Approved: 3-26-97
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on March 17, 1997 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Emalene Correll, Legislative Research Department
Norman Furse, Revisor of Statutes
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

Meg Henson, Director of Government Affairs, Kansas Medical Society
Lawrence T. Buening, Jr., Executive Director, Kansas Board of Healing Arts

Others attending: See attached list

Hearing on HB 2288 - Treatment of obesity

Meg Henson, Kansas Medical Society, testified before the Committee in support of **HB 2288** which would authorize physicians licensed by the Board of Healing Arts to treat obesity with any type of controlled substance, as may be defined by rules and regulations adopted by the Board of Healing Arts. Ms. Henson noted that KMS believes some regulations of these drugs is necessary, and that the Board should be given a flexible regulatory framework to promulgate regulations consistent with current medical practice. The KMS work group has pledged to work with the Board to create regulatory language which would protect patients to the fullest extent possible, yet allow physicians to prescribe these drugs for the benefit of their patients and in accordance with federal law as noted in her written testimony. (Attachment 1)

Larry Buening, Board of Healing Arts, also testified in support of **HB 2288** and noted that the Board has received innumerable inquires about the use of Phentermine and Fenfluramine (Phen/Fen) in combination to treat obesity and for longer than 90 days which is the current law for most obesity drugs. Mr. Buening stated that the Board is of the opinion some controls are appropriate, but that a mechanism needs to exist to allow guidelines and standards to change along with the medical advances as noted in his written testimony. (Attachment 2)

Action on HB 2288

After Committee discussion, Senator Hardenburger made a motion that the Committee recommend **HB 2288** favorably for passage, seconded by Senator Steineger. The motion carried.

Introduction of Concurrent Resolution

The Chair called the Committee's attention to interest in and the need to introduce a Concurrent Resolution that would establish a task force to study the accessibility of personal records and information which are held in the public domain, and to determine the adequacy of current state law in protecting the privacy of individual citizens. A draft of the Senate Concurrent Resolution was distributed to the Committee for their review. (Attachment 3)

After Committee discussion, Senator Steineger made a motion the Committee recommend introduction of the proposed Senate Concurrent Resolution, seconded by Senator Becker. The motion carried.

Adjournment

The meeting was adjourned at 10:45 a.m.

The next meeting is scheduled for March 18, 1997

KMS

KANSAS MEDICAL SOCIETY

March 17, 1997

To: Senate Public Health and Welfare Committee

From: Meg Henson
Director of Government Affairs

Subj: HB 2288 - Treatment of Obesity

The Kansas Medical Society appreciates the opportunity to appear today on HB 2288, which was introduced at our request, relating to the regulation of obesity drugs by the Board of Healing Arts. The bill would give the board the flexibility to regulate these drugs in accordance with current medical practice. KMS supports this legislation.

Current law in Kansas gives the Board of Healing Arts authority to promulgate rules and regulations governing the "short term treatment of obesity." Until very recently, physicians could not legally prescribe any obesity drug for more than 90 days per year. As a result of this limit, many physicians simply did not prescribe these drugs for their patients. Patients traveled across state lines to neighbor states to receive these drugs, where they received little or no monitoring. Other patients "doctor-hopped," seeing one physician for 90 days, then changing physicians and receiving another 90 day cycle, etc. These realities appear inconsistent with the purpose of these laws, which is to protect the public and guard against abuse.

At our request, the Board of Healing Arts promulgated a temporary regulation addressing the use of Redux, a relatively new obesity drug. The regulation allows physicians to prescribe the drug for up to 360 days in a two-year period, which is consistent with the FDA's one year approval of the drug. This regulation was seen as a "temporary fix," addressing the immediate concerns of our members. Because the regulation is temporary, however, it will expire at the end of March. Further, it relates to only one drug. It is our hope that the Legislature will enact this legislation so that the board is given the flexibility to regulate this and other weight loss drugs as new drugs are introduced and practice guidelines change.

HB 2288 is the product of a working group, created by KMS and comprised of physicians, pharmacists, pharmacologists and dieticians who specialize in weight loss treatment. Members of this group expressed a need for giving the board more flexibility than current law allows in treating obesity. When the law was originally enacted in 1984, it reflected current medical practice. Since then, several new drugs have been introduced which have been proven safe for longer periods of time. However, because the law restricts the board's regulation to short term treatment, the board does not feel it has the authority to promulgate rules and regulations to reflect current medical practice.

