicating the diagnosis and purpose for which controlled substance anorectics were utilized in your treatment of Patient 12.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment.
 - c) Also, on at least five visits since on or about November 21, 1991, you utilized controlled substance anorectics when Patient 12 failed to lose weight.
 - d) Also, from on or about December 5, 1991, through on or about March 24, 1992, you concurrently dispensed two different controlled substance anorectics in amounts that exceeded the recommended dosage.
- 13) On or about November 20, 1972, you began utilizing controlled substance anorectics in your treatment of Patient 13 (as identified on the attached

Patient Key - Key confidential; to be withheld from public disclosure), a 47-year-old woman. Patient 13 received controlled substance anorectics on a regular basis from on or about November 20, 1972, through in or about June 1993.

- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 13 without indicating the diagnosis and purpose for which the controlled substance was utilized.
- b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment. In addition, you routinely failed to weigh the patient.
- c) Also, you routinely utilized controlled substance anorectics when your records failed to reflect that the patient was losing weight.
- d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics. For example, see 30 visits from on or about December 6, 1988, through on or about November 12, 1991. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
- e) Your records reveal that on or about March 17, 1987, you dispensed "phen tabs for pep and to elevate mood." Again on or about June 30, 1992, July 28, 1992, August 25, 1992, September 22, 1992, February 9, 1993, and March 9, 1993, you dispensed "Adipex for energy." On or about October 19, 1992, you dispensed "Adipex for fatigue/energy." On or about March 27, 1993, June 29, 1993, and June 3, 1994, you dispensed "Adipex for fatigue." Dispensing of a controlled substance anorectic for any of the above-mentioned indications is inappropriate.
- f) Your records reveal that on or about March 12, 1984, Patient 13's blood pressure was elevated to 140/90. On or about November 27, 1984, her blood pressure was 140/98. On or about February 2, 1987, her blood pressure was 152/90 and you placed her on two antihypertensive medications, Lopressor and Adalat. On or about January 6, 1989, her blood pressure was 170/86. On or about August 7, 1990, her blood pressure was 150/98. On or about April 2, 1991, her blood pressure was 160/92. Despite the patient's history of hypertension, you utilized controlled substance anorectics on a regular basis in your treatment of Patient 13, and continued to do so through or

about June 1993. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics.

- g) On many occasions you prescribed controlled substances in your treatment of Patient 13 without indicating the diagnosis and purpose for which the controlled substances were utilized. For example, you prescribed Ativan, a schedule IV controlled substance anxiolytic, on or about January 5, January 31 and June 20, 1989. Also, you prescribed Darvocet N-100, a schedule IV controlled substance analgesic, on or about May 22, 1990, January 25, and April 2, 1991, April 7, 1992, and March 9, 1993.
- 14) On or about April 3, 1973, you began utilizing controlled substance anorectics in your treatment of Patient 14 (as identified on the attached Patient Key - Key confidential; to be withheld from public disclosure), a 42-year-old woman. Patient 14 received controlled substance anorectics on a regular basis from on or about April 3, 1973, through on or about February 10, 1987, and from on or about November 27, 1989, through on or about February 7, 1994.
- a) Since November 17, 1986, you utilized controlled substance anorectics in your treatment of Patient 14 without indicating the diagnosis and purpose for which the controlled substance was utilized.
 - b) Further, when you utilized controlled substance anorectics, you failed to determine whether the patient had made a good-faith effort to lose weight before initiating treatment. You also failed to obtain a thorough history, perform a thorough physical exam, and rule out the existence of any recognized contraindications before initiating treatment. In addition, on some occasions you failed to weigh the patient.
 - c) Also, you routinely utilized controlled substance anorectics when Patient 14 failed to lose weight.
 - d) On many occasions you dispensed more than the recommended dosage of controlled substance anorectics. For example, see 10 visits from during or about February 1991, through on or about March 2, 1992. In addition, you utilized the controlled substance anorectics on a long-term basis which deviated from the recommended usage.
 - e) Your records reveal that on or about November 29, 1993, you dispensed "Adipex for fatigue." Dispensing of a controlled substance anorectic for "fatigue" is inappropriate.

- f) Your records reveal that the patient had a history of hypertension and was on antihypertensive medications during treatment. She demonstrated elevated blood pressure readings on many visits and your records note that the patient often presented for "hypertension check." For example, see on or about June 8, 1992, and March 15, 1993. In fact, on or about February 7, and April 18, 1994, your records stated, "History of hypertension." Despite the patient's history of hypertension, you utilized controlled substance anorectics on a regular basis in your treatment of Patient 14. Moderate to severe hypertension is a contraindication for the use of controlled substance anorectics.

Your acts, conduct, and/or omissions as alleged in paragraphs (1) through (14) above, individually and/or collectively, constitute "(f)ailure 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 (14) 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.

Further, your acts, conduct, and/or omissions as alleged in subparagraphs (1)(b), (1)(f), (2)(a), (2)(e), (3)(a), (4)(a), (5)(a), (6)(a), (7)(a), (8)(a), (9)(a), (9)(g), (10)(a), (11)(a), (12)(a), (13)(a), (13)(g), and (14)(a) 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: 4731-11-02(D), Ohio Administrative Code. Pursuant to Rule 4731-11-02(F), Ohio Administrative Code, violation of Rule 4731-11-02(D), Ohio Administrative Code, also violates Sections 4731.22(B)(2) and (6).

Further, your acts, conduct, and/or omissions as alleged in subparagraphs (1)(e), (2)(d), (3)(d), (4)(d), (5)(d), (6)(d), (7)(d), (8)(d), (9)(d), (10)(d), (11)(d), (12)(d), (13)(d), through (14)(d) 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: 4731-11-04(B), Ohio Administrative Code. Pursuant to Rule 4731-11-04(C), Ohio Administrative Code, violation of Rule 4731-11-04, Ohio Administrative Code, also violates Sections 4731.22(B)(2),(3) and (6), Ohio Revised Code.

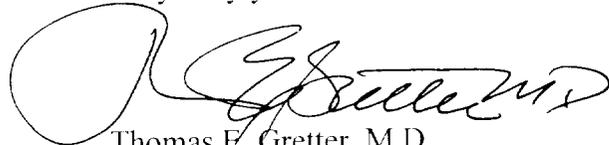
Further, your acts, conduct, and/or omissions as alleged in subparagraphs (1)(c), (2)(b), (3)(b), (4)(b), (5)(b), (6)(b), (7)(b), (8)(b), (9)(b), (10)(b), (11)(b), (12)(b), (13)(b), and (14)(b) above,

April 12, 1995

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,

A handwritten signature in black ink, appearing to read "T. E. Gretter, M.D.", written in a cursive style.

Thomas E. Gretter, M.D.
Secretary

TEG/bjm
Enclosures
CERTIFIED MAIL # P 348 888 221
RETURN RECEIPT REQUESTED