

**STATE BOARD NEWS -- AUGUST 1998 ISSUE**  
**(State Section Only)**

**LICENSE RENEWAL - 1998-1999**

By the time you receive this newsletter, you should have received the forms to renew your Ohio pharmacist or pharmacy intern license for 1998-1999. If you have not received them by August 15, 1998, contact the Board office immediately at 614/466-4143. Your current license to practice pharmacy in Ohio expires on September 15, 1998. The complete renewal application must be received at the Board office prior to that date so that you may continue to practice pharmacy in Ohio.

**OHIO JURISPRUDENCE C.P.E. PROGRAM BEING OFFERED IN TOLEDO AREA**

Four hours of Continuing Pharmacy Education credits, including one hour of Jurisprudence credit, will be provided by the Cincinnati Drug and Poison Information Center. DRUGS OF ABUSE AND THE HEALTH PROFESSIONAL: "AVOIDING THE PITFALLS" will be offered to pharmacists licensed in the State of Ohio. Speakers include Theodore Parran, M.D., Cleveland; Tim Benedict, R.Ph., Ohio Board of Pharmacy; William Schmidt, L.P.A., Ohio State Medical Board; and Sgt. John Burke, Cincinnati Police Pharmaceutical Diversion Squad.

The session will take place on Sunday, November 15, 1998 from 6:00 p.m. to 10:30 p.m. at the University of Toledo College of Pharmacy, Wolfe Hall, Room 1205. The registration fee is \$35.00. For more information, contact John Burke or Carol Guffey at 513/352-1610.

**DURACT® - APPROVED FDA LABELING, THE PATIENT, THE PRESCRIBER, AND THE PHARMACIST**

On June 22, 1998, a "voluntary recall" letter was sent to healthcare professionals by Wyeth-Ayerst for Duract® stating that the recall was due to "post marketing reports of severe hepatic failure, resulting in four deaths and eight liver transplants". The recall letter stated that the drug was "indicated for the short-term (10 days or less) management of acute pain". The recall letter further stated that:

... In February 1998, the company and the Food and Drug Administration agreed on labeling changes to further emphasize that DURACT should be used for 10 days or less. These changes were initiated in response to earlier reports of serious events associated with longer-term use.

Although the revised labeling reduced the number of prescriptions of longer duration and the reports of severe liver events, it did not eliminate them," says Dr. DeVane. "The company has now concluded that further steps to limit use of a potent NSAID pain reliever such as DURACT to just 10 days would not be feasible or effective. In light of

these circumstances, as well as the availability of other therapies, Wyeth-Ayerst has decided to withdraw the product.

On Wednesday, June 24, 1998, a patient called the Board office and alleged that her physician, a neurosurgeon, had prescribed this drug to her for a period of six months and had ceased to prescribe it several months ago. The patient alleged that the doctor simply stated when asked why he would no longer prescribe the drug that "it was an experimental drug and that she couldn't have any more".

Newspaper reports in June 1998 indicating that the drug had been withdrawn from the market caused the patient to contact the manufacturer and request that they pay for a "liver test". The manufacturer's representative told her that her problem was with the prescriber and that the drug was never meant to be used for chronic pain - only for use by dentists when extracting teeth.

The patient was upset to learn that the drug had been prescribed and dispensed to her for a period exceeding the ten days as documented in the official labeling approved by the Food and Drug Administration. Her physician was treating her for chronic back pain and she was never informed by the prescribing physician or dispensing pharmacist that the drug was being prescribed "off-label" with the potential of causing severe hepatic failure.

Where did the health care system fail? Why was this patient subjected to the risk of serious liver damage without having been involved in the decision as to whether or not she should take the risk of using this medication for chronic back pain? The patient alleges that she was not counseled by the dispensing pharmacist or practitioner regarding the use of this drug.

What were the compelling reasons for FDA approving this high-risk drug for marketing? Do warnings required by the FDA and agreed to by the manufacturer for high risk drugs affect the way physicians prescribe such drugs when legislation has been enacted allowing physicians to prescribe drugs for unapproved uses as does official FDA policy? Do prescribers really know what's on the official FDA labels?

The official labeling approved for Duract® by the FDA and included in the 1998 PDR states the following:

## **WARNINGS**

### **HEPATIC EFFECTS**

Elevations of one or more liver tests may occur during DURACT therapy. ....  
Short-term management of pain should generally be less than ten days duration.  
Because hepatotoxicity may develop without a prodrome of distinguishing symptoms, if a physician chooses to administer DURACT for a longer duration, the patient's transaminases, particularly ALT, should be monitored for evidence of hepatotoxicity after 4 weeks.

Since the prescriber decided to use the drug off-label for chronic pain, was this done, and if not, why not?

