



ALABAMA BOARD OF MEDICAL EXAMINERS **NEWSLETTER**

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DEA Describes Policy On Importing Controlled Drugs

The following is a portion of a policy statement made by Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency in testimony to Congress on June 7, 2001.

The US law pertaining to illicit controlled substances is contained in the Controlled Substances Act of 1970 (CSA). Enforcement of the CSA is the responsibility of the DEA. The Food and Drug Administration (FDA) also plays a critical role with regard to controlled substances. As the Federal authority for regulating all controlled and non-controlled prescription drugs from a health and safety perspective, the FDA's authority is contained in the Food, Drug and Cosmetic Act (FDCA). Thus, controlled substances are subject to regulation by both the FDA and the DEA. Together, the FDCA and the CSA provide a framework to protect the health and safety of the American public, and collaboratively, DEA and FDA strive for consistent application of Federal laws. Additionally, the United States Customs Service is responsible for enforcing the import and export provisions of the CSA at US land borders.

The CSA contains a personal medical use exemption to allow international travelers, both US citizens and others, to enter and leave the US with controlled substances for their legitimate personal medical use. Specifically, Section 956(a) of the CSA, entitled "Exemption Authority, Individual Possessing Controlled Substance," states that the "Attorney General may by regulation exempt from sections 952(a) and (b), 953, 954 and 955 of this title any individual who has a controlled substance (except substances in Schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes a declaration (or gives such other notification) as the Attorney General may by regulation require."

This exemption is consistent with the 1971 Convention on Psychotropic Substances. Article 4 (a) of the Convention states, with respect to psychotropic substances other than those in Schedule I, parties may permit: "The carrying by international travellers of small quantities of preparations for personal use; each Party shall be entitled, however, to satisfy itself that these preparations have been lawfully obtained[.]" The official commentary to the treaty explains the purpose of this provision: "[This provision] applies only to small quantities needed for personal use, i.e. to such quantities as the traveller may require during his journey or voyage and until

he is able to provide himself with the medicine in question in the country of destination... In view of the express provision that each Party (i.e. the countries of transit and destination) is entitled to satisfy itself that the preparations have been lawfully obtained, it would be useful to require the traveller to carry a medical prescription or in cases in which the prescription is withheld by the pharmacist, a duplicate or satisfactory copy of the prescription showing that the preparations have been lawfully acquired."

Clearly, the treaty seeks to provide a means to allow international travelers to carry personal use quantities of controlled substance medications while visiting foreign countries. The CSA exemption does the same; however, neither the treaty nor US statutes permit controlled substances to be imported under the personal medical use provision via overnight courier, unaccompanied baggage, parcel service, US or international mail. Nor does the exemption permit one person to enter or depart the US with controlled substances intended for the personal medical use of another person.

As set forth in the DEA regulation on this issue, 21 CFR Section 1301.26, anyone who seeks to import a controlled substance for personal medical use must satisfy all of the following requirements:

- (a) The controlled substance is in the original container in which it was dispensed to the individual; and
- (b) The individual makes a declaration to an appropriate official of the US Customs Service stating:
 - 1) The controlled substance is possessed for his/her personal use, or for an animal accompanying him/her;
 - 2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or if such does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any; and
- (c) The importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.

The "Controlled Substances Trafficking Prohibition Act" ("the Act") (Pub. L. 105-357), was introduced in the US House of Representatives on April 1, 1998, to amend the Personal Medical Use Exemption. It was signed into law by the President on November 10, 1998. The Act addressed the fact that large quantities of controlled substances were being brought into the US from Mexico by individuals misusing the exemption in order to divert pharmaceutical controlled substances into illicit channels. The bill amended the CSA to prohibit any US resident from entering the US with more

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DEA Describes Policy

than 50 dosage units of a controlled substance through a land border crossing with Mexico or Canada unless they demonstrate that they possess a valid prescription for the substance, issued by a properly licensed US physician. This does *not* mean that any US resident may enter the United States with up to 50 dosage units of a particular controlled substance “no questions asked.” Rather, the resident must satisfy all the requirements set forth in 21 CFR 1301.26. States may impose additional requirements as well.

