Approved 2-18-86
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Senator Roy M. Ehrlich at
Chairperson

10:00 a.m./~~p.m.~~ on February 11, 1986 in room 526-S of the Capitol.

All members were present except:

Committee staff present:
Bill Wolff, Clarene Wilms

Conferees appearing before the committee:
Ron Hein, Johnson & Johnson
Ken Schafermeyer, Kansas Pharmacists Association
Jerry Slaughter, Kansas Medical Society
Everett L. Willoughby, Executive Secretary of Kansas Board of Pharmacy, written testimony
Lyle Eckert, Director of the Bureau of Emergency Medical Services
Al Dimmitt, Program Director, Emergency Medical Training Program, School of Allied Health, University of Kansas Medical Center
Lt. Bill Jacobs, Kansas Highway Patrol
Others Attending: See attached list

Chairman Ehrlich presented the minutes for correction or approval. Senator Anderson moved that the minutes be approved with a second by Senator Walker. Motion carried.

HCR-5013 was on the agenda for final action today. However, due to conflict with another extended committee meeting, final action was postponed until Thursday, February 13, 1986.

SB-501 An Act concerning the uniform controlled substances act; relating to the dispensing of schedule I substances;

Ron Hein testified and presented written testimony supporting SB-501. Mr. Hein stated that in the state of Kansas there is no mechanism to permit rescheduling or permit marketing drugs in Kansas when the Federal Government reschedules a particular drug from schedule I to schedule II. It was also requested that the bill be amended so that the effective date would be upon publication in the Kansas Register. Attachment I

Ken Schafermeyer testified supporting SB-501. Mr. Schafermeyer stated that this bill would enable the drugs changed from schedule I to schedule II to be designated, then prescribed and dispensed in Kansas without waiting for the legislators to act. He also stated that if the bill could be put into effect upon publication in the Kansas Register it would permit prompt response on this issue.

Written testimony by Everett L. Willoughby supporting passage of SB-501 was presented to the committee. Attachment II

Jerry Slaughter spoke in support of SB-501.

SB-542 An Act concerning emergency medical services; relating to the demonstration program in manual cardiac defibrillation;

Lyle E. Eckhart testified and presented written testimony in support of SB-542. Attachment III Mr. Eckhart expressed the concern of whether or not SB-81 could be amended to continue the regulations to expire on the same date as SB-542 (July 1, 1987)? Also, he questioned whether or not the effective date of this bill could commence with the publication in the Kansas Register since they will expire on May 1, 1986.

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 526-S, Statehouse, at 10:00 a.m./~~p.m.~~ on February 11, 19 86

Al Dimmitt testified and presented written testimony in support of SB-542. Attachment IV Mr. Dimmitt stated that he felt more data was needed to compile adequate information.

Lt. Bill Jacobs testified in support of SB-542.

The committee will meet at 10:00 a.m. February 12, 1986.

Meeting adjourned at 10:25 a.m.

SENATE

PUBLIC HEALTH AND WELFARE COMMITTEE

DATE February 11, 1986

(PLEASE PRINT)

NAME AND ADDRESS		ORGANIZATION
Theresa Shively	Topeka	Kansas NARAL
Barb Reinert		Planned Parenthood
Anne Moriarty	Topeka	KS Nat'l Org. of Women
John Peterson	Topeka	Ks Assn Prof Psychologists
John Kelly	Topeka	KS DD Council
B.J. Sabol	"	KDH&E
Ruth Wilkin	"	AAUW
Lila Paslay	"	ARC/Kansas
Ron Hein	"	Johnson & Johnson
Jerry Slaughter		KMS
Ken Schafermeyer	"	KS Pharmacists Assn
Lt. Bill Jacobs	Topeka	Kansas Highway Patrol
Al Dimmitt	Kansas City Ks	KU Medical Center
Lyle Eckhart	Topeka	KHP-EMS

2-11-86

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232-7263

TESTIMONY TO SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
RE: SB501 ON FEBRUARY 11, 1986

Mr. Chairman, and Members of the Committee:

I am Ron Hein, legislative counsel for Johnson and Johnson. I speak today in support of SB501, and would urge your approval of the bill. Two years ago, Janssen Pharmaceutica, a subsidiary of Johnson and Johnson, was permitted to market a new anesthetic after extensive investigation and approval by the Food and Drug Administration and the Drug Enforcement Agency at the federal level resulted in a rescheduling from Schedule I to Schedule II. In most states, the federal action was followed by state approval either automatically, by regulatory action, or by virtue of the Legislature being still in session. In Kansas, however, there was no mechanism to permit rescheduling or other approval to permit marketing of the drug in Kansas, all be it that the federal government permitted it. This particular anesthetic offered significant advantages to patients over previously available drugs, so there was considerable desire by physicians, including surgeons and anesthesiologists to utilize the drug for the benefit of the patients in Kansas. However, that could not be done. It was not until the Legislature reconvened in 1985 that the anesthetic was subsequently rescheduled in Kansas and permitted to be marketed here.

