CR 87-108

CERTIFICATE

STATE OF WISCONSIN)
)SS
CONTROLLED SUBSTANCES BOARD)

I, the Chairperson of the Controlled Substances Board and custodian of the official records, certify that the annexed rule relating the classification of substances in chapter 161, the uniform controlled substances act, was duly approved and adopted by this board on September 16, 1987. I further certify that this copy has been compared by me with the original on file in this board and that it is a true copy of the original, and of the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand at the University of Wisconsin Medical Sciences Center in the city of Madison, this 19th day of January, 1988.

June L. Dahl

June L. Dahl, Ph.D.

3-1-88

ORDER OF
THE CONTROLLED SUBSTANCES BOARD
ADOPTING CSB 2.19, WIS. ADM. CODE

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 making changes in the classification of Talacen and Talwin Compound; quazepam and midazolam; combinations of tiletamine and zolazepam; alfentanil; 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP); nabilone, and acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl to conform Wisconsin law to federal law.

1. Talacen and Talwin Compound

The controlled substances board may reschedule substances pursuant to the rule-making procedures of chapter 227.

The controlled substances board is transferring two analgesic drug products to lower schedules of chapter 161, the uniform controlled substances act: Talacen, which is pentazocine hydrochloride equivalent to 25 mg base in combination with acetaminophen 650 mg base, from schedule II to schedule IV; and Talwin Compound, which is pentazocine hydrochloride equivalent to 12.5 mg base in combination with aspirin 325 mg, from schedule III to schedule IV.

Because of significant abuse, Wisconsin has controlled all pentazocine products more stringently than has the federal government. Pentazocine was finally placed in schedule IV of the federal controlled substances act in 1978, approximately four years after the controlled substances board added pentazocine to schedule III in Wisconsin, effective September 1, 1974.

In 1979, Wisconsin began to experience a new and serious problem of pentazocine abuse. Talwin, pentazocine hydrochloride 50 mg, was increasingly being diverted from legitimate channels in the state to illicit use. A combination of Talwin and tripelennamine, known as "Ts and Blues," was injected by abusers as a heroin substitute. There were multiple responses to the problem, including increased law enforcement efforts against organized elements, investigations of physicians and pharmacists, professional education, treatment of abusers, and rescheduling of Talwin. Talwin was transferred from schedule III to the more restrictive schedule II in order to tighten its control under state law and regulations governing record keeping, prescribing and dispensing. The scheduling change was accomplished by the legislature at the recommendation of the controlled substances board, and on April 21, 1982, all pentazocine products except Talwin Compound were moved to schedule II. As a reduced-strength combination product, it was allowed to remain in schedule III because there was no evidence it was subject to

the increasing trend of abuse associated with single-entity Talwin. The manufacturer, Winthrop Laboratories, a division of Sterling Drug, Inc., subsequently withdrew Talwin 50 from the United States market. Winthrop then introduced two new products, Talacen and Talwin-Nx. Because both products contain more than 12.5 mg pentazocine, they automatically became schedule II controlled substances under Wisconsin law.

Representatives of the manufacturer have asked that Talacen and Talwin Compound, and Talwin-Nx be considered for lower scheduling.

The controlled substances board took the request under advisement and in 1985 conducted a review of the information available concerning the abuse of pentazocine products in Wisconsin. In order to bring the matter officially before the board, a proposal to transfer Talacen and Talwin-Nx from schedule II to schedule III was included in proposed CSB 2.17 Wis. adm. code.

A public hearing was held February 19, 1986. The hearing record is available. A representative of the manufacturer testified in support of the proposal, and presented national data to show the sharp decline in abuse of pentazocine due to withdrawal of Talwin and introduction of Talwin-Nx. The board pointed out that the same data indicate that pentazocine is nonetheless still being abused, and at a degree higher than before the epidemic of "Ts and Blues" began.

Representatives of the Milwaukee police department testified in opposition to the proposal, and presented data showing that Talwin-Nx arrests continue at about 50 per year despite addition of naloxone and control of the drug in schedule II. According to this testimony, pentazocine is the third most commonly abused drug after marijuana and cocaine in the Milwaukee area.