For example, if there is evidence that the drugs are not for legitimate personal medical use (e.g., the same person has made repeated attempts over a short time period to import new packages of controlled substances for claimed personal medical use; or the person has a variety of different controlled substances under circumstances that are indicative of diversion), the importation does not comply either with §956(a)(1) nor the DEA regulations and must, therefore, be disallowed.

Furthermore, the requirement specified in 21 CFR 1301.26(c) - that the importation for personal medical use is authorized or permitted under other Federal laws and state law - must be satisfied regardless whether the person importing is a US resident with no more than 50 dosage units of a controlled substance. For example, if a person were seeking to import a particular controlled substance for personal medical use, and the Food and Drug Administration advised the United States Customs Service that importation of the drug should be disallowed under the Food, Drug, and Cosmetic Act, the importation would not comply with 21 CFR 1301.26(c) and would have to be denied.

In the same way, if a person sought to import a controlled substance for purported personal medical use when entering the United States in a border state that prohibits either the importation or possession of the controlled substance, such importation must be disallowed under 21 CFR 1301.26(c).

Since the passage of the Act, DEA has received information from the United States Customs Service that indicates that individuals are circumventing provisions of the Personal Medical Use Exemption by making repeated trips across the border to obtain controlled substances. DEA is currently considering ways of addressing this problem, such as amending DEA's regulations to provide the clarity and guidance that the Customs Service needs to develop a clear, concise and enforceable policy for its inspectors at the Nation's land borders. ■

Ultram® Abuse and Dependence Among Health Professionals

Gregory E. Skipper, M.D., FASAM, Medical Director
Alabama Physician Health Program

Tramadol, Ultram®, despite its low abuse potential, poses some risk for health professionals. Because of numerous case reports of abuse of this drug among physicians, the State of Alabama Medical Licensure Commission requested in February 2001 that the State Board of Health consider adding Ultram to the schedules of controlled substances. In May of 2001 the Controlled Substances Advisory Committee met to review this issue. It was the third time this committee has met to consider this drug since 1996.

Tramadol has been available in the United States as an uncontrolled prescription analgesic since 1995. Tramadol is

in the top 50 most prescribed drugs¹ and it has been heavily detailed and marketed to physician's offices. It is a centrally acting oral analgesic that has both opioid activity and monoamine reuptake inhibition. While the mode of action of Tramadol is not completely understood, animal studies suggest that these two complementary mechanisms appear applicable: binding of parent and M1 metabolite to mu opioid receptors and weak inhibition of the reuptake of norepinephrine and serotonin. This mu opioid receptor that is bound by Tramadol is the euphorogenic receptor associated with addictive potential. Tramadol appears to be a full agonist (i.e., it has no antagonist properties).

Prior to the release of Tramadol, the Food and Drug Administration, FDA, and its Drug Abuse Advisory Committee, DAAC, considered at length its abuse potential in order to comply with the Controlled Substances Act regarding whether to recommend that it be scheduled as a controlled substance. Tramadol had an acknowledged potential for abuse based upon: (1) reports from Europe of abuse, where Tramadol had been available for years², (2) its mode of analgesic action involving the stimulation of opiate mu receptors, and (3) a concern regarding the history of other similar opiate analgesics being initially introduced in the United States as “non-addictive” and later being found to have serious abuse problems requiring subsequent scheduling (e.g., Darvon, Stadol, Talwin, and others). However, despite these concerns, because the abuse potential appeared relatively low, based upon available information at that time, Tramadol was not scheduled, and a “wait and see” policy was adopted.

Twenty-seven physicians referred to the Alabama Physician Health Program for substance related disorders since 1996 have given histories that included abuse of Tramadol. Several patterns of abuse are noted among physicians: primary Tramadol dependence, Tramadol relapse, and Tramadol substitution. Primary Tramadol dependence includes cases where Tramadol was the initial drug of choice, the sole drug of use, or was a significant part of an initial episode of a drug dependence syndrome. Tramadol relapse includes cases where an individual was in recovery from previous addiction but relapsed to addictive use involving Tramadol. Tramadol substitution involves individuals who switch to Tramadol in an effort to change from a more addictive and potent drug to Tramadol. If Tramadol is substituted for a more potent opiate analgesic, there is a tendency to increase the dose until an equivalent therapeutic effect is attained. This is hazardous, as there is significant potential for seizures with Tramadol when the dose is increased.