This last year, it came to my attention that a form of treatment for chemotherapy treatment patients designed to mitigate or eliminate nausea during the cancer treatment itself might face a similar fate. The National Cancer Institute was distributing a drug under a research grant of authority to various hospitals in Kansas, and finally the drug was apparently going to be rescheduled by the DEA. However, it was conceivable that Kansans who had previously been able to utilize the drug would, ironically, be unable to use the drug after the feds permitted the drug to be marketed commercially. Since the NCI could no longer make the drug available on a research basis, and until Kansas rescheduled, it would not be legal to distribute commercially here. (See attachment)

I made numerous legislators aware of this anomaly in our Uniform Controlled Substances Act this last fall. Throughout the summer, various groups concerned with this anomaly in Kansas law

Attachment I
2/11/86 S. PH&W

Attachment I

met to consider alternative solutions. Our proposed solution is SB501. This mechanism will permit drugs which have been rescheduled at the federal level and which have now been found to have medical purposes to be prescribed and dispensed for the benefit of patients in Kansas during the period of time that the Legislature is not in session.

Johnson and Johnson wholeheartedly supports this effort to ensure that Kansas citizens are not denied, even for a 9 month period, the opportunity to benefit from new found medical breakthroughs and advances. We feel that the criteria set out in the legislation insures against any abuse.

I would urge, however, that the bill be amended to provide for an effective date upon publication in the Kansas Register.

I would be happy to answer any questions that the committee might have.

Ronald R. Hein
Legislative Counsel
Johnson and Johnson

ATTACHMENT I

SUFENTA® (sufentanil citrate) Injection
NDA approved May 4, 1984
Rescheduled by DEA May 25, 1984

STATE	DATE AVAILABLE AS CII
Alabama	June 25, 1984
Alaska	May 25, 1984
Arizona	May 25, 1984
Arkansas	July 1, 1984
California	May 25, 1984
Colorado	May 25, 1984
Connecticut	May 25, 1984 [May 8, 1985]
Delaware	May 25, 1984
Florida	[August 1 - October 1, 1984] September 14, 1984; June 20, 1985
Georgia	May 25, 1984
Hawaii	June 18, 1984
Idaho	September 10, 1984
Illinois	October 19, 1984
Indiana	May 25, 1984
Iowa	August 10, 1984
Kansas	April 25, 1985
Kentucky	May 25, 1984
Louisiana	May 25, 1984
Maine	May 25, 1984
Maryland	May 25, 1984
Massachusetts	May 25, 1984
Michigan	May 25, 1984
Minnesota	January 26, 1985
Mississippi	July 1, 1985
Missouri	July 2, 1984
Montana	October 13, 1984
Nebraska	May 25, 1984
Nevada	May 25, 1984
New Hampshire	May 25, 1984
New Jersey	May 25, 1984
New Mexico	August 6, 1984
New York	May 25, 1984
North Carolina	October 1, 1984
North Dakota	June 24, 1984
Ohio	May 25, 1984
Oklahoma	May 25, 1984
Oregon	May 25, 1984
Pennsylvania	May 25, 1984
Puerto Rico	November 3, 1984
Rhode Island	July 24, 1984
South Carolina	May 25, 1984
South Dakota	May 25, 1984
Tennessee	May 25, 1984
Texas	May 25, 1984
Utah	May 25, 1984
Vermont	May 25, 1984
Virginia	May 25, 1984
Washington	August 16, 1984
Washington, D.C.	July 13, 1984
West Virginia	June 13, 1985
Wisconsin	November 1, 1984
Wyoming	May 25, 1984

2-11-86

Kansas State Board of Pharmacy

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PHONE (913) 296-4056

STATE OF KANSAS

JOHN CARLIN
GOVERNOR

EVERETT L. WILLOUGHBY
EXECUTIVE SECRETARY

LYNN E. EBEL
BOARD ATTORNEY

SENATE BILL 501

CONTROLLED SUBSTANCES ACT

Everett L. Willoughby, Executive Secretary
Kansas State Board of Pharmacy

Senate Bill 501, if passed would give the Kansas State Board of Pharmacy the authority to pass rules and regulations specifying certain Schedule I controlled substances as a Schedule I designated prescription substance.

The key to this statement is the word "designated." This designation would be done only for a controlled substance that has been rescheduled federally by the Drug Enforcement Administration from a Schedule I to a Schedule II or a newly approved drug which is scheduled federally but would not be scheduled in Kansas until done so by a vote of the Legislature.

After the Board of Pharmacy passes a regulation designating the substance a Schedule I designated prescription substance, it could be prescribed and dispensed in Kansas until the Legislature could approve the rescheduling to a Schedule II controlled substance.

