

Approved \_\_\_\_\_

Date

4-10-92

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by SENATE ROY M. EHRLICH at \_\_\_\_\_  
Chairperson

10:00 a.m. ~~p.m.~~ on April 6, 1992 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Legislative Research  
Bill Wolff, Legislative Research  
Norman Furse, Revisor's Office  
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

Bob Williams, Kansas Pharmacists Association  
Tom Hitchcock, Board of Pharmacy  
Clifford Berman, Baxter Care Corporation

Chairman Ehrlich called the meeting to order at 10:00 a.m.

The Chairman announced that minutes of March 30, 31, and April 1, 1992, were distributed to the Committee for review.

**Continued Hearing on HB 3064 - Out-of-state pharmacy registration.**

Bob Williams, Kansas Pharmacists Association, submitted written testimony on HB 3064. Mr. Williams briefed the Committee on the deliberations with the American Association of Retired Persons before the House Committee. The Kansas Board of Pharmacy has attempted to gain some regulatory control over the increased number of nonresident pharmacies mailing prescription medication to Kansas residents. The KPA does not believe that requiring nonresident pharmacies to register with the Kansas Board of Pharmacy and requiring them to comply with regulations established by the Board is an "undue burden" and urges support of the bill. (Attachment 1)

Considerable Committee discussion related to the need for such legislation, and a request was made to provide proof if a problem does exist with mail-order prescription medication. Mr. Williams stated the issue isn't the fact the community pharmacies are with errors, however, in Kansas those problems can be reported to the Kansas Board of Pharmacy and situations rectified compared to dealing with pharmacies from out-of-state. It was pointed out that the restrictions now in place in other states have not resulted in increased costs, and most people in Kansas that receive prescription medication from out-of-state assume that practice is sanctioned by the Board of Pharmacy. Staff questioned that the bill requires the out-of-state pharmacy meet certain requirements under Kansas law, and if the other state law differs in certain aspects established in this bill, then that state would not be able to ship prescription medications into Kansas. Mr. Williams stated that if those states are not providing care at the level as outlined in the bill, then they would be restricted from doing so, and there is not much variance between states in regard to labeling laws.

Tom Hitchcock, Board of Pharmacy, submitted written testimony in support of HB 3064 and stated he opposes any amendment to the bill. HB 3064 would require that the Board of Pharmacy register a pharmacy that advertises, contracts and solicits to send prescription drugs into the state from a pharmacy located in another state. This registration would allow the Board to protect the health and welfare of the public relating to all pharmacies dispensing prescriptions without restrictions to location. (Attachment 2) During Committee discussion, it was again questioned if this legislation is needed. Mr. Hitchcock gave an example of a situation involving two different mail

CONTINUATION SHEET

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE,  
room 526-S, Statehouse, at 10:00 a.m./p.m. on April 6, 1992.

order pharmacies, - one was within the state that was registered with the Board of Pharmacy and a resolution was made with those individuals concerned, and the other complaint was turned over to the Board of Pharmacy in their respective state. Communicating face to face is much easier in solving prescription problems than over a 1-800 number. The Federal Food, Drug and Cosmetic Act prescribes what is on the prescription label and manufacturer's label, however, individual states expand on those requirements for the safety of the public and information provided for the pharmacies. Mr. Hitchcock stated there is not that much differentiation between the labeling requirements in Kansas and other states. Batch lots are not a requirement in Kansas. In regard to hearing a complaint, it was pointed out that if there is enough evidence and reason to have a hearing, it is presented to the Board, and the Board directs the agency or attorney to take action against the pharmacy. 13 out-of-state pharmacies are registered with the Board.

Clifford Berman, Baxter Healthcare Corporation (a mail-order pharmacy), submitted written testimony in opposition to **HB 3064** in its present form, and in particular subsection (c). Mr. Baxter stated they have filled over 20 million prescriptions, never been sued for malpractice and never disciplined by the Board of Pharmacy in Illinois. If their company has to comply with the laws of 50 states, the costs to patients would be unnecessarily increased to cover the additional administrative expenses necessary to undertake educating their employees as to the laws of each state and to ensure compliance with those laws. Mr. Berman stated they are in favor of registration, but recommends subsection (c) of the bill be stricken. He also suggested their willingness to meet with the Board of Pharmacy to rectify those differences. (Attachment 3)

Written testimony on **HB 3064** was received from the following: Mary Holmgren, Super-D Drugs, Topeka pharmacist; Mrs. Geneva B. Watkins, Overland Park AARP; Frank Lawler, Leawood AARP; and Clarence Arndt, Overland Park AARP. (Attachments 4 - 7)

The Chairman announced that because of the time element, continuation of hearing on **HB 3064** will be held at the next meeting.

Pages assisting at the Committee meeting were sponsored by Senator Walker.

The meeting was adjourned at 11:00 a.m. The next meeting is scheduled for April 7, 2:00 p.m., Room 527-S.

SENATE  
PUBLIC HEALTH AND WELFARE COMMITTEE

DATE 4-6-92

(PLEASE PRINT)  
NAME AND ADDRESS

ORGANIZATION

Clifford Beriman

Baxter Healthcare Corp.