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Western Kansas office • 108 E 12th St. • Hays KS 67601 • 913.625.8215 • 800.2

Senate Public Health and Welfare
Date: 3-17-97
Attachment No. 1

KMS believes that some regulation of these drugs is necessary. For this reason, we do not believe that use of these drugs should be unregulated. However, we do believe that the board should be given a flexible regulatory framework to promulgate regulations consistent with current medical practice. The KMS work group has pledged to work with the board to create regulatory language which will protect patients to the fullest extent possible, yet will allow physicians to prescribe these drugs for the benefit of their patients and in accordance with federal law.

Thank you very much for considering our comments. I will be happy to answer any questions.

KANSAS BOARD OF HEALING ARTS

BILL GRAVES
Governor

LAWRENCE T. BUENING, JR.
Executive Director

235 S. Topeka Blvd.
Topeka, KS 66603-3068
(913) 296-7413
FAX # (913) 296-0852

MEMORANDUM

TO: Senate Committee on Public Health and Welfare

FROM: Lawrence T. Buening, Jr.
Executive Director

DATE: March 17, 1997

RE: **HOUSE BILL NO. 2288**

Senator Praeger and committee members, thank you for the opportunity to appear on behalf of the Kansas State Board of Healing Arts in support of House Bill No. 2288. This bill amends K.S.A. 65-2837a of the Healing Arts Act and will allow the Board to determine appropriate limitations on the use of controlled substances for weight loss.

In May, 1995, Readers Digest published an article concerning use of Phentermine and Fenfluramine (Phen/Fen) which is appended as ATTACHMENT 1. Since that time the Board office has received innumerable inquiries about the use of these 2 drugs in combination and for longer than 90 days. The Board has become acutely aware of the public's interest in and demand for Phen/Fen. ATTACHMENT 2 is a copy of an article from the Arkansas Democrat-Gazette dated September 14, 1996 which discusses the problems that might arise when there are no guidelines or when there is a total prohibition.

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Because of these inquiries and concerns that Kansas citizens were likewise going to adjacent states which had no restrictions on use of Phen/Fen, the Board in August, 1995, determined it would commence a clinical investigation and allow doctors to apply for and obtain approval to use Phen/Fen. Authority for the project is found at K.S.A. 65-2837a(b)(6). ATTACHMENT 3 is the Patient Worksheet for the clinical investigation which is on-going by the Board. At the present 3,076 patients have been included in the study and the information is being entered into a database which will provide the Board with information on weight loss history, side effects, and geographical demand.

In May, 1996, Redux was approved by the FDA for use in treatment of obesity and was specifically authorized for use beyond 90 days and up to 1 year. Redux is widely publicized as the "hot" new diet pill - see ATTACHMENT 4. Again, in an attempt to meet the needs of the citizens, the Board has adopted a temporary amendment to K.A.R. 100-23-1 to enable use of Redux for a period of 360 days in a 2-year period. The public hearing on the permanent amendment to K.A.R. 100-23-1 is set for Friday, March 21.

K.S.A. 65-2837a was adopted by the 1984 Legislature and was based on a Wisconsin law. The Wisconsin experience reflected that, following adoption of the law, prescriptions for amphetamines and sympathomimetic amines decreased by 90%. However, in October 1992, the Wisconsin law was amended and it is now unprofessional conduct to use Schedule II amphetamines or sympathomimetic amines for weight control. The current Kansas law also makes use of schedule II drugs for treatment of obesity unlawful. It also restricts use of these drugs in Schedules III and IV. Recent studies and continuing medical advances may make weight control drugs safe and effective both in combination, like Phen/Fen, or for extended periods like Redux.

Regulation of a physician's prescribing practice is a critical public policy decision. The Board is of the opinion that some controls are appropriate, but that a mechanism needs to exist to allow guidelines and standards to change along with the medical advances. ATTACHMENT 5 is a copy of the Practice Guidelines of the American Society of Bariatric Physicians.

Thank you for the opportunity to appear before you in support of House Bill No. 2288. I would be happy to respond to any questions.

