

## **STATE BOARD NEWS -- AUGUST 1996 ISSUE**

### **LICENSE RENEWAL - (1996-1997)**

By the time you receive this Newsletter, you should have received the forms for renewal of your license to practice pharmacy in Ohio for 1996-1997. If you have not received the renewal forms, you should *immediately* contact the Board Office (614/466-4143). Your current license to practice pharmacy in Ohio expires on September 15, 1996 and an application for renewal must be received by the Board office prior to that date in order to continue to practice pharmacy in Ohio.

### **NEW SCHEDULE IV WEIGHT CONTROL MEDICATION - DEXFENFLURAMINE (REDUX™)**

The Board of Pharmacy has been inundated with requests for information about this new weight control medication from the public and from health professionals since news reports first appeared on TV and were published in major newspapers throughout the United States. The first inquiries were from the public and were about when and how they may obtain the drug.

The second wave of questions came from prescribers regarding when the drug would be on the shelves in pharmacies and available for dispensing to patients. Prescribers indicated that patients were requesting that the drug be prescribed for their use due to the news media reports.

Following the shipment of the drug product to pharmacies, the third wave of inquiries came from pharmacists and prescribers about whether or not the Medical Board rules applied to the use of this drug and, if so, how did they apply.

Pharmacy Board staff met with the prescribing committee of the State Medical Board on June 12, 1996 to discuss these issues and a "Compliance Bulletin" was issued to all pharmacists practicing in Ohio on June 17, 1996. **The State Medical Board rules apply to dexfenfluramine (Redux™) as long as it is a Schedule IV controlled substance** (OAC Rule 4731-11-04). As stated in Compliance Bulletin 96-003, the following information needs to be considered by pharmacists when dispensing dexfenfluramine for weight loss purposes in Ohio:

- (1) Currently, Redux™ is a Schedule IV controlled substance. Thus, it falls under the requirements of OAC Rule 4731-11-04.
- (2) A pharmacist may only dispense a fourteen-day supply of the drug. The approved package insert calls for a maximum dosage of 30mg per day. Thus, a pharmacist may dispense a total of 28 doses of the 15mg capsules every fourteen days.
- (3) A practitioner may not authorize refills. A new prescription, written or oral, must be issued after a reduction in weight is documented by the practitioner within every fourteen days.

- (4) The length of time that Redux™ may be prescribed is different than for fenfluramine and the other weight-reduction products. The package insert, official labeling approved by the FDA, indicates that Redux™ may be used for up to one year. Fenfluramine and the other diet products are only indicated for “a short period (a few weeks).”
- (5) In the Redux™ package insert, under “Precautions”, combination therapy with other weight-loss agents is not recommended. Thus, under OAC Rule 4731-11-04(B)(3), its use in combination with other weight-loss agents is not permitted.
- (6) The “Indications And Usage” section of the Redux™ package insert contains a height and weight chart showing which patients meet the standards of obesity for Redux™ therapy. Patients with BMI values of 30 or greater qualify. Patients with BMI of 27 to 29 may qualify for Redux™ therapy if they have a concomitant risk factor. While it is the physician’s responsibility to assure compliance with this guideline, pharmacists should be aware of its implications.

Since this is a new drug, pharmacists should read the package insert and familiarize themselves with Redux™ prior to dispensing. Due to the fact that this is a new product, most computer software programs will not provide information regarding the need for auxiliary labels, potential drug interactions, and factors to be taken into account when prescribed for obese patients with concomitant medical conditions such as diabetes, hypertension, or dyslipidemia.

The last paragraph of the compliance bulletin which was mailed to all practicing pharmacists in Ohio and is repeated above in this Newsletter states that: “*While it is the physician’s responsibility to assure compliance with this guideline, pharmacists should be aware of its implications*”. Practicing pharmacists should refer to previous issues of this newsletter where the concept of “corresponding responsibility” has been discussed. Previous newsletter articles have also pointed out the fact that prescriptions that have not been issued pursuant to the Medical Board rules and other federal and state laws and rules are not legal prescriptions. Accordingly, pharmacists filling such prescriptions do not have legal authorization to dispense a controlled substance.

Dispensing a controlled substance without a legal prescription is classified as “trafficking” in controlled substances pursuant to the provisions of Ohio Revised Code Chapter 2925. (Drug Crimes).