111 Barclay Blvd, Lincolnshire, IL 60069

(opponent)

John Eivsky Topeka

Medco Containment

LISA Getz

Wichita Hospitals

BILL HENRY, TOPEKA

PMA

KEVIN R LANDIS TOPEKA

CHRISTIAN SCIENCE COMMITTEE  
ON PUBLICATION FOR KANSAS

Martha Jenkins Topeka

Ks. Govt. Consulting

Chip Wheelen Topeka

Ks Med Soc

Margot Ariz Missouri

Boehringer Ingelheim

John Mc Baumgardner Lawrence, Ks

Kansas Pharmacists Assoc

Anita Kolusch Topeka

"

Carol J. Morgan Topeka

"

Rebecca Fin Topeka

"

Ks Pharm. Assoc.

Bill Sneed TOPEKA

HIAA

Robert Sneed "

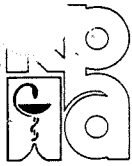
Ks Govt Consulting

Michael Wright Houston, Tx.

Syntex Labs, Inc.

Robert Epps

SPS



THE KANSAS PHARMACISTS ASSOCIATION  
1308 SW 10TH STREET  
TOPEKA, KANSAS 66604  
PHONE (913) 232-0439  
FAX (913) 232-3764

ROBERT R. (BOB) WILLIAMS, M.S., C.A.E.  
EXECUTIVE DIRECTOR

**TESTIMONY**  
**SENATE PUBLIC HEALTH & WELFARE COMMITTEE**  
**HB 3064**  
**April 1, 1992**

My name is Bob Williams, I am Executive Director of the Kansas Pharmacists Association. Thank you for this opportunity to address the committee regarding House Bill 3064.

In your consideration of House Bill 3064 it is important for you to keep in mind that pharmacy is a health care profession, not a commodity. Unfortunately, in our society we have come to take prescription medication, and the benefits of prescription medication, for granted. Long gone are the days when prescription medication could only be purchased at a local drug store. Medication can now be purchased via "mail order" from pharmacies not located in the State of Kansas. In some cases these mail order pharmacies dearly love the fact that many in the third party benefits community have accepted their miscasting that pharmacy is nothing more than a commodity, so many widgets moving in interstate commerce.

The truth is, drugs are unique among all products. Not only are they injury producing, they are injury reducing as well. Oftentimes harm from a prescription medication is unforeseeable and unpreventable, and for that reason the law has recognized that drugs are to be afforded special status as unavoidably unsafe products.

The United States is the only country in the world that allows prescription drugs to be mailed to the ultimate consumer. In other countries, prescription drugs

*Senate P.H.W.*  
*Attachment #1*  
*4-6-92*

are regulated in a manner analogous to poisons. Acknowledging the enormous capacity of potent medications not only to help, but also to harm. This peculiarity of the United States approach is best illustrated in the example of Warfarin Sodium. Warfarin is the active ingredient in several common household pesticides. As such, it is illegal to mail Warfarin to the ultimate consumer. But warfarin is also Coumadin, a blood thinner, and as such, it is routinely mailed to mail order drug consumers.

For a number of years, in the interest of public health, the Kansas Board of Pharmacy has attempted to gain some regulatory control over the increased number of nonresident pharmacies mailing prescription medication to Kansas residents. Attached to my testimony is a paper trail which was begun in 1984 between the Board of Pharmacy and the Kansas Attorney General in an attempt to clarify the Board's authority to regulate nonresident pharmacies. In May of 1991 the Kansas Pharmacists Association sent a letter to the attorney general requesting he take action concerning the refusal by some nonresident pharmacies to register with the Kansas Board of Pharmacy. His response, dated June 19, 1991, indicated there is "a potential ambiguity in the application of registration requirements." The provisions outlined in HB 3064 are to eliminate the ambiguity of KSA 65-1643.

During the House deliberations of HB 3064 we went to great lengths to work out the differences concerning HB 3064. As a result the American Association of Retired Persons (AARP) supports HB 3064. Chief among the concerns expressed are the provisions on page 4, lines 24 through 34.

It is the position of the Kansas Pharmacists Association that requiring non-resident pharmacies to abide by the Kansas Controlled Substances Act, Kansas Drug Product Selection Laws, and Kansas laws regarding the labeling of prescription medication is not an undue burden. I have copies of the Kansas requirements for

product selection and labeling of prescription medication. Upon reviewing these requirements, if the committee views these as burdensome, the Kansas Pharmacists Association would be delighted to work with the committee to remove these requirements from the Kansas Pharmacy Practice Act.

In regards to controlled substances, the Kansas Board of Pharmacy does an excellent job of keeping the Kansas laws in line with federal law. However, situations can occur where the Kansas law is more restrictive than federal law. For example, a few years ago Kansas moved anabolic steroids from the list of legend drugs to a Schedule IV Controlled Substance. This action predated action by the federal government. Should the language on page 4, line 25 through 26 be struck or diluted in any fashion, in the anabolic steroid example above, nonresident pharmacies would not have been obligated to follow Kansas law regarding the dispensing of anabolic steroids.