With an increasing number of high-risk drugs being approved for marketing by FDA and FDA's reliance on the warning section of the official labeling to protect the patient, it is impor-

tant that pharmacists counsel patients on the safe and effective use of these drugs. It is also important that if such drugs are being used off-label that the pharmacist discusses such uses of the drug with the prescriber and what must be done to protect the patient from harm. Patients should also be involved in the decision as to whether or not a high-risk drug prescribed off-label should be used.

## **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:**

### *Settlement Agreements Effective 03/09/98:*

Sarah Anne Hudson-DiSalle, R.Ph.; Columbus - May not be a preceptor or train pharmacy interns for two years.

Mary Elizabeth Starr, R.Ph.; Gahanna - License suspended indefinitely and may not be employed by or work in a facility licensed by the Board while suspended.

### *Settlement Agreements Effective 03/11/98:*

Brent Douglas Salisbury, R.Ph.; Madison - May not be a preceptor or train pharmacy interns for two years.

Thomas W. Schultz, R.Ph.; Geneva - May not be a preceptor or train pharmacy interns for two years.

### *Settlement Agreements Effective 04/06/98:*

Matthew Earl Fisher, R.Ph.; Columbus - License suspended indefinitely and may not be employed by or work in a facility licensed by the Board while suspended.

Joann P. Waltz Golden, R.Ph.; Franklin, TN - May not be a preceptor or train pharmacy interns for two years.

Mary P. Maloof, R.Ph.; Westlake - May not be a preceptor or train pharmacy interns for

two years.

John Thomas Millward, R.Ph.; Valley City - May not be a preceptor or train pharmacy interns for two years.

Elizabeth A. Petit, R.Ph.; Strongsville - May not be a preceptor or train pharmacy interns for two years.

*Orders Effective 04/13/98:*

Rodney Allen Keller, R.Ph.; Tiffin - License suspended indefinitely, minimum six months, and may not be employed by or work in a facility licensed by the Board while suspended.

Larry Devonne Shaffer, Jr., R.Ph.; Uhrichsville - License suspended indefinitely, minimum twelve months, and may not be employed by or work in a facility licensed by the Board while suspended.

*Settlement Agreement Effective 05/04/98:*

Ronald James Marinelli, Jr., Pharmacy Intern; Columbus - License revoked and may not be employed by or work in a facility licensed by the Board.

*Orders Effective 05/14/98:*

Laurence Robert Cappel, R.Ph.; Grand Blanc, MI - License renewal refused.

William John Hocevar, Jr., R.Ph.; Madison - License revoked.

John Paul Tekulve, R.Ph.; Cincinnati - License suspended indefinitely and may not be employed by or work in a facility licensed by the Board while suspended.

*Summary Suspension of Licenses:*

Mary Berk-Mortus, R.Ph.; Strongsville - Effective 06/16/98.

Gregory G. Korte, R.Ph.; Miamisburg - Effective 04/06/98.

Michael David Perciful, R.Ph.; Mount Vernon - Effective 04/07/98.

John Paul Tekulve, R.Ph.; Cincinnati - Effective 01/27/98.

**STATE MEDICAL BOARD:**

*[A more detailed history is available on the Internet at: <http://www.state.oh.us/med/> then click on the License On-line Lookup box, then follow the instructions.]*

Nader Afrooz, M.D.; Youngstown - License revoked - 03/13/98.

Jose Benutto, M.D.; Waverly - License permanently retired - 03/01/98.

Patricia Joan Bonitatibus, M.D.; Wheeling, WV - License revoked - 10/15/97.

Douglas Paul Bosack, M.D.; Toledo - License suspended indefinitely, minimum three months - 05/13/98.

Eugene Allan Brewer, M.D.; Sayre, PA - License suspended indefinitely, minimum 3 months - 11/19/97.

Arthur C. J. Brickel, M.D.; Beachwood - License suspended, minimum three months - 12/31/97.

Paul P. Chu, M.D.; Dayton - License suspended indefinitely - 02/11/98. License reinstated 04/09/98.

Juan J. Cruz, M.D.; Wapakoneta - License revoked - 11/04/97.

Richard Graham Day, M.D.; Cambridge - License suspended, minimum three months - 11/12/97. License reinstated; may prescribe but shall not administer, dispense, order (except by written or verbal patient-specific orders), or possess any controlled substances - 04/09/98.

Howard E. Fagan, M.D.; Cleveland - License revoked - 12/17/97.

Steve M. Friday, D.P.M.; Bellbrook - License reinstated; ineligible to hold, and shall not apply for, registration with the D.E.A. to prescribe, dispense, or administer controlled substances without prior Board approval, and shall not be permitted to order, write orders for, give verbal orders for, dispense, or administer controlled substances under the D.E.A. registration of the hospital or institution in which he is employed, is training, and/or has privileges - 04/09/98.