In conformance with the Federal Controlled Substances Act of 1970, a controlled substance is placed in Schedule I when the Food and Drug Administration has determined, after clinical investigation of presently known facts, that the substance has no known medically accepted use. Occasionally, after new clinical evidence has been presented and investigated and the evidence of medical value outweighs possible side effects and potential for abuse, the substance is rescheduled from a Schedule I to a Schedule II.

Presently, controlled substances in Kansas can be scheduled or rescheduled only by the Legislature when it is in session. This has led to instances which have prevented the people of Kansas from being treated with a drug which has been rescheduled federally, but not in our state. This has deprived our citizens of the use of some of the latest scientific and medical advances.

A case in support was the federal rescheduling on May 25, 1984 of Sufentanil Citrate, a potent analgesic/anesthetic used during surgery, from a Schedule I to a Schedule II. It was not until

2/11/86 Attachment II S. PH&W

Attachment II

April 25, 1985, when it was rescheduled in Kansas by an act of the Legislature, that the physicians could use the drug. This was a period of eleven months that Kansans, undergoing surgery, were deprived of the safety and rapid recovery from anesthesia offered by Sufentanil.

If Senate Bill 501 is passed, an important new or rescheduled drug could be made available, possibly within thirty to sixty days of the time it was released federally.

The Kansas State Board of Pharmacy considers this to be a very important bill and its passage would be in conformance with their charged responsibility of protecting the public health and welfare.

ELW:arb

2-11-86

SUMMARY OF TESTIMONY
BEFORE THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

SENATE BILL 542

PRESENTED BY THE KANSAS HIGHWAY PATROL

February 10, 1986

APPEARED IN SUPPORT

The Kansas Highway Patrol and the State Emergency Medical Services Council support Senate Bill 542. This will extend the legislation passed in 1985 to permit the pilot program created to be continued one year.

As stated in the report to the legislature covering the results of the first six months of the pilot program the incidence of treatable cardiac arrests in the target area of the study was only 65% of the number anticipated based on 1983 data. The numbers are insufficient to complete the study.

The following facts have been established and are relevant in the consideration of this bill.

1. We anticipate the continued participation of essentially all of the selected services if the pilot program is extended.

2. A spot check of qualified personnel was conducted in five cities in November and we concluded the skills were being adequately retained by participation in monthly drills.

3. Based on these five visits the attrition rate of qualified personnel appears to be acceptable with only a minimal loss due to attendants moving to other cities.

4. The consensus of ambulance directors was that patient care was improved in the participating services.

The extension of this bill should be considered on the basis of potential future enabling legislation to create authority for select services to provide this level of service. It is clear the requirement for such service by all of the communities in Kansas is not feasible. Consequently the required training should be offered in only those communities desiring such service and with the support of the medical community.

We respectfully suggest consideration of two concerns about this bill.

1. K.A.R. 109-3-1 through K.A.R. 109-3-4 were adopted under the authority granted under SB 81. Can this bill be amended to continue the regulations to expire on the same date as the bill (i.e. July 1, 1987)?

2. Can the effective date of this bill commence with publication in the Kansas Register which would extend the regulations without a lapse since they will expire on May 1, 1986.

Attachment III
2/11/86 S. PH&W

Attachment III

2-11-86

Testimony of: Al Dimmitt, Program Director
Emergency Medical Training Program
School of Allied Health
University of Kansas Medical Center

February 11, 1986

This testimony is offered in support of Senate Bill 542 which will extend the pilot study on EMT-Defibrillation.

The results of the study for the period June 16, 1985 to December 15, 1985, while consistent with findings by other studies, don't provide a sample large enough to show unequivocal conclusions. Of the eleven patients presenting in rhythms treatable by countershock, three (27%) were resuscitated in the field, and admitted to the hospital. Of these three, two died in the subsequent 24 hours; one was dismissed. One other patient survived an arrest in which countershock was not indicated.

A review of related data received to date indicates that several factors unique to this study period may be affecting outcome. First, the number of arrests, when compared to 1983 data is significantly lower. Secondly, the location of the incidents made response times longer, and rendered patients unresponsive to resuscitation. It is interesting to note that in the subgroup who were defibrillated, the response time was 6.72 minutes as compared to 7.62 minutes in the entire group of 32 treated victims. A final variable which is harder to define is the time between onset of the condition and the call for help. Many arrests are either not witnessed or not recognized causing delays in EMS response.

When this study was initiated, we expected to be able to propose statewide implementation of an EMT-Defibrillation program during this legislative session. The data I have summarized here is not adequate to support such a request. Passage of Senate Bill 542 will allow the collection of more data which will permit a responsible analysis of the efficiency of defibrillation by specially trained Emergency Medical Technicians.

Thank you for your consideration.

Attachment IV
2/11/86 S. PH&W

Attachment IV