Nonresident pharmacies which oppose registering with the Board of Pharmacy indicate such legislation could violate the Commerce Clause and Supremacy Clause of the United States Constitution. Attached to my testimony is a letter from the Attorney General to the Kansas Board of Pharmacy dated March 2, 1990 which states "In summary, a state law requiring pharmacies which sell or deliver prescription-only drugs to be registered with the state board, whether those pharmacies are located within or outside the state's borders, is not invalidated by the Commerce Clause or Supremacy Clause of the United States Constitution so long as the regulation does not create an undue burden on commerce." The Kansas Pharmacists Association does not believe that requiring nonresident pharmacies to register with the Kansas Board of Pharmacy and requiring them to comply with regulations established by the Board is an "undue burden" any more than those laws,

rules and regulations which apply to all other groups who are involved in interstate commerce.

I have attached to my testimony a listing of those states which require the registering/licensing of non-resident pharmacies. The language contained in HB 3064 was based on legislation passed in Delaware, Alabama, Texas and California. Nonresident pharmacies (including Medco) are registered in those states. There have been no challenges and the cost of their prescription medications have not increased as a result of enactment of this legislation.

Additionally, I would like to call the committee's attention to a memo the Kansas Board of Pharmacy received February 10, 1991 from the FDA regarding unapproved mail order drugs. As the attached memo indicates, six overseas companies are illegally advertising "foreign versions" of approved prescription drugs. In some cases the drugs are counterfeit--lacking any real similarity to the approved drug. While the attached certainly represents the bottom of the barrel, it is an indication of the growing concern and need for regulatory control of nonresident pharmacies by the Kansas Board of Pharmacy.

The Kansas Pharmacy Practice Act is in place to protect Kansas residents. To permit nonresident pharmacies to flout the Kansas Pharmacy Practice Act is tantamount to saying we might as well repeal all such laws. Kansas residents need the security in knowing that they are afforded appropriate protection under the law regardless of where they purchase their prescription medication.

The Kansas Pharmacists Association urges the committee to support HB 3064.

Thank you.



STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

2ND FLOOR, KANSAS JUDICIAL CENTER, TOPEKA 66612

ROBERT T. STEPHAN  
ATTORNEY GENERAL

MAIN PHONE (913) 296-2215  
CONSUMER PROTECTION 296-3751  
ANTITRUST 296-9299

July 20, 1984

ATTORNEY GENERAL OPINION NO. 84- 71

Lynn E. Ebel  
Attorney, Kansas Board of Pharmacy  
Davis, Davis, McGuire & Thompson  
P.O. Box 69  
400 Shawnee Street  
Leavenworth, Kansas 66048

Re: Public Health -- Examination and Registration of  
Pharmacists -- Registration of Out of State Pharmacists  
Doing Business in Kansas

Synopsis: The requirements of the Kansas Pharmacy Act, K.S.A.  
65-1601 et seq extend to all persons within or without  
the state who deliver prescription drugs in Kansas.  
Cited herein: K.S.A. 65-1636, K.S.A. 1983 Supp.  
65-1626, 65-1631, 65-1643.

\* \* \*

Dear Ms. Ebel:

As counsel for the Kansas Board of Pharmacy, you request our opinion regarding the authority of the board to require out of state pharmacies doing business in Kansas to hold Kansas pharmacy licenses and be subject to the board's regulations.

K.S.A. 65-1636 is contained in the Kansas Pharmacy Act, K.S.A. 65-1625 et seq., and provides:

Ew



Lynn E. Ebel  
Page Two

"Except as otherwise provided in this act, the sale and distribution of drugs shall be limited to pharmacies operating under registrations as required by this act and the actual sale or distribution of drugs shall be made by a registered pharmacist or other person acting under his or her immediate personal direction and supervision."

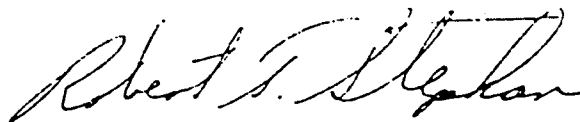
K.S.A. 1983 Supp. 65-1626(i) states that to "distribute means to deliver . . . any drug." Subsection (g) states that to "dispense means to deliver prescription medication to the ultimate user pursuant to the lawful order of a practitioner."

The term pharmacy is defined at K.S.A. 1983 Supp. 65-1626(s) as "premises, laboratory, area or other place (1) where drugs are offered for sale, where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed . . .". As noted above, only pharmacies operating under the direction of a registered pharmacist may distribute drugs in Kansas under K.S.A. 65-1636. K.S.A. 1983 Supp. 65-1643(f) provides that it is unlawful for "any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board . . .".