When the incidence of abuse and dependence of Tramadol among health professionals is examined there appears to be a much higher rate among this group than among the general population. It has been suggested that health professionals are the “point men” who demonstrate abuse and dependence with new prescription drugs prior to problems in the general public. According to physicians who have developed dependence, availability and false reassurance regarding risk may be factors that have increased the chance of inappropriate use and dependence.

According to the Drug Abuse Warning Network (DAWN) study in 1999 there were 1113 estimated ER episodes involving Tramadol as compared to 1313 for Hydromorphone and 512 for Meperidine. In Cincinnati a study of Tramadol³ found that there were 362, 107, 515, and 326 Tramadol abuse calls in 1995, 1996, 1997, and 1998, respectively, to the Drug and Poison Information Center.

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Ultram® Abuse

The Cincinnati police documented diversion of 7,258 doses of Tramadol from 9/97–12/97 and 11,385 doses in 1998. Tramadol was listed in the top 10 diverted prescription drugs. Their conclusion was that physicians need to consider the abuse potential and monitor patients for dependence and that tighter controls need to be considered.

The manufacturer has aggressively marketed this drug and many physician offices contain samples supplied by the drug company. Because the drug is not scheduled, its supply and storage as a sample is not constrained as are scheduled drugs. The low or absent abuse potential is mentioned frequently by drug salespersons, and the drug is compared to nonsteroid antiinflammatory drugs with regards to its use and risk. Tramadol is not a non-steroidal anti-inflammatory drug (NSAID) and has no anti-inflammatory activity.

The package insert has been upgraded three times regarding the abuse potential of the drug since it was released. The current warning is: "Cases of abuse and dependence on TRAMADOL have been reported. TRAMADOL should not be used in opioid-dependent patients. Since TRAMADOL can reinstate physical dependence, it is not recommended for patients with a tendency to drug abuse, a history of drug dependence, or chronically using opioids." The problem is that often we do not know who has "a tendency to drug abuse!"

Concluding its deliberation, the Alabama Controlled Substances Advisory Committee decided not to recommend scheduling Tramadol at this time. Instead, they decided to continue to study the issue of Tramadol abuse and requested that the drug company participate in educational efforts to decrease risk of abuse of this drug in Alabama. Tramadol abuse and dependence is a risk for health professionals and they should be aware of this risk and use this drug with care.

¹ www.RxList.com

² Richter W, Barth H, Flohe L, Giertz H (1985) Clinical investigation on the development of dependence during oral therapy with Tramadol. *Arzneimittelforschung* 35:1742-1744

³ Krummen K, Nelson E, Tsipis G, Siegel E, Bottei E. Cincinnati Drug and Poison Information Center, Children's Hospital Medical Center, Cincinnati, OH■

Alabama Board of Medical Examiners PUBLIC ACTIONS April - June 2001

On April 18, 2001, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of Tad R. Connine, M. D., license number 22898, La Plata MD. Dr. Connine is no longer authorized to practice medicine in Alabama.

On April 18, 2001, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of Jerry H. Crump, M. D., license number 13179, Enterprise AL. Dr. Crump is not authorized to practice medicine in Alabama.

On May 16, 2001, the Board accepted the voluntary surrender of the Alabama Controlled Substances Certificate of Morgan Jackson Moore, M. D., license number 1272, Andalusia AL. Dr. Moore is no longer authorized to prescribe controlled substances in Alabama.

On May 16, 2001, the Board accepted the voluntary sur-

render of the certificate of qualification and license to practice medicine in Alabama of Carl A. Hyman, M. D., license number 16977, Mobile AL. Dr. Hyman is not authorized to practice medicine in Alabama.

On June 27, 2001, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of Winston Ellis Bradley, Jr., M. D., license number 10292, Jasper AL. Dr. Bradley is no longer authorized to practice medicine in Alabama.

On June 27, 2001, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of Glenn R. McDaniel, Jr., M. D., license number 15251, Birmingham AL. Dr. McDaniel is no longer authorized to practice medicine in Alabama.

On June 27, 2001, the Board accepted the voluntary surrender of the Alabama Controlled Substances Certificate of Charles David Quarles, M. D., license number 11755, York AL. Dr. Quarles is no longer authorized to prescribe controlled substances in Alabama.

