Approved: 2-16-00
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chairperson Sandy Praeger at 10:00 a.m. on February 8, 2000 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Norman Furse, Revisor of Statutes
Lisa Montgomery, Revisor of Statutes
Emalene Correll, Legislative Research Department
Hank Avila, Legislative Research Department
JoAnn Bunten, Committee Secretary

Conferees appearing before the committee:

Larry Froelich, Executive Director, Kansas Board of Pharmacy
David Furnas, Kansas Press Association
Kirk Lowry, Trial Lawyers Association

Others attending: See attached list

Hearing on: SB 511– Confidentiality of complaints and other information relating thereto received by the state board of pharmacy

Larry Froelich, Executive Director, Kansas Board of Pharmacy, testified in support of **SB 511** which would prevent the disclosure of information related to a complaint filed with the Board of Pharmacy in order to maintain confidentiality and prevent the identification of persons who are the subject or sources of the information. The bill would allow for some exceptions, and information could be disclosed in a proceeding or appeal that is legally conducted by the Board. Mr. Froelich explained the procedure that the Board follows when a complaint comes into the Board's office as noted in his written testimony. (Attachment 1)

David Furnas, Kansas Press Association, spoke in opposition to **SB 511**. He noted that hiding from the public an allegation limits the public's ability to know that complaints are being filed, perhaps repeatedly, against a pharmacist, and there may be circumstances, particularly involving health-related issues where the name of the complainant could be withheld. Mr. Furnas felt that optional closure should not apply to the substance of the complaint, and the records of the complaints should remain open for the scrutiny by the public and the public's watchdogs. (Attachment 2)

Kirk Lowry, Trial Lawyers Association, noted that they have no objection with the apparent intent of **SB 511**, which is to close complaints until a determination of probable cause had been made by the investigative committee, but felt that the bill needed additional clarification in order to accomplish this goal without closing records once probable cause is determined. Mr. Lowry suggested the Committee consider proposed amendments as noted in his written testimony. (Attachment 3)

Hearing on: SB 512–Controlled substances scheduled under the uniform controlled substances act

Larry Froelich, Board of Pharmacy, testified in support of **SB 512** which would add Ketamine, an anesthetic used mostly on animals, to the controlled substances listed in Schedule III of the Controlled Substances Act. Mr. Froelich noted that the bill would also add Zaleplon, a sedative, to Schedule IV, and remove Dronabinal, a synthetic stimulant, from Schedule II and include it in Schedule III of the Controlled Substances Act. (See Attachment 1)

There were no opponents to **SB 512**.

Hearing on: SB 541–Non-human institutional drug rooms

Larry Froelich, Board of Pharmacy, testified in support of **SB 541** which would create a new type of pharmacy registration, the non-human institutional drug room. This would be a location where prescription-only drugs, for use in treatment of or experimentation on non-humans, are stored as part of an accredited college of veterinary medicine. Mr. Froelich noted the Kansas State Veterinary Medical Teaching Hospital Pharmacy

purchase and supply medications to animals, and they have recently employed a pharmacist. He also pointed out that KSU is willing to work with the Board to resolve various problems relating to this bill. (See Attachment 1) During Committee discussion it was suggested the term "Non-human institutional drug room" in **SB 541** be changed to a more appropriate name.

There were no opponents to **SB 541**.

Randy Forbes, Counsel for the Board of Pharmacy, and Dr. Dirk Hansen, Executive Secretary for the Board of Veterinarian Examiners, were present to answer questions during Committee discussion on the Board of Pharmacy bills.

Adjournment

The meeting was adjourned at 11:00 a.m.

The next meeting is scheduled for February 9, 2000.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
GUEST LIST

DATE: 2-8-00

NAME	REPRESENTING
Dirk Hull	Bd of Vet Examiners
Bob Williams	Ks Pharmacists Assoc
Larry Froelich	Ks Board of Pharmacy
Brad Hubin	Ks Pharmacists Assoc.
David Farmas	Ks Press Association
Randy Forbes	Ks. Pharmacy Brd.
Keith R Landis	Christian Science Committee on Publication for Kansas
Kirk Lowry	KTLA
[illegible]	KTLA
Stan Kenton	Ks Press
Tim Wood	VCHS