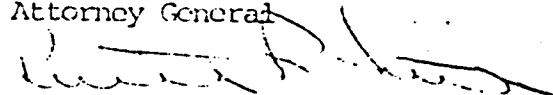
In none of the foregoing statutes is there any language of limitation which suggests that only Kansas residents are subject to the board's control. Rather, Kansas statutes provide for the registration on a reciprocal basis of out of state pharmacists without examination. K.S.A. 1983 Supp. 65-1631(d). We therefore conclude that the language of the Kansas Pharmacy Act does not suggest that its provisions are limited to pharmacies within this state.

A consideration of the purpose of the act also suggests that there was no intent to limit the application of the act. The state's interest in establishing and maintaining high standards in the dispensation of prescription drugs is clear. See, e.g., *State ex rel. v. Fadely*, 180 Kan. 652, 665 (1957). We therefore conclude that both the language and purpose of the Kansas Pharmacy Act require that out of state pharmacies doing business in Kansas hold a Kansas pharmacy license and be subject to all Kansas regulations.

Very truly yours,



ROBERT T. STEPIEN  
Attorney General



Kenneth R. Smith  
Assistant Attorney General

# Kansas State Board of Pharmacy

LANDON STATE OFFICE BUILDING  
900 JACKSON AVENUE, ROOM 513  
TOPEKA, KANSAS 66612-1220  
PHONE (913) 296-4056

STATE OF KANSAS



MIKE HAYDEN  
GOVERNOR

## MEMBERS

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EXECUTIVE SECRETARY  
TOM C. HITCHCOCK  
BOARD ATTORNEY  
JOHN C. WHITAKER

TO: Robert Stephan  
Attorney General

FROM: Tom C. Hitchcock  
Executive Secretary

RE: Registration of Out-of-State Pharmacies

DATE: August 18, 1989

In a recent Attorney General opinion, it was stated that the Board of Pharmacy had adequate authority to require out-of-state pharmacies that routinely mail prescriptions into Kansas to become registered and abide by Kansas Pharmacy law. (Ref: AG Opinion 84-71)

The Board of Pharmacy has requested and received from the following companies their appropriate registration application:

1. Walgreens, 519 W. Lone Cactus, Phoenix, AZ
2. Butler Healthmart Pharmacy, 18 N. Delaware, Butler, MO
3. Preferred Prescriptions, 201 E. Armour Blvd., Kansas City, MO

The following companies have been requested by the Board of Pharmacy to comply with pharmacy registration but have refused to do so:

1. Feld Prescription Service, 5023 Grover, Omaha, NE 68106
2. AARP Pharmacy Service, 3823 Broadway, Kansas City, MO 64111
3. MEDCO Corporation, 700 W. 3rd Avenue, Columbus, OH 43212
4. MEDCO Corporation, 15001 Trinity Blvd, Suite 300, Fort Worth, TX 76155
5. MEDCO Corporation, 5373 S. Arville, Las Vegas, NV 89118

The Board requests the Attorney General's office to review the latter group and take appropriate intervention in order to reach compliance with Kansas law.

If you have any questions, please feel free to contact this office.

TCH:arh

# Kansas State Board of Pharmacy

LONDON STATE OFFICE BUILDING  
900 JACKSON AVENUE, ROOM 513  
TOPEKA, KANSAS 66612-1220  
PHONE (913) 296-4056

STATE OF KANSAS

December 18, 1989

## MEMBERS

DANA L. CREITZ, JR., PARSONS  
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KARLA K. KNEEBONE, NEODESHA  
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## EXECUTIVE SECRETARY

TOM C. HITCHCOCK

## BOARD ATTORNEY

~~JOHN C. HAYDEN~~

DANA KILLINGER



MIKE HAYDEN  
GOVERNOR

Mr. Robert T. Stephan  
Attorney General  
State of Kansas  
Judicial Center  
Topeka, KS 66612

## BUILDING MAIL

Dear Mr. Stephan:

On behalf of the Kansas State Board of Pharmacy, I request your opinion with respect to mail-order prescription businesses not located in Kansas and their responsibilities under Kansas law.

Specifically, are mail-order prescription businesses not located in Kansas but which fill prescription orders by mail to Kansas residents, required to be registered under the Kansas Pharmacy Act? Also, if the above registration is required, would such be constitutional under the Commerce Clause and Supremacy Clause of the United States Constitution?

The Board of Pharmacy thanks you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Tom C. Hitchcock".

Tom C. Hitchcock  
Executive Secretary

TCH:kmo



STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

2ND FLOOR, KANSAS JUDICIAL CENTER, TOPEKA 66612-1597

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FEB 23 1990

KANSAS STATE  
BOARD OF PHARMACY

ROBERT T. STEPHAN  
ATTORNEY GENERAL

February 23, 1990

MAIN PHONE: (913) 296-2215  
CONSUMER PROTECTION: 296-3751  
TELECOPIER: 296-6296

Tom Hitchcock, Executive Secretary  
Kansas State Board of Pharmacy  
Landon State Office Bldg., Room 513  
Topeka, Kansas 66612-1220

Re: Public Health -- Regulation of Pharmacists -- Registration  
or Permit Required; Out-of-State Mail Order Pharmacies

Dear Mr. Hitchcock:

I have reviewed your opinion request dated December 18, 1989 regarding registration of mail order pharmacies. I have also reviewed Attorney General Opinion No. 84-71 in which I stated that the requirements of the pharmacy act extend to all persons within or without the state who deliver prescription drugs in Kansas.