### **DISCIPLINARY ACTIONS**

The disciplinary actions listed below include only those where the individual’s license to practice has been suspended, revoked, or restricted, and does not include those actions where the individual’s license to practice has been placed on probation or has been reinstated without restrictions, or a monetary penalty imposed by the board.

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the licensing board which regulates that profession or activity, as follows:

State Dental Board (614/466-2580);  
State Medical Board (614/466-3934);  
State Nursing Board (614/466-3947);

State Optometry Board (614/466-5115);  
State Pharmacy Board (614/466-4143);  
State Veterinary Medical Board (614/644-5281);  
Drug Enforcement Administration (216/522-3705).

#### STATE PHARMACY BOARD:

##### *Order Effective 03/13/95:*

Penny Parnell, R.Ph.; Cambridge - Board refused to renew license, and registrant may not apply again for renewal prior to April 1, 2005.

##### *Orders Effective 04/29/96:*

Leon David Kessel, R.Ph.; Westerville - License suspended 90 days.

Jack R. Osman, R.Ph.; Vanceburg, KY - May not train pharmacy interns or be a preceptor, and may not serve as a responsible pharmacist for two years.

Joseph Claire Salmen, R.Ph.; Leetonia - License suspended indefinitely, and may not be employed by or work in a facility licensed by the Board while suspended.

Peter Pang-Yen Sung, R.Ph.; Centerville - License revoked.

Tom Louy Ambulance Service, T.D.; Waterville - Refused to renew license.

Vogelsongs Family Pharmacy, T.D.; Lucasville - Refused to renew license.

##### *Summary Suspension of Licenses:*

David Allen Ansell, R.Ph.; Vermilion - Effective 06/12/96.

William James Crane, R.Ph.; Loveland - Effective 06/12/96.

Robert J. Dougherty, R.Ph.; Urbana - Effective 06/12/96.

David Scott Herrmann, R.Ph.; Middletown - Effective 06/12/96.

Anthony Savoca, R.Ph.; Westlake - Effective 06/12/96.

#### STATE MEDICAL BOARD:

Kevin R. Berry, M.D.; Columbus - License summarily suspended - 04/18/96.

Emma L. Cintron, M.D.; Perrysburg - License suspended indefinitely - 03/14/96.

John M. Davis, M.D.; Hilliard - License summarily suspended - 04/18/96. License suspended indefinitely, minimum one year, and must immediately surrender DEA registration - 06/12/96.

William Harold Fiegenschuh, Jr., M.D.; Alliance - License suspended indefinitely - 03/13/96.

Larry Carl Kaye, D.P.M.; Mayfield Heights - License summarily suspended - 04/18/96.

Suresh Kolli, M.D.; Rocky River - License revoked - 08/22/95.

William Patrick Maher, D.O.; Westerville - License summarily suspended - 04/18/96.

Iqbal Nasir, M.D.; Bowling Green - License revoked - 04/19/96.

Michael Anthony Nowak, M.D.; Youngstown - Shall not prescribe, order, dispense, administer, or possess (except those prescribed for him by another authorized by law) any controlled substances without prior approval of Board - 04/17/96.

Dennis Paul Orr, D.O.; Canfield - License summarily suspended - 05/09/96.

William Anthony Price, M.D.; Boardman - License summarily suspended - 04/18/96.

Ronald Joseph Richter, M.D.; Cincinnati - License revoked - 03/04/96.

Harry A. Schutte, D.O.; Columbus - License revoked - 10/11/95.

Rajinder Singh, M.D.; East Liverpool - Shall not prescribe, dispense, or administer drugs to his family members or to himself, and shall not dispense, administer, or possess any controlled substances - 04/17/96.

Mattie L. Vaughn, M.D.; Cincinnati/Columbus - License revoked - 06/25/96.

James C. Ward, D.O.; North Olmsted - License revoked - 07/08/96.

Mark Aaron Weiner, D.O.; Toledo - Shall immediately surrender his DEA Certificate, and shall be ineligible to hold, and shall not apply for, registration with DEA to prescribe, dispense, or administer controlled substances without prior Board approval; May order, write orders for, give verbal orders for, dispense, or administer controlled substances under the DEA registration of the hospital or institution during the course of his residency - 04/17/96.

Frederick Benjamin Winston, M.D.; Cincinnati - License revoked - 04/17/96.

# # #