CR 85-209

CERTIFICATE

STATE OF WISCONSIN)

) SS

CONTROLLED SUBSTANCES BOARD)

I, June L. Dahl, Ph.D., Chairman of the controlled substances board and custodian of the official records of said board, do hereby certify that the annexed rule, relating to the classification of buprenorphine, methaqualone and dronabinol in the uniform controlled substances act was duly approved and adopted by this board on February 19, 1986.

I further certify that this copy has been compared by me with the original on file in this board and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand at the Medical Sciences Center in the city of Madison, this 15th day of July, 1986.

June L. Dahl

June L. Dahl, Ph.D., Chairman

9/86

ORDER OF
THE CONTROLLED SUBSTANCES BOARD
ADOPTING RULES

Relating to changes in classification of controlled substances in the schedules of chapter 161, the uniform controlled substances act.

Analysis prepared by the controlled substances board:

The controlled substances board is changing the classification of buprenorphine, methaqualone, and dronabinol to conform Wisconsin law to federal law.

1. Buprenorphine

According to state law s. 161.11(4), stats., if any substance is rescheduled under federal law, the controlled substances board shall take similar action to reschedule the substance, unless it objects.

On February 28, 1985, the drug enforcement administration published a final rule, 50 FR 8104, transferring buprenorphine from schedule II to schedule V of the federal controlled substances act, effective throughout the U.S. on April 1, 1985. Buprenorphine was in schedule II of the CSA by virtue of its derivation from thebaine. Buprenorphine is an analgesic which will continue to be classified as a narcotic drug. The DEA took this action upon receipt of a letter from the department of health and human services recommending that buprenorphine be rescheduled to schedule V, to be consistent with its potential for abuse and with its approval by the food and drug administration in 1982 of a new drug application. An approved NDA is a prerequisite to marketing any new drug for therapeutic purposes in the United States.

In making the decision to reschedule buprenorphine into schedule V, the DEA found that:

1. Buprenorphine has a low potential for abuse relative to the drugs or other substances in schedule IV.
2. Buprenorphine has a currently accepted medical use in treatment in the U.S.
3. Abuse of buprenorphine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

The controlled substances board did not object to placement of buprenorphine in schedule V within the 30-day period specified in s. 161.11(4), stats. On September 18, 1985, the controlled substances board reviewed and concurred in the findings of the federal government with respect to buprenorphine. A public hearing was held on February 19, 1986. No testimony was offered.

While the board has in the past and may in the future exercise authority to require a different level of control over a substance than required by the federal government, the board has no reason to differ with placement of

buprenorphine in schedule V of the uniform controlled substances act at this time.

2. Methaqualone

According to state law, s. 161.11(4), stats., if any substance is rescheduled under federal law, the controlled substances board shall take similar action to reschedule the substance, unless it objects.

On August 27, 1984, the drug enforcement administration published a final rule, 49 FR 33870, rescheduling the depressant drug methaqualone from schedule II to schedule I of the federal controlled substances act, effective on the date of publication. This rule was promulgated to comply with public law 98-329 which requires the attorney general to reschedule methaqualone and the secretary, department of health and human services to withdraw approval of the new drug application for methaqualone.

The controlled substances board declined to object to transfer of methaqualone to schedule I within the 30-day period specified in s. 161.11(4), stats. On December 5, 1984, the controlled substances board reviewed and concurred with the findings of the federal government with respect to methaqualone. A public hearing was held on February 19, 1986. No testimony was offered.

While the board has in the past and may in the future exercise authority to require a different level of control over a substance than required by the federal government, the board has no reason to differ with placement of methaqualone in schedule I of the uniform controlled substances act at this time, and is promulgating CSB 2.17 to accomplish the change. It is noted, however, that while the board found that methaqualone met the statutory tests for transfer to schedule I, the board expressed several concerns with respect to the process that brought about the change in federal scheduling. A record of these concerns are contained in the summary of proceedings, controlled substances board, October 17, 1984.

3. Dronabinol

According to state law s. 161.11(4), stats., if any substance is rescheduled under federal law, the controlled substances board shall take similar action to reschedule the substance, unless it objects.

On October 18, 1985 the drug enforcement administration published a proposed rule, 50 FR 42186, rescheduling synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules from schedule I to schedule II. Dronabinol is the synthetic equivalent of the isomer of delta-9-tetrahydrocannabinol, or THC, which is the principal psychoactive substance in marijuana. This action follows the May 31, 1985 approval of a new drug application by the food and drug administration. FDA approval enables a new drug to be marketed for therapeutic purposes, and establishes that it has an accepted medical use in treatment in the U.S. When a schedule I drug is approved by FDA, it becomes eligible for transfer to lower schedules. Marketing of such a product is delayed until the federal and state scheduling changes are made.

On December 5, 1985 the controlled substances board reviewed and concurred with the proposed conclusions of the federal government with respect to dronabinol, and made the following findings:

1. Dronabinol has a high potential for abuse; and

2. Dronabinol has currently accepted medical use in treatment in the United States.

3. The abuse of dronabinol may lead to severe psychic or physical dependence.

Further, the controlled substances board recognized that some Wisconsin citizens who are cancer chemotherapy patients currently receive THC in an investigational program sponsored by the national cancer institute and licensed by the board under s. 161.335, stats. The board has evaluated both this program and the FDA summary basis of approval, and has concluded that this form of THC is useful in the treatment of nausea and vomiting which is refractory to other antiemetic treatments, and that the availability of this form of THC is in the public interest and should be continued. Because the NCI THC program will be withdrawn after dronabinol is placed in federal schedule II, the board promulgated this proposed rule prior to receipt of a final order rescheduling dronabinol under federal law in order to reduce unnecessary delays in marketing dronabinol in Wisconsin and to eliminate possible disruption in supply to cancer patients.

On February 19, 1986, a public hearing was held. No testimony was offered.

On May 13, 1986, the drug enforcement administration published a final rule 51 FR 17476, transferring FDA approved dronabinol products from schedule I to schedule II.

Pursuant to authority vested in the controlled substances board by S.161.11(4), stats., the board hereby adopts CSB 2.17 Wis. adm. code relating to buprenorphine, methaqualone and dronabinol as follows:

Chapter CSB 2.17. Addition of buprenorphine to schedule V; transfer of methaqualone from schedule II to schedule I; transfer of dronabinol from schedule I to schedule II.

SECTION 1. Subsection (1m) of section 161.22, stats., is adopted to read:

(1m) Narcotic drugs. Unless specifically excepted under federal regulations or unless listed in another schedule, any quantity of the following substances or their salts, isomers or salts of isomers, if salts, isomers or salts of isomers exist under the specific chemical designation.

(a) Buprenorphine

SECTION 2. Paragraph (b) of s. 161.14(5), stats., is adopted to read:

(b) Methaqualone

SECTION 3. Subsection (7)(am) of s. 161.16, stats., is repealed.

SECTION 4. New subsection (10)(a) of s. 161.16, stats., is adopted to read:

(10) Hallucinogenic substances.

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. food and drug administration approved drug product. (Other names for dronabinol are (6aR-trans)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo(b,d)pyran-1-01, or (-)-delta-9-(trans)-tetrahydrocannabinol.)

The rules and repeals contained in this order shall take effect on the first day of the month following it's publication in the Wisconsin administrative register.

Dated: July 15, 1986

June L. Dahl

June L. Dahl, Ph.D.
Chairman
Controlled Substances Board