After considering the statutory mandate of K.S.A. 1989 Supp. 65-1636, I reach the same conclusion as I did in the 1984 Attorney General opinion. That statute provides a rule that, in order to sell or distribute prescription drugs, you must be a pharmacy with a licensed pharmacist responsible for the sale. While there may be some areas which need guidelines for administration, such as the mechanics for registering out-of-state mail order pharmacies, such guidelines might be appropriately set out in rules and regulations.

If we may be of further assistance, please feel free to contact us.

Very truly yours,

A handwritten signature in cursive script that reads "Robert T. Stephan".

ROBERT T. STEPHAN  
Attorney General of Kansas

RTS:MWS:bas

# Kansas State Board of Pharmacy

LONDON STATE OFFICE BUILDING  
900 JACKSON AVENUE, ROOM 513  
TOPEKA, KANSAS 66612-1220  
PHONE (913) 296-4056

*Bob Williams*  
*FYI*

March 6, 1990

STATE OF KANSAS



MIKE HAYDEN  
GOVERNOR

*for BOT  
March Meeting*

## MEMBERS

DANA L. CREITZ, JR., PARSONS  
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EXECUTIVE SECRETARY  
TOM C. HITCHCOCK  
BOARD ATTORNEY  
DANA W. KILLINGER

MEMO TO: Board Members  
Board Inspectors  
Board Attorney

FROM: Tom Hitchcock *Tom Hitchcock*

SUBJECT: Out-of-State Pharmacies

About a year ago I was directed to pursue licensing out-of-state pharmacies that are sending prescriptions to Kansas residents. The office communicated with several mail-order pharmacy companies and a few complied. As a result, the letter of August 18, 1989 was generated and sent to the office of the Attorney General. Following such letter was a great deal of research assigned to Daniel Kolditz, Assistant Attorney General.

As a result of the work by Mr. Kolditz, which included several meetings between us, the recommendation was another letter to request an A.G. opinion. The new request would include the question of constitutionality of requirement for out-of-state pharmacies, that fill prescriptions by mail to Kansas residents, become licensed in Kansas and comply with Kansas Pharmacy Statutes.

Such request was sent to the Attorney General by the letter of December 18, 1989. The reply did not come as an Attorney General Opinion, but in a response letter over the signature of the Attorney General as enclosed.

The response will be discussed further at the April meeting of the Board. I need guidance as what direction to proceed.

Enclosures  
TCH:tch

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MAR 05 1990

KANSAS STATE  
BOARD OF PHARMACY



STATE OF KANSAS

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MAR 05 1990

KANSAS STATE  
BOARD OF PHARMACY

OFFICE OF THE ATTORNEY GENERAL

2ND FLOOR, KANSAS JUDICIAL CENTER, TOPEKA 66612-1597

ROBERT T. STEPHAN  
ATTORNEY GENERAL

March 2, 1990

MAIN PHONE: (913) 296-2215  
CONSUMER PROTECTION: 296-3751  
TELECOPIER: 296-6296

Tom C. Hitchcock, Executive Secretary  
Kansas State Board of Pharmacy  
Landon State Office Building, Room 513  
Topeka, Kansas 66612

Dear Mr. Hitchcock:

As Attorney General I recently stated in a letter addressed to you and dated February 23, 1990 that, in order to sell or distribute prescription-only drugs in Kansas, you must be a pharmacy with a licensed pharmacist responsible for the sale. You ask whether the statutes imposing this requirement are constitutional under the Commerce Clause and Supremacy Clause of the United States Constitution.

States may not impose an undue burden on interstate commerce, neither may state law discriminate against interstate commerce. If the state law works evenhandedly against both interstate and intrastate commerce, the test to apply is whether there is an undue hardship on interstate commerce. To determine this, a balancing test is applied to weigh the burden imposed on commerce against the benefit received by the law or regulation. The state has a legitimate interest in protecting the public health, safety and welfare through laws regulating pharmacies. As long as the licensing requirements and regulatory mechanisms do not become too onerous, the state law is legitimate. Insofar as additional legislation is needed, either by the legislature's enactment of statutes or the board's promulgation of rules, such additional legislation should be written to create the least restrictive means of achieving the desired goals. If this is accomplished, the state's exercise of authority should withstand a challenge based on the Commerce Clause.

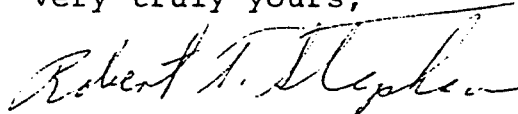
Regarding the Supremacy Clause, there are three ways the preemption doctrine is invoked. Congress may intend to appropriate the entire field of a phase of commerce so that

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there is no room for supplementary state action. Secondly, state law which directly conflicts with an act of Congress is preempted. Finally, state law which conflicts with a manifest intent of a congressional act is preempted. We are not aware of federal law which preempts state regulation of out-of-state pharmacies.