May 1995 $2.25

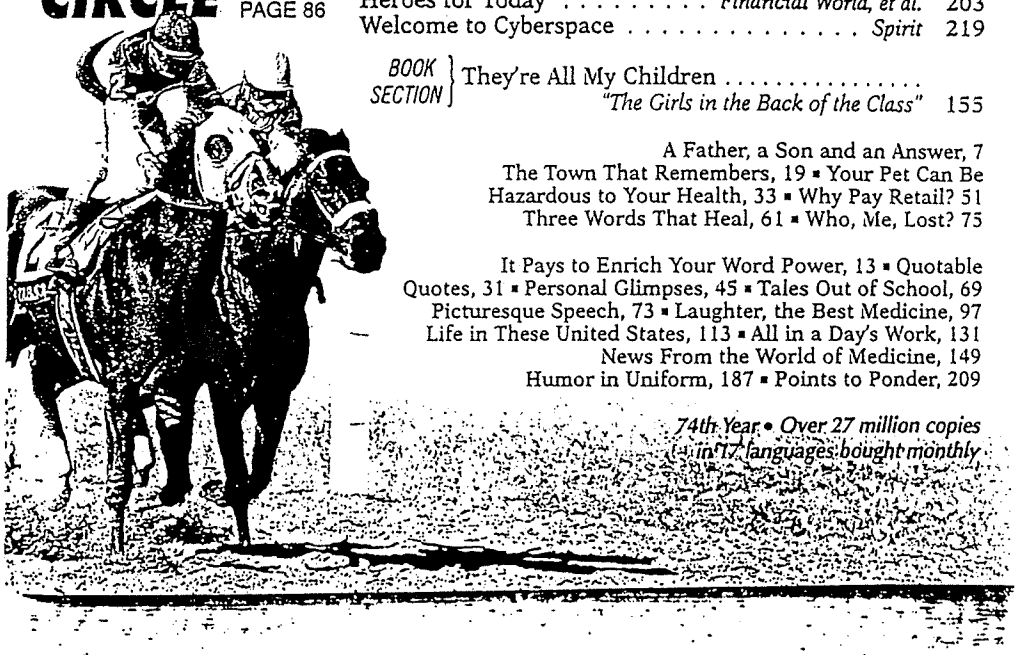
Reader's Digest

World's Most Widely Read Magazine

WELFARE GONE HAYWIRE
PAGE 92

RETURN OF A GOLDEN KNIGHT
PAGE 124

JOURNEY TO THE WINNER'S CIRCLE PAGE 86



74th Year • Over 27 million copies in 17 languages bought monthly

ATTACHMENT 1

2-3

ATTACHMENT 2

AR-0190 DAILY NEWSPAPER
ARKANSAS DEMOCRAT-GAZETTE
Little Rock, AR

Circ-(M) 179,609 (S) 292,057

SEPTEMBER 14, 1996

Bacon's

2947

Panel votes to suspend diet doctor

BY KAREN McALLISTER
Democrat-Gazette Health Writer

The Arkansas State Medical Board voted Friday to suspend the license of an Osceola doctor who prescribed diet pills to 613 patients in one day last month.

Medical Board attorney William H. Trice III said Dr. George Pollock will continue to hold his license until the board prepares an order and serves the doctor with papers at his clinic.

"Even if it is legitimate treatment, it would be hard to provide adequate care at that rate," Trice said.

Pollock will have a hearing before the board at its December meeting.

Since July, Pollock has been prescribing fen-phen — a combination of appetite suppressants — to patients at least 9 pounds overweight. Pollock said he charges patients $35 and does not give physical exams before writing prescriptions for Fenflauimine and Phentermine. He sees patients individually only by special request.

Sixty to 70 percent of Pollock's patients travel to his clinic from Tennessee, where doctors are

See LICENSE, Page 14A

Arkansas Democrat-Gazette

2947 cr

License

• Continued from Page 1A

prohibited from prescribing the drugs.

In an interview at his office Tuesday, Pollock said he stays too busy for one-on-one consultations and in March started using a video to introduce patients to his diet plan.

Health Department investigators visited Pollock's office recently on behalf of the medical board. On Tuesday, Pollock said he was assured there were no problems with his practice.

"I know more about this than anyone on the medical board," Pollock said.

When Pollock learned Friday about the board's emergency suspension, he said, "I have a bunch of patients depending on me. I think this is terrible."

The fen-phen combination is selling out throughout the country, and its popularity has spawned an industry of diet clinics. Since Pollock started prescribing the combination, two specialty clinics have opened in West Memphis.

Both drugs are legal in Arkansas, but state and federal law prohibits doctors from prescribing drugs without a legitimate medical reason and appropriate medical exams. A federal Drug Enforcement Agency investigator said the agency is investigating fen-phen clinics in Northeast Arkansas but would not say whether Pollock was the subject of an inquiry.