A pharmacist-educator encouraged placement of pentazocine in schedule IV rather than schedule III in the interests of uniformity with federal law.

Following the public hearing the board voted to delete the proposed changes in classification of pentazocine from proposed rule CSB 2.17 in order to consider the control of pentazocine separately from the other drug control issues in CSB 2.17 about which there was no disagreement.

On March 19, 1986, the board reviewed the information and testimony which had been provided at the public hearing. Taking into consideration the considerable amount of information pertaining to the factors enumerated in s.161.11(1), stats., the board concluded that both Talacen and Talwin Compound have a low potential for abuse relative to substances in schedule III; that they have currently accepted medical use in treatment in the United States; and that abuse of these substances may lead to limited physical dependence or psychological dependence relative to the substances in schedule III. Thus, the potential for abuse of these products is more consistent with the control criteria of schedule IV rather than in schedule II or III. The board made the requisite findings and voted to move Talacen from schedule II to schedule IV, and Talwin

Compound from schedule III to schedule IV, and to use the 30-day notice without hearing procedure under chapter 227.

On June 18, 1986, the board again considered moving Talwin-Nx from schedule II to a lower schedule and declined to do so.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(1) and (2), stats., the board creates CSB 2.19 Wis. adm. code relating to the rescheduling of Talacen and Talwin Compound.

2. Quazepam and Midazolam

According to state law s.161.11(4), stats., if any substance is designated, rescheduled or deleted as a controlled substance under federal law the board shall take similar action to control or decontrol the substance, unless it objects.

On March 25, 1986, the drug enforcement administration published a final rule, 51 FR 10190, placing quazepam and midazolam into schedule IV of the federal controlled substances act. Quazepam and midazolam are members of the benzodiazepine family.

Pursuant to s.161.11(4), stats, the controlled substances board on July 15, 1987, took action to similarly control these substances under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to quazepam and midazolam, and made the following findings:

1) quazepam and midazolam each has a low potential for abuse relative to the drugs or other substances listed in schedule III;

2) quazepam and midazolam each has a currently accepted medical use in treatment in the United States; and

3) abuse of quazepam and midazolam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

On July 15, 1987, the board voted to control quazepam and midazolam in schedule IV of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to quazepam and midazolam.

3. Tiletamine and Zolazepam

According to state law s.161.11(4), stats., if any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the board shall take similar action to control or decontrol the substance, unless it objects

On January 21, 1987, the drug enforcement administration published a final rule, 52 FR 2221, placing preparations which contain both tiletamine and zolazepam into schedule III of the federal controlled substances act. The combination of tiletamine and zolazepam, in a one-to-one ratio, has been developed as an anesthetic agent for dogs and cats.

Pursuant to s.161.11(4), stats., the controlled substances board on February 18, 1987, took action to similarly control these substances under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to mixtures of tiletamine and zolazepam and salts thereof, and made the following findings:

1) mixtures of tiletamine and zolazepam have a potential for abuse less than drugs or other substances in schedule I and II;

2) certain mixtures of tiletamine and zolazepam have an accepted medical use in treatment in the United States; and

3) abuse of mixtures of tiletamine and zolazepam may lead to moderate or low physical dependence or high psychological dependence.

As a result of these findings the board voted to control tiletamine and zolazepam mixtures in schedule III of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to mixtures containing tiletamine and zolazepam.

4. Alfentanil

According to state law s.161.11(4), stats., if any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the board shall take similar action to control or decontrol the substance, unless it objects.

On January 23, 1987, the drug enforcement administration published a final rule, 52 FR 2516, rescheduling alfentanil from schedule I to schedule II of the federal controlled substances act. Alfentanil is an opiate as defined in 21 U.S.C. 802(17)(a).

Pursuant to s.161.11(4), stats., the controlled substances board on February 18, 1987, took action to similarly control this substance under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to alfentanil and made the following findings:

1) alfentanil has a high potential for abuse;

2) alfentanil has a currently accepted medical use in treatment in the United States; and

3) abuse of alfentanil may lead to severe psychological or physical dependence.