In summary, a state law requiring pharmacies which sell or deliver prescription-only drugs to be registered with the state board, whether those pharmacies are located within or outside the state's borders, is not invalidated by the Commerce Clause or Supremacy Clause of the United States Constitution so long as the regulation does not create an undue burden on commerce.

Very truly yours,



ROBERT T. STEPHAN  
Attorney General of Kansas

RTS:MWS:bas



STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

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ROBERT T. STEPHAN  
ATTORNEY GENERAL

MAIN PHONE: (913) 296-2215  
CONSUMER PROTECTION: 296-3751  
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June 19, 1991

Hugh Snell, President  
The Kansas Pharmacists Association  
1308 West 10th  
Topeka, Kansas 66604

Dear Mr. Snell:

Attorney General Stephan asked that I respond to your letter dated May 31, 1991, requesting investigation and action by this office with regard to out-of-state mail order pharmacies. As you are aware, this issue has been previously addressed by this office and you note several letters in your correspondence. A review of this office's past statements and position with regard to this issue indicates that if the registration of an out-of-state pharmacy is not required by K.S.A. 65-1643, then such pharmacy is not constrained by K.S.A. 65-1636. Because of a potential ambiguity in the application of registration requirements, it was suggested to your counsel that legislative amendments were necessary in order to clarify whether the complained of actions were clearly prohibited by Kansas law. Thus far, such legislative clarifications have not been forthcoming. Therefore, based upon previous legal research and consideration of the facts you present, and because it does not appear that the situation has in any way changed since our last review of this matter, we hereby decline your request for an investigation by this office.

Very truly yours,

OFFICE OF THE ATTORNEY GENERAL  
ROBERT T. STEPHAN

Theresa Marcel Nuckolls  
Assistant Attorney General

TMN:bas

cc: John Campbell, Deputy AG, Litigation  
Dan Kolditz, Deputy AG, Consumer  
cc: Tom Hitchcock, Exec. Secretary  
Board of Pharmacy

RECEIVED

JUN 20 '91

K. PH. A.

1-13



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FEB 10 1992

KANSAS STATE  
BOARD OF PHARMACY

From: ORA-DFSR (FDA500) Delivered: Fri 31-Jan-92 10:02 EST Sys 157  
Subject: PRESS RELEASE  
Mail Id: IPM-157-920131-090400154

TO: NR-1 (STATE HEALTH OFFICERS)  
NR-2 (BOARDS OF PHARMACY)  
NR-3 (DIRECTORS OF AGRICULTURE)  
NR-4 THRU NR-16, NR-39 THRU NR-43 (STATE DRUG OFFICIALS)

INFO: ASTHO -- JOY EPSTEIN  
NABP -- CARMEN CATIZONE  
AFDO -- WHITNEY ALMQUIST  
NASDA -- BOB AMATO

FROM: HEINZ G. WILMS, DIRECTOR, DIVISION OF FEDERAL-STATE RELATIONS,  
ORO/FDA

DATE: JANUARY 31, 1992

SUBJECT: PRESS RELEASE - IMPORT ALERT - UNAPPROVED MAIL-ORDER DRUGS

THE FOOD AND DRUG ADMINISTRATION ANNOUNCED TODAY IT HAS ISSUED AN IMPORT ALERT AGAINST UNAPPROVED MAIL-ORDER DRUGS PROMOTED BY SIX OVERSEAS COMPANIES.

MANY OF THESE DRUGS ARE ILLEGALLY ADVERTISED IN PERIODICALS AND THROUGH DIRECT MAIL, AS FOREIGN VERSIONS OF APPROVED PRESCRIPTION DRUGS. THE PROMOTION AND DISTRIBUTION OF UNAPPROVED DRUG PRODUCTS WITHIN THE UNITED STATES IS ILLEGAL.

"IN SOME CASES, THE DRUGS ARE COUNTERFEIT -- LACKING ANY REAL SIMILARITY TO THE APPROVED DRUG. THE UNCERTAIN CHARACTER AND QUALITY OF THESE DRUGS CONSTITUTE AN UNREASONABLE RISK TO THE PUBLIC HEALTH," FDA COMMISSIONER DAVID A. KESSLER, M.D., SAID.

THE IMPORT ALERT INSTRUCTS FDA FIELD OFFICES TO AUTOMATICALLY DETAIN ALL IMPORTED UNAPPROVED PRESCRIPTION PRODUCTS MANUFACTURED BY SIX OVERSEAS COMPANIES WHICH HAVE PROMOTED THEIR PRODUCTS IN THIS COUNTRY. THE COMPANIES CITED ARE INTERPHARM, INC., OF NASSAU, BAHAMAS; NORTHAM MEDICATION SERVICE INTERNATIONAL PHARMACY OF NASSAU, BAHAMAS; INHOME SERVICES OF DELEMONT, SWITZERLAND; INTERNATIONAL PRODUCTS OF HANNOVER, GERMANY; AZTECA TRIO INTERNACIONAL, S.A. DE C.V., OF ZONA RIO TIJUANA, MEXICO; AND INTERLAB OF LONDON, ENGLAND.