Pollock initially greets his patients through a 12-minute video played in a room lined with folding chairs. On a first visit, a nurse weighs patients and checks their blood pressure. Patients are then escorted in groups of up to 30 to a waiting room to watch Pollock's video. Pollock then meets the group to talk about his program and the drugs' side effects.

The session concludes with Pollock calling out names and distributing fen-phen prescriptions. He advises patients to return each month for refills. On return visits, a nurse weighs the patient and checks vital signs.

On Tuesday, office manager Dorothy Crockett talked to groups about their weight loss, answered questions and distributed prescriptions.

Pollock said he is dealing only with patients' obesity and suggests they get physicals from their primary-care doctor.

Nancy Grace, who has traveled from Jackson, Tenn., twice to Pollock's office, said she didn't mind not meeting with the doctor privately.

"When I first came here I just wanted to get out and try it," said Grace, who lost 12 pounds in her first month on the program and hopes to lose 30 more. Grace took a vacation day from her factory job to avoid the Saturday crowds at the Osceola clinic.

Fenflauimine kills appetite but leaves patients drowsy, while Phentermine speeds up metabolism and reportedly acts as an "upper."

Both drugs have been on the market and sold separately for more than 30 years. They became popular in the early 1990s after Dr. Michael Weintraub received a National Institute of Health grant to study them as part of a total medical treatment for obesity.

Pollock said his fen-phen business evolved as patients demanded the prescriptions. Word spread quickly after he first prescribed the combination in July 1995. By January 1996, Pollock was seeing up to 66 patients a day and by August, an average of 200 a day. On Aug. 3 — a Saturday — Pollock wrote prescriptions for 613 patients.

Pollock repeatedly said, "I'm not running them through like cattle."

On Sept. 9, the Osceola Wal-Mart filled 500 prescriptions for Fenflauimine and Phentermine, said pharmacist Leigh Ann Ross. The two prescriptions — sold under the trade names Pondimin and Ionamin — cost about $80.

Pollock gives his patients a list of 22 potential side effects, including severe dizziness, chest pains, hyperactivity, rapid heartbeat, and blurred vision. Pollock and patients said the drugs curb their appetites so much that they have to remind themselves to eat.

2-4

PHEN - FEN RESEARCH PROJECT

PATIENT WORKSHEET

PATIENT NAME _____

PATIENT ID ___ ___ ___ - ___ ___ ___

PHYSICIAN NAME _____

PHYSICIAN COUNTY _____

INTERVAL	WEIGHT	SIDE EFFECT CODE	DATE
INITIAL			
THREE MONTH			
SIX MONTH			
NINE MONTH			
TWELVE MONTH			
18 MONTH			
TERMINATION			

TERMINATION REASON (circle one)	achieved weight loss goal	side effects	unknown	other (explain below)

SIDE EFFECTS (Circle all that apply):

A none	B dry mouth, unpleasant taste	C headache	D heart palpitations, tachycardia	E restlessness, insomnia	F impotence, change in libido	G Other

SIDE EFFECTS:
(NARRATIVE)

DISQUALIFICATIONS:
(NARRATIVE)

EPTEMBER 23, 1996 $2.95

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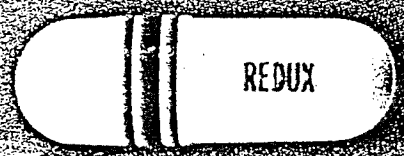
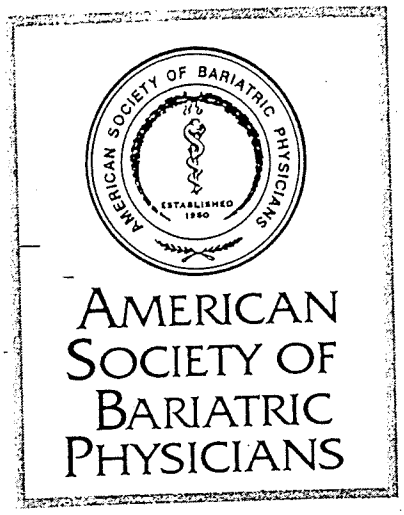
THE HOT NEW DIET PILL



Redux really seems to work. But is it too good to be true?