As a result of these findings the board voted to reschedule alfentanil from schedule I to schedule II of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to the rescheduling of alfentanil.

5. 1-Methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP)

According to state law s.161.11(4), stats., if any substance is designated, rescheduled or deleted as a controlled substance under federal law, the board shall take similar action to control or decontrol the substance, unless it objects.

On January 23, 1987, the drug enforcement administration published a final rule, 52 FR 2515, placing 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) into schedule I of the federal controlled substances act. MPPP and PEPAP are potent analogs of meperidine, a schedule II synthetic narcotic analgesic. Produced in clandestine laboratories, MPPP and PEPAP have been identified in illicit drug traffic. MPPP in particular has been associated with the production of drug-induced Parkinson's disease in a number of users.

Pursuant to s.161.11(4), stats., the controlled substances board on February 18, 1987, took action to similarly control these substances under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to MPPP and PEPAP and made the following findings:

1) MPPP and PEPAP each has a high potential for abuse;

2) MPPP and PEPAP each has no currently accepted medical use in treatment in the United States; and

3) MPPP and PEPAP each lacks accepted safety for use under medical supervision.

As a result of these findings the board voted to control 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) into schedule I of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP).

6. Nabilone

According to state law s.161.11(4), stats., if any substance is designated, rescheduled or deleted as a controlled substance under federal law, the board shall take similar action to control or decontrol the substance, unless it objects.

On April 7, 1987, the drug enforcement administration published a final rule, 52 FR 11042, placing nabilone into schedule II of the federal controlled substances act. Nabilone is a synthetic substance which is chemically and pharmacologically similar to the tetrahydrocannabinols. Nabilone is useful in the treatment of nausea and vomiting which is refractory to other antiemetic treatments.

Pursuant to s.161.11(4), stats., the controlled substances board on May 20, 1987, took action to similarly control nabilone under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to nabilone and made the following findings:

1) nabilone has a high potential for abuse;

2) nabilone has a currently accepted medical use in treatment in the United States; and

3) abuse of nabilone may lead to severe psychological or physical dependence.

As a result of these findings the board voted to control nabilone in schedule II of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to nabilone.

7. Acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl.

According to state law s.161.11(4), stats., if any substance is designated, rescheduled or deleted as a controlled substance under federal law, the board shall take similar action to control or decontrol the substance, unless it objects.

On May 29, 1987, the drug enforcement administration published a final rule, 52 FR 20070, placing acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl into schedule I of the federal controlled substances act. These six substances are potent analogs of the schedule II synthetic narcotic analgesic fentanyl. The six fentanyl analogs have been produced in clandestine laboratories, identified in drug evidence submissions and associated with a number of overdose deaths.

Pursuant to s.161.11(4), stats., the controlled substances board on June 17, 1987, took action to similarly control these substances under state law. In doing so, the board reviewed and concurred with the conclusions of the federal government with respect to acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl and made the following findings:

1) acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each has a potential for abuse;

2) acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each has no currently accepted medical use in treatment in the United States; and

3) acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each lacks accepted safety for use under medical supervision.

In addition, while the drug enforcement administration concluded that acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl have a potential for abuse, the controlled substances board determined that these substances have a high potential for abuse. The drug enforcement administration subsequently concluded that these substances have a high potential for abuse

As a result of these findings the board voted to control acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl in schedule I of the uniform controlled substances act.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(4), stats., the board creates CSB 2.19 Wis. adm. code relating to acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl.

8. Prazepam

On July 15, 1987, the controlled substances board adopted a resolution proposing that the listing for prazepam be renumbered in order to place the substance in correct alphabetical order.

Authority: Sections 161.11(1), (2) and (4), stats.

Statute interpreted: Sections 161.14, 161.16, 161.18, 161.20, stats.

Initial regulatory flexibility analysis: CSB 2.19 Wis. adm. code will not have a significant economic impact on small businesses in Wisconsin.

Fiscal estimate: None.