THESE COMPANIES HAVE BEEN PROMOTING A WIDE VARIETY OF PRODUCTS PURPORTED TO TREAT VARIOUS CONDITIONS, INCLUDING DEPRESSION, HIGH BLOOD PRESSURE, FUNGAL INFECTIONS, FATIGUE, CHRONIC BRONCHITIS AND HAIR LOSS.

1-14

A RISK TO THE PATIENT'S HEALTH. DR. KESSLER SAID SO-CALLED "FOREIGN VERSIONS" OF PRESCRIPTION DRUGS ARE OFTEN OF UNKNOWN QUALITY WITH INADEQUATE DIRECTIONS FOR USE.

FOR MANY YEARS FDA HAS PERMITTED -- AND WILL CONTINUE TO PERMIT -- ITS FIELD OFFICES TO EXERCISE DISCRETION REGARDING THE RELEASE FOR ENTRY INTO THE UNITED STATES OF SMALL "PERSONAL-USE" QUANTITIES OF DRUGS SOLD ABROAD BUT NOT APPROVED IN THE UNITED STATES -- PROVIDED THAT THE DRUGS DO NOT POSE UNREASONABLE SAFETY RISKS, THAT THEIR USE IS NOT PROMOTED IN THE UNITED STATES AND THAT THEY ARE FOR A SERIOUS CONDITION FOR WHICH THERE IS NO SATISFACTORY TREATMENT AVAILABLE IN THIS COUNTRY. THE POLICY WAS DESIGNED TO GIVE FDA FIELD OFFICES DISCRETION TO RELEASE SMALL QUANTITIES OF MEDICINES WITH WHICH INDIVIDUALS RETURNING TO THE UNITED STATES MAY HAVE BEEN TREATED WHILE TRAVELING ABROAD AND TO ALLOW INDIVIDUALS WITH SERIOUS CONDITIONS THE ABILITY TO IMPORT, UNDER CERTAIN LIMITED CONDITIONS, PERSONAL-USE QUANTITIES OF UNAPPROVED DRUGS THAT THEY BELIEVE MIGHT BE HELPFUL IN TREATING THEIR CONDITIONS.

PERSONAL-USE QUANTITIES ARE GENERALLY CONSIDERED TO BE AMOUNTS FOR A PATIENT'S TREATMENT FOR THREE MONTHS OR LESS. IMPORTS INVOLVING LARGER QUANTITIES ARE NOT PERMITTED AS THEY LEND THEMSELVES TO COMMERCIALIZATION.

FDA APPROVES DRUGS ON THE BASIS OF SCIENTIFIC DATA PROVING THEM TO BE SAFE AND EFFECTIVE. FDA-APPROVED LABELING PROVIDES INFORMATION ON HOW AND WHEN THE DRUGS CAN BE USED TO MAXIMIZE THEIR EFFECTIVENESS AND MINIMIZE THEIR HARMFUL SIDE EFFECTS. THE MANUFACTURING FACILITIES AND PROCEDURES FOR APPROVED PRODUCTS ARE ALSO CAREFULLY REGULATED BY FDA TO ENSURE PRODUCT INTEGRITY.

THE UNAPPROVED DRUGS PROMOTED BY THESE OVERSEAS OPERATIONS LACK THESE SAFEGUARDS AND QUALITY ASSURANCE STANDARDS.

CONSUMERS SHOULD ALSO BE AWARE THAT THE ACQUISITION AND USE OF PRESCRIPTION DRUGS WITHOUT THE VALID PRESCRIPTION OF A PHYSICIAN OR OTHER LICENSED HEALTH PROFESSIONAL MAY VIOLATE STATE OR LOCAL LAWS. FDA WARNS THAT SEVERE ADVERSE REACTIONS, INCLUDING DEATH, CAN RESULT FROM THE IMPROPER USE OF PRESCRIPTION DRUGS.

PERSONS WITH QUESTIONS ABOUT IMPORTATION OF DRUGS FOR PERSONAL USE SHOULD CONSULT WITH THEIR LOCAL FDA DISTRICT OFFICE OR THE FDA IMPORTS OPERATIONS BRANCH IN ROCKVILLE, MD., AT (301) 443-6553.

THE FOOD AND DRUG ADMINISTRATION IS ONE OF THE EIGHT PUBLIC HEALTH SERVICE AGENCIES WITHIN HHS.