Kansas State Board of Pharmacy

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STATE OF KANSAS

EXECUTIVE DIRECTOR
LARRY FROELICH

BILL GRAVES
GOVERNOR

2000 KANSAS LEGISLATIVE SESSION
SENATE BILL No. 511
Senate Committee on Public Health and Welfare

Senator Sandy Praeger, Chairperson
Committee Members

I am Larry Froelich, Secretary for the Kansas Board of Pharmacy. Thank you for allowing me to testify on **SB 511** on behalf the Board of Pharmacy. I would like to explain the procedure the Board of Pharmacy follows when a complaint comes into the office. The agency is very small. There are two people employed within the office processing applications. The office issues close to **8,000** permits, licenses and registrations. Whenever a complaint arrives in the office, a folder is made regarding the complaint and I assign the investigation to one of three pharmacist inspectors located throughout the State, depending on the territory that the complaint involves. The inspector investigates the complaint and prepares a report for the Investigative Committee. What if the complaint turns out to be a frivolous complaint? Is that complaint available to anyone prior to the Investigative Committee reviewing the complaint? SB-511 would help me, by making this information confidential.

We read of this summers problem that were encountered when the press tried to obtain certain documents from various agencies. I am not an advocate for changing the KORA. When professional livelihoods are involved, it seems very appropriate to error on the side of caution when it comes to disclosing information that could be potentially damaging.

The Board of Pharmacy respectfully requests **favorable passage of SB-511** by the Committee.

TESTIMONY ON SB-512:

The Board of Pharmacy is requesting that the Committee support changes to the Kansas Controlled Substances Act that will reflect changes already done by the Uniform Controlled Substances Act.

Senate Public Health and Welfare
Date: 2-8-00
Attachment No. 1

Prescription drugs that have a potential for abuse are "scheduled" as controlled substances according to the potential for psychological and physical abuse potentials. Drugs with the highest possibility of abuse are scheduled within the lowest numbered categories (i.e. Scheduled I is the highest abuse potential).

Statute Changes:

- Dronabinol (Marinol®) is currently a Schedule II controlled substance in Kansas. It has been changed federally to a Schedule III controlled substance.
- Ketamine (Ketalar®) is currently not listed as a controlled substance in Kansas. It has been changed federally to a Schedule III controlled substance.
- Zaleplon (Sonata®) is a new drug that is currently not listed as a controlled substance in Kansas. It has been added federally to the listing of Schedule IV controlled substances.
- The remaining changes are combining revisions that were enacted during the last session.

Since these changes are already enacted federally, I would like to request that the changes be effective upon publication in the Kansas Register. The Board of Pharmacy respectfully requests **favorable passage of SB-512** by the Committee with this change.

TESTIMONY ON SB-541:

Kansas State Veterinary Medical Teaching Hospital Pharmacy purchases and supplies medications to animals. It recently started employing a pharmacist. Should the Board of Pharmacy license them? If yes, then under which licensing category? KSU labeled this as a "dispensary" for years to explain the category, before employment of a pharmacist.

- **Retail Pharmacy**: If registered under this category, the Retail Pharmacy must be closed when the pharmacist is not on duty.
- **Hospital Pharmacy**: Health and Environment will not give them a medical care facility license due to several factors (Cleanliness, patients, etc.) and our medical care facility regulation addresses registered nurses entering the pharmacy when a pharmacist is not on the premises.
- **Institutional Drug Room**: Although their current license with us states as such, they do not fit in the definition as one according to K.S.A. 65-1626(o).
- **Distributor**: The medications within the facility are not distributed, but rathe dispensed to the clients.

Finally, can this "dispensary" sell to others not affiliated with the University? Some off-site veterinarians consult with the Hospital and then need to obtain the medications needed. Can labeled medications be dispensed (i.e. prescriptions)? Can full packages of manufacturer labeled products be sold? Can controlled substances be dispensed? Who can do the dispensing?

KSU is willing to work with the Board to resolve this matter. They want to do that which is legally correct. This language has been forwarded to them and discussed. If further modifications are needed, both parties are willing to solve this.

The Board of Pharmacy respectfully requests **favorable passage of SB-541** by the Committee.

Thank you for allowing me to present the Board's position. I will stand for any questions.

(o) (1) **"Institutional drug room"** means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:
(A) Inmates of a jail or correctional institution or facility;
(B) residents of a juvenile detention facility, as defined by the Kansas code for care of children and the Kansas juvenile justice code;
(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas; or
(D) employees of a business or other employer.
(2) "Institutional drug room" does not include:
(A) Any registered pharmacy;
(B) any office of a practitioner; or
(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

(p) **"Medical care facility"** shall have the meaning provided in K.S.A. 65-425 and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b and amendments thereto except community mental health centers and facilities for the mentally retarded.