On June 27, 2001, the Board accepted the voluntary restriction on the certificate of qualification and license to practice medicine in Alabama of Daryl A. Ellis, M. D., license number 18084, Columbus GA, which provides for monitoring by the Board of his health status.■

Medical Licensure Commission PUBLIC ACTION REPORT April – July 2001

On March 28, 2001, the Medical Licensure Commission entered an order which temporarily suspended the Alabama medical license of James Frederick Graves, Jr., M.D., license number 16215.

On April 9, 2001, the Medical Licensure Commission entered an order which issued to Marcus Edward Ward, M.D., license number 11178, a reprimand, assessed an administrative fine in the amount of \$1,000, and required Dr. Ward to obtain additional continuing medical education for the year 2001.

On April 11, 2001, the Medical Licensure Commission entered an order which revoked the Alabama medical license of Joseph Ayer Beckwin, M.D., license number 12480.

On April 11, 2001, the Medical Licensure Commission entered an order which revoked the license to practice medicine of John Elliot Polson Sams, D.O., license number DO-262.

On April 25, 2001, the Medical Licensure Commission issued an order which temporarily suspended the Alabama medical license of Ricky Joe Nelson, M.D., license number 12557.

On April 25, 2001, the Medical Licensure Commission entered an order which temporarily suspended the Alabama medical license of Carl A. Hyman, M.D., license number 16977.

On April 25, 2001, the Medical Licensure Commission entered an order which dismissed the Administrative Complaint filed by the Board of Medical Examiners against Jerry Henry Crump, M.D., based upon Dr. Crump's voluntary surrender of his Alabama medical license, license number 13179.

On April 25, 2001, the Medical Licensure Commission entered an order which dismissed the Administrative Complaint filed by the Board of Medical Examiners regard-

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MLC Public Actions *continued*

ing the withdrawal of the application for reinstatement of the Alabama medical license of Philip Anderson Miller, M.D., license number 5898.

On April 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent which issued a reprimand and assessed an administrative fine to Janet McBarron, M.D., license number 17602.

On April 25, 2001, the Medical Licensure Commission entered an order which revoked the medical license of Pascual Herrera, Jr., M.D., license number 13663.

On May 7, 2001, the Medical Licensure Commission entered an order which issued to Steven Mark Hayden, M.D., license number 13468, a reprimand and assessed an administrative fine in the amount of \$6,000.00.

On May 23, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$5,000.00. to Sam C. West, Jr., M.D., license number 8923.

On July 6, 2001, the Medical Licensure Commission entered an Order which placed on probation, in compliance with Mississippi, the medical license of Steven Morris, III, M.D., license number 22674.

On July 9, 200, the Medical Licensure Commission revoked the Alabama medical license of James Frederick Graves, Jr., M.D., license number 16215.

On July 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$2,500.00 to Jay W. Ripka, M.D., license number 14557.

On July 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$2,500.00 to Harold Walker Brown, M.D., license number 2992, based upon his noncompliance in obtaining annual continuing medical education.

On July 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$2,500.00 to Kendal Irwin Foster, M.D., license number 12209, based upon his noncompliance in obtaining annual continuing medical education.

On July 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$2,500.00 to Michael Jude Naughton, M.D., license number 12757, based upon his noncompliance in obtaining annual continuing medical education.

On July 25, 2001, the Medical Licensure Commission entered a Stipulation and Consent Order which issued a reprimand and assessed an administrative fine in the amount of \$2,500.00 to Chudy Nathaniel Okoye, M.D., license number 7286, based upon his noncompliance in obtaining annual continuing medical education. ■

Pain, Opioids & the Law

Fall 2001 Schedule

September 21 - Mobile Country Club

September 28 - Dothan Country Club

September 29 - Montgomery Museum of Fine Arts

October 27 - Huntsville, Location to be announced

Speakers to include:

Sandra Durham, M.D.

Sandra Frazier, M.D.

Larry Lockhart, DEA

Ed Munson, Alabama BME

Call 800-239-6441

for registration information

Alabama Board of Medical Examiners NEWSLETTER is published quarterly for physicians who hold a license to practice medicine or osteopathy in the state of Alabama. The newsletter is designed to keep the licensed physicians of Alabama updated as to developments in the regulation of the practice of medicine in this state. The Board welcomes your comments, questions or other input.

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