John Brennehan Gardiner, D.O.; Columbus - License revoked effective 03/22/96; Must immediately cease prescribing controlled substances and is ineligible to treat new patients - 02/20/96.

Thomas L. Geraci, D.P.M.; Hilliard - License reinstated; must surrender his D.E.A. registration immediately, and shall be ineligible to hold, and shall not apply for, registration with the D.E.A. to prescribe, dispense, or administer controlled substances without prior Board approval - 03/11/98.

Wayne L. Harrison, M.D.; Cincinnati - Pre-hearing suspension effective 03/12/98.

Ahmad Hosseinipour, M.D.; Youngstown - License revoked - 02/24/98.

Larry Carl Kaye, D.P.M.; Cleveland - License revoked - 03/14/97.

Benjamin Paul Kelch, D.O.; Columbus - License summarily suspended - 02/14/98. License suspended indefinitely, minimum of three years - 05/13/98.

Alfred George Ernest Kitchen, M.D.; Vermillion - License revoked - 11/20/97.

Paul Edward Kleffner, D.O.; Columbus - License suspended for 22 months from 07/01/96 and, upon reinstatement, license is permanently limited to restrict doctor's practice to chart review and rendering opinions as to disability or impairment; shall immediately surrender his D.E.A. Certificate, shall be ineligible to hold, and shall not apply for, registration with the D.E.A. to prescribe, dispense, or administer controlled substance, shall not prescribe, administer, dispense, order, write orders for, or give verbal orders for any controlled substances, and shall not be permitted to order, write orders for, give verbal orders for, dispense, or administer controlled substances under the D.E.A. registration of the hospital or institution in which he is employed, is training, and/or has privileges - 04/09/98. License reinstated with above restrictions - 05/01/98.

Kenneth Kerwood Kline, M.D.; Lancaster - May prescribe but shall not administer, dispense, order (except by written or verbal patient-specific orders), or possess any controlled substances - 04/09/98.

Peter Yule Leonardson, M.D.; Defiance - License permanently retired - 02/11/98.

John Samuel McDonald, M.D.; Columbus - Shall not prescribe, administer, dispense, order, write orders for, or give verbal orders for, any controlled substances for himself or for any family member for a minimum of two years- 04/09/98.

James Brickley McGriff, D.O.; Degraff - License suspended indefinitely, minimum six months - 05/13/98.

Frederico Santos Medina, Jr., M.D.; Pepper Pike - License permanently retired - 12/03/97.

Bradford James Murphy, D.O.; Kettering - License suspended indefinitely, minimum ninety days - 05/13/98.

John C. O'Bell, M.D.; Okemos, MI - License revoked - 05/13/98.

Dennis Paul Orr, D.O.; Canfield - License revoked - 01/16/97.

Susan Lillian Osova, M.D.; Boardman, OH/Arden Hills, MN - Automatic suspension effective 02/27/97.

Paul Edward Pancoast, M.D.; Toledo - Pre-hearing suspension effective 10/09/97. License suspended indefinitely, minimum two years retroactive to October 8, 1997 - 04/13/98.

James Nicholas Passias, D.O.; Columbus - License revoked - 02/12/98.

Joseph Martin Pastor, M.D.; Newbury/Cleveland Heights - License suspended indefinitely - 12/03/97. License reinstated - 01/14/98.

Mansour Phalsaphie, M.D.; Henderson, KY - License revoked - 02/11/98.

Kolli Mohan Prasad, M.D.; Boardman - License suspended indefinitely, minimum three years - 03/12/98.

Howard E. Rissover, M.D.; Cincinnati - License revoked - 11/20/97.

Mark Kevin Roders, M.D.; Hudson - License suspended indefinitely - 10/09/97.

Laura Rosenbaum-Bloom, M.D.; Cincinnati - License suspended from 12/20/97 to 01/19/98.

Gary Evan Sivak, M.D.; Elyria - License suspended indefinitely, minimum ninety days; Must immediately surrender DEA license - 04/09/98.

Terrance E. Smith, M.D.; Westerville - License suspended indefinitely, minimum thirty days - 01/05/98. License reinstated - 02/04/98.

Clifford Michael Sonnie, M.D.; Medina - Pre-hearing suspension effective 12/04/97. License suspended indefinitely, minimum two years, retroactive to 12/03/97 - 06/09/98.

Samuel Varghese, M.D.; Cincinnati - License permanently retired - 09/24/97.

Paul Richard West, D.O.; Marietta - May not possess, order, or dispense controlled substances without prior Board approval - 11/12/97.

Herman Samuel Yassall, D.O.; Brookfield - License suspended indefinitely, minimum one year - 04/09/98.

Thomas Anthony Zoldowski, D.P.M.; Toledo - Shall refrain from self-prescribing and from prescribing to any family member for five years- 05/19/98.