U. S. Department of Justice

Drug Enforcement Administration
Kansas City District Office
8600 Farley, Suite 200
Overland Park, Kansas 66212
(913) 652-9127

July 6, 1999

All Kansas State Boards

Enclosed is a copy of the July 2, 1999, Federal Register, Volume 64, No. 127 which discuses the rescheduling of synthetic dronabinol <(-)-^9(trans)-tetrahydrocannabinol)> (Marinol) in sesame oil from a schedule II to Schedule III. This is a Final Rule that became effective as of July 2, 1999.

If you have any questions regarding this action please contact Jayne M. Tomko, Diversion Group Supervisor at telephone number (913) 652- 9127.

Sincerely,

George E. Spaulding
Assistant Special Agent in Charge

By: Jayne M. Tomko
Jayne M. Tomko
Diversion Group Supervisor

1-4

of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

PART 520— ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(4)(iii)(C) by removing "012286, 053389, and 054273" and adding in its place "000010, 012286, and 053389".

§ 520.2345d [Amended]

3. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing "054273," and adding "000010," before "046573".

PART 558— NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.15 [Amended]

5. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* is amended in paragraphs (g)(1) and (g)(2) by removing "Fermenta Animal Health Co." and adding in its place "Boehringer Ingelheim Vetmedica, Inc."

Dated: June 28, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–17761 Filed 7–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–183F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Ketamine Into Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance ketamine, including its salts, isomers, and salts of isomers, into schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of ketamine and products containing ketamine.

EFFECTIVE DATE: August 12, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

Ketamine hydrochloride is marketed in the United States as a general anesthetic for use in human medicine under the trade name Ketalar®. It is also marketed as a veterinary product under various names including Ketaject®, Ketaset®, and Vetalar®. Since 1982, more than 775 reports of ketamine diversion or abuse have been received by the DEA. More than 568 law enforcement reports described encounters of individuals who sold the drug, who had it in their possession and/or were under its influence. Veterinary clinic burglaries which were directed at ketamine were described also. The balance of the reports were of ketamine abuse related hospital emergency department visits.

The wide geographic distribution and prevalence of diversion and/or abuse of ketamine, the spreading notoriety of ketamine as a party drug, Special 'K' or 'K', and the involvement of teenagers and young adults caused the DEA to submit to the Department of Health and Human Services (DHHS) information related to each of the eight factors which are determinative of control under the CSA. The DHHS responded by letter, recommending that ketamine be added to schedule III.

The pharmacological and behavioral effects of ketamine are similar, but somewhat less intense and shorter in duration, to those of the schedule II substance, phencyclidine (PCP). Low dose intoxication with ketamine results in impaired attention, learning, and memory functions. Higher doses may result in ataxia, dizziness, elevated blood pressure, mental confusion, hyperexcitability, catalepsy (the inability to move), amnesia, convulsions, a delusional dream-like state, hallucinations, and psychosis. Long-term use of ketamine is associated with hallucinatory flashbacks, an inability to concentrate, psychological dependence, and tolerance. Reports of ketamine abuse leading to physical or psychological dependence consistent with schedule III criteria have been published.

Diversion of ketamine pharmaceutical products from practitioners has been the most frequently documented source of the drug, with the primary sources being veterinary clinics. The liquid pharmaceutical product is injected or, more commonly, evaporated and the resultant power inhaled (snorted). Clandestine manufacture of ketamine has not been encountered. In contrast to that of PCP, the synthesis of ketamine is difficult.

Notice of Proposed Rule Making

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health in accordance with section 201(b) of the CSA [21 U.S.C. 811(b)], and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to Sections 201(a) and 201(b) of the CSA [21 U.S.C. 811(a) and 811(b)] proposed the placement of ketamine, including its salts, isomers, and salts of isomers, into schedule III of the CSA in an April 9, 1999, Federal Register notice (64 FR 17299). The notice provided an opportunity for all interested persons to submit their comments or objections in writing on the proposed scheduling of ketamine on or before June 8, 1999.