ATTACHMENT 5



BARIATRIC PRACTICE GUIDELINES

AMERICAN SOCIETY OF BARIATRIC PHYSICIANS
5600 S. Quebec Street
Suite 109A
Englewood, CO 80111
(303) 770-2526

Adopted 1974
Revised 1979, 1982, 1988, 1991, 1996

BARIATRIC PRACTICE GUIDELINES
American Society of Bariatric Physicians

These guidelines provide suggestions for the work-up and follow-up of the bariatric patient. They are not intended to replace, and indeed cannot replace, the bariatrician's judgement regarding a particular patient's treatment. Neither are they intended to represent legal requirements for providing "good medical practice." The bariatrician is the one most capable of determining what is or is not appropriate for an individual patient.

A. Initial Patient Work Up

The course of treatment should be based on the patient's history, physical examination, laboratory work and ECG (when indicated).

1. **History**
   A history of each patient should be taken and recorded. It should include an evaluation of dietary status, a weight history and a history of mental status. Whenever this is a self fill-in, or computerized history, or one taken by assistants, the bariatrician should personally evaluate significant positive responses and make appropriate notations.

2. **Physical Examination**
   The physical examination should include the following:
   a. Height, weight, blood pressure and pulse.
   b. Additional examinations should be done which are appropriate for the patient's age and state of health. Usually this would include examinations of the head, neck, thyroid, heart, lungs, abdomen and extremities. The patient's records should indicate the status of observations made.

3. **Diagnostic Studies**
   a. Laboratory Work:
      An "executive-type" profile including testing for thyroid function (TSH suggested) should be completed in addition to other laboratory work if indicated.
   b. Electrocardiogram:
      The bariatrician should consider the potential benefits of obtaining an electrocardiogram if there is past or present evidence of cardiac disease and if the patient has coronary risk factors such as hypertension, hyperglycemia, dyslipidemia or a strong family history of cardiac disease.
   c. Optional Tests:
      Body composition using skinfolds, infrared or impedance testing may be performed as additional testing. Other tests may be included at the discretion of the bariatrician.

4. **Patient Counseling**
   Appropriate counseling should be given to patients on proper eating habits, exercise, behavior modification, medications and other aspects of therapy, prior to and during the weight loss program.

When prior medical records can be obtained indicating any of the above procedures have recently been completed, the bariatrician may avoid unnecessary duplication by performing only those exams needed to complete the bariatric work-up.

5. **Return Visits**
   The bariatrician should provide adequate periodic follow-up and counseling for the patient.

B. Medications and Other Therapeutic Modalities

1. The bariatrician should weigh the potential benefits and risks of any medication or modality used. Significant sources of such information include journal articles, experience of colleagues, labeling, textbooks, The ASBP Anorectic Usage Guidelines and personal education, training and experience. Each of these sources may provide valuable information, and no single source should be used to the exclusion of others.

2. When appropriate, the bariatrician should provide information on the benefits and risks of the proposed treatment modalities to be used and should inquire as to the patient's understanding of the benefits and risks.

3. When medications are dispensed, they should be packaged and labeled in accordance with applicable laws and appropriate records should be kept.

C. Maintenance

A program, as developed by the individual bariatrician, should be provided for helping the patient in maintaining the weight loss that has been achieved.

Senate Concurrent Resolution No. XXXX

By Senator Praeger

A CONCURRENT RESOLUTION establishing a task force to study the accessability of personal records and information which are held in the public domain, and to determine the adequacy of current state law in protecting the privacy of individual citizens.

WHEREAS, the state has a vital interest in having access to certain personal information about individual citizens in order to carry out the necessary functions of government; and

WHEREAS, the state has an obligation to assure individuals that information gathered and held by the state through one of its agencies will only be used for intended and lawful purposes; and

WHEREAS, the growing use of computers to access information held in the public domain through the Internet has raised questions of confidentiality and privacy: Now, therefore

Be it resolved by the Senate of the State of Kansas, the House of Representatives concurring therein: That a task force be established to study the extent to which personal information is gathered and maintained in the public domain, the accessability and availability of such information to the public, the extent to which such information should be confidential and not subject to disclosure except for expressly intended purposes, the adequacy of current laws and regulations in protecting the privacy of individual citizens by limiting access to such information; and recommendations for legislative and regulatory changes to address the problem; and

Be it further resolved: That a task force be formed consisting of 9 members, three appointed by the Governor, two appointed by the president of the Senate, one appointed by the minority leader of the Senate, two appointed by the speaker of the House of Representatives, and one appointed by the minority leader of the House of Representatives. The Governor shall select one member to serve as chairperson; and

Be it further resolved: That the task force shall submit its report and recommendations to the Governor and the legislature on or before January 12, 1998.

Senate Public Health & Welfare
Date: 3-17-97
Attachment No. 3