Therefore, pursuant to the authority vested in the controlled substances board by s.161.11(1),(2) and (4), stats., the board proposes to create CSB 2.19 Wis. adm. code, as follows:

Section 1, CSB 2.19. Transfer of Talacen from schedule II to schedule IV; transfer of Talwin Compound from schedule III to schedule IV; renumber prazepam in schedule IV; addition of quazepam and midazolam to schedule IV; addition of preparations containing both tiletamine and zolazepam into schedule III; renumber alphaprodine in schedule II; addition of alfentanil to schedule II; addition of 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) to schedule I; addition of nabilone to schedule II; renumber acetylmethadol in schedule I; addition of acetyl-alpha-methylfentanyl, alpha-methyl-thiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl into schedule I.

Paragraph (b) of s.161.20(4), stats., is created to read:

(b) not more than 25 milligrams per dosage unit of pentazocine with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

Paragraph (b) of s.161.18(4), stats., is repealed.

Paragraph (km) of s.161.20(2), stats., is renumbered to read:

(mg) Prazepam;

Paragraph (hg) of s.161.20(2), stats., is created to read:

(hg) Midazolam;

Paragraph (mm) of s.161.20(2), stats., is created to read:

(mm) Quazepam;

Paragraph (km) of s.161.18(3), stats., is created to read:

(km) Tiletamine and Zolazepam or any salt thereof;

Paragraph (a) of s.161.16(3), stats, is renumbered to read:

(am) Alphaprodine;

Paragraph (a) of a.161.16(3), stats., is renumbered to read:

(a) Alfentanil;

Paragraph (rg) of s.161.14(2), stats., is created to read:

(rg) MPPP 1-methyl-4-phenyl-4-propionoxypiperidine);

Paragraph (vg) of s.161.14(2), stats., is created to read:

(vg) (PEPAP) 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine.

Paragraph (b) of s.161.16(10), stats., is created to read:

(b) Nabilone (another name for nabilone: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7, 8, 10, 10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo[b,d]pyran-9-one)

Subsection (2) of s.161.14, stats., is amended to read:

(2) Opiates. Unless specifically excepted under federal regulations or unless listed in another schedule, any of the following opiates, or their isomers, esters, ethers, salts, salts of isomers, esters or ethers, if isomers, esters, ethers, salts or salts of isomers exist within the specified chemical designation (for purposes of paragraph (tg) only, the term isomer includes the optical and geometric isomers):

Paragraph (a) of s.161.14(2), stats., is renumbered to read:

(am) Acetylmethadol;

Paragraph (a) of s.161.14(2), stats., is created to read:

(a) Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Paragraph (cg) of s.161.14(2), stats., is created to read:

(cg) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Paragraph (dg) of s.161.14(2), stats., is created to read:

(dg) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Paragraph (rj) of s.161.14(2), stats., is created to read:

(rj) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Paragraph (tg) of s.161.14(2), stats., is created to read:

(tg) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Paragraph (xm) of s.161.14(2), stats., is created to read:

(xm) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]propanamide);

Effective date: This rule shall take effect on the first day of the month following its publication in the Wisconsin administrative register.

Dated: 1/19/88

Agency: Controlled Substances Board
June L. Dahl, Ph.D., Chairperson

June L. Dahl

State of Wisconsin \ DEPARTMENT OF HEALTH AND SOCIAL SERVICES

CONTROLLED SUBSTANCES BOARD
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January 19, 1988

RECEIVED
JAN 20 1988
Revisor of Statutes
Bureau

Gary L. Poulson, Assistant Revisor
Revisor of Statutes Bureau
Wisconsin Administrative Code
Suite 702
30 West Mifflin Street
Madison, Wisconsin 53702

Dear Mr. Poulson:

On behalf of the Controlled Substances Board, I am submitting a certified copy of CSB 2.19 for publication in the next Wisconsin Administrative Register.

It is my understanding that the effective date is the first day of the month following publication in the Register.

Thank you for your assistance.

Sincerely,

David E. Joranson
Controlled Substances Policy Specialist
Staff, Controlled Substances Board
Bureau of Community Programs

Enclosures