Comments

The DEA received five comments regarding the proposal. Comments in support of the proposal were received from the American Animal Hospital Association (AAHA), the American Veterinary Medical Association (AVMA), the American Association of Equine Practitioners (AAEP) and a practicing veterinarian. The AAHA, which represents 16,000 veterinary care providers, commented that the movement of ketamine into Schedule III was in the best interest of the veterinary industry and the general public. The AVMA, on behalf of 62,000 members, stated that the security and record keeping required of Schedule III controlled substances will prevent diversion and unauthorized use of ketamine while providing a reasonable mechanism for the continued responsible use of ketamine for legitimate purposes by members of the veterinary profession. The AAEP which reaches 3.2 million horse owners through its more than 8,200 members world wide strongly supports the placement of ketamine into Schedule III.

U. S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

OCT - 8 OCT 0 6 1999

Mr. Carmen Catizone
Executive Director
National Association of Boards
of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068

Dear Mr. Catizone:

Enclosed is the Drug Enforcement Administration (DEA) final rule placing Zaleplon (Sonata®) into Schedule IV of the Controlled Substances Act (CSA) as a depressant. The rule was published in the Federal Register and became effective on September 15, 1999.

The DEA is attempting to disseminate this information as widely as possible to the appropriate industry associations.

The complete text of the Zaleplon (Sonata®) final rule is available on the U.S. Government Printing Office (GPO) website: http://www.access.gpo.gov/nara/cfr/index.html, which provides access to the Federal Register. This text is also on the DEA home page: http://www.usdoj.gov/dea/programs/diversion/notices.

Your assistance in helping DEA distribute this Final Notice to those affected by its provisions is greatly appreciated. Thank you for supporting DEA efforts in preventing drug diversion.

If you have any questions regarding this scheduling action, please contact David Gauvin, Drug and Chemical Evaluation Section, at (202) 307-7183.

Sincerely,

Tuanne D. Woodworth

for John H. King
Deputy Assistant Administrator
Office of Diversion Control

Enclosure

1-6

Kansas Press Association, Inc.

5423 SW 7th St., Topeka, KS 66606 • (785)271-5304 • Fax (785)271-7341• www.kspress.com

Kansas Press Association
Testimony before
Senate Public Health and Welfare Committee
February 8, 2000

It is critical for the public to have access to information that allows them to know if a review process is being conducted fairly and in the public interest – particularly when the review is conducted by persons from the same profession.

Hiding from the public an allegation limits the public's ability to know that complaints are being filed, perhaps repeatedly, against a pharmacist. The validity of a charge is influenced by who is making such a complaint.

For the media – and particularly for newspapers – this proposal to close the records is not a high profile issue. Surely, cases that go before the courts take on a greater public interest but not a greater public concern. The records of the complaints should remain open for the scrutiny by the public and the public's watchdogs.

At a very minimum, the permissive nature of closure should be changed. Additionally, the substance of the complaint should remain open – and not at the option of the Board. Information from a proceeding should be a public record and not considered optional.

There may be circumstances, particularly involving health-related issues where the name of the complainant could be withheld, but optional closure should not apply to the substance of the complaint.

The Kansas Press Association would ask the committee to reject this request.

Senate Public Health and Welfare
Date: 2-8-00
Attachment No. 2

Jerry R. Palmer *
LJ Leatherman

ATTORNEYS
Palmer, Lowry, Leatherman & White
L.L.P.

Kirk W. Lowry
Gary D. White Jr.

TO: Members of the Senate Public Health and Welfare Committee

FROM: Kirk Lowry, President
Kansas Trial Lawyers Association

RE: SB 511

DATE: Feb. 8, 2000

Madame Chair and members of the Senate Public Health and Welfare Committee, thank you for the opportunity to comment on SB 511. I speak today on behalf of the Kansas Trial Lawyers Association.

The KTLA understands that the apparent intent of this bill is to close complaints until a determination of probable cause has been made by the investigative committee. We have no objection to this intent. However, SB 511 needs additional clarification in order to accomplish this goal, without closing records once probable cause is determined.

We respectfully suggest the following amendments:

1) Section 1 (a) line 18: strike "may" and add "shall;"
2) Section 1 (a) (4) add "once any complaint has been determined to have probable cause;"
3) Section 1 (a) (5) add "upon order of the court or subpoena."

Thank you for the opportunity to present our views and we welcome an opportunity to work with the bill's proponents in clarifying this proposal.

Senate Public Health and Welfare
Date: 2-8-00
Attachment No. 3