#####

RECEIVED

FEB 10 1992

KANSAS STATE  
BOARD OF PHARMACY

From: ORA-DFSR (FDA500) Delivered: Tue 28-Jan-92 14:35 EST Sys 157  
Subject: IMPORT ALERT  
Mail Id: IPM-157-920128-131340224

TO: ~~NR-1~~ (STATE HEALTH OFFICERS)  
~~NR-3~~ (BOARDS OF PHARMACY)  
NR-4 THRU NR-16, NR-39 THRU NR-43 (STATE DRUG OFFICIALS)

INFO: AFDO -- WHITNEY ALMQUIST  
ASTHO -- JOY EPSTEIN  
NABP -- CARMEN CATIZONE  
NAAG -- EMMITT CARLTON  
MEXICO -- DRA. MERCEDES JUAN  
REGIONAL FOOD AND DRUG DIRECTORS  
DISTRICT DIRECTORS  
STATE CO-OP PROGRAM MANAGERS

FROM: ACTING DIRECTOR, DIVISION OF FEDERAL-STATE RELATIONS, OFFICE OF  
REGIONAL OPERATIONS, ORA

DATE: JANUARY 28, 1992

SUBJECT: FDA IMPORT ALERT #66-57 -- "AUTOMATIC DETENTION OF FOREIGN  
MANUFACTURED UNAPPROVED PRESCRIPTION DRUGS PROMOTED TO INDIVIDUALS  
IN THE U.S."

On January 27, the Food and Drug Administration issued the subject Import Alert as one means of dealing with illegal promotion and importation of unapproved prescription drugs of foreign origin.

Unapproved prescription drugs, promoted and shipped into the U.S. by the distributors named in the alert, present serious safety and effectiveness concerns. In addition, approved U.S. versions of the drugs being promoted and distributed by these firms are available.

FDA has alerted all Import Program Managers that prescription drugs shipped by the named firms are to be automatically detained. Drugs covered by a current approved NDA or IND are unaffected.

FDA has concluded that shipments of these foreign manufactured unapproved prescription drugs are inappropriate for release under the personal importation policy, contrary to what the distributors claim in their promotional materials.

If you have any comments, questions, etc. regarding Import Alert #66-57, please contact me at (301)443-3360.

/s/  
Jon R. May, Ph.D., R.Ph.

1/16

ALTA ENT

Date: January 27, 1992

From: Acting Director, Import Operations Branch (HFC-131)

Subject: Import Alert #66-57 "Automatic Detention of Foreign Manufactured Unapproved Prescription Drugs Promoted to Individuals in the U.S."

To: Import Program Managers

Info: All Major Field Offices  
Resident Posts

TYPE OF ALERT: AUTOMATIC DETENTION

PRODUCT : FOREIGN MANUFACTURED UNAPPROVED PRESCRIPTION DRUGS

PRODUCT CODE : 66 [ ] [ ] [ ] [ ] [ ]

HARMONIZED CODE :

PROBLEM : New drug without an approved New Drug Application (NDA) (DRND)

PAC : 56008H

COUNTRY : ALL

MANUFACTURER/SHIPPER : See Attachment

MANUFACTURER SHIPPER I.D.#: N/A

IMPORTER'S I.D.# : N/A

CHARGE : "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an approved new drug application [Unapproved New Drug, Section 505(a)]."

RECOMMENDING OFFICE : HFC-131

REASON FOR ALERT : FDA has observed an increase in the promotion and importation of unapproved prescription drugs of foreign origin. Unapproved prescription drugs present serious safety and effectiveness concerns. Moreover, approved U.S. versions of these drugs are available. Therefore, this import alert is being established to provide a listing of known distributors.

1-17

INSTRUCTIONS : Automatically detain all dosage forms and shipments, commercial and personal, of foreign manufactured unapproved prescription drugs from distributors listed in the attachment. Districts should determine whether the drugs are covered by a current approved NDA or IND.

FDA has concluded that shipments of these foreign manufactured unapproved prescription drugs are inappropriate for release under the personal importation policy.

FOI : No purging is required

KEYWORDS : NEW DRUG (NDA), Prescription Drugs

/s/  
John W. Browne

ATTACHMENT IMPORT ALERT #66-57 DISTRIBUTORS OF FOREIGN MANUFACTURED UNAPPROVED PRESCRIPTION DRUGS PROMOTED TO INDIVIDUALS IN THE U.S.

PRODUCT	SOURCE	COUNTRY
ALL PRESCRIPTION DRUGS	INTERPHARM, INC. INTERNATIONAL PHARMACY	NASSAU, BAHAMAS
ALL PRESCRIPTION DRUGS	NORTHAM Medication Service International Pharmacy	NASSAU, BAHAMAS
ALL PRESCRIPTION DRUGS	INHOME HEALTH SERVICES	DELEMONT, SWITZERLAND
ALL PRESCRIPTION DRUGS	International Products	HANOVER, GERMANY
ALL PRESCRIPTION DRUGS	AZTECA TRIO INTERNACIONAL S.A. de C.V.	ZONA RIO TIJUANA, MEXICO
ALL PRESCRIPTION DRUGS	INTERLAB	LONDON, ENGLAND

1-18

# SAVE 30%-60%

on your prescription  
medications with  
**NORTHAM** equivalents

Hismanal 10 mg  
**\$83.50/100**

Prozac 20 mg  
**\$99.00/100**

Zantac 150 mg  
**\$89.00/100**

Zovirax 200 mg  
**\$48.00/100**

Cipro 500 mg  
**\$198.00/100**

Seldane 60 mg  
**\$45.00/100**

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NOV 15 1991

KANSAS STATE  
BOARD OF PHARMACY



**NORTHAM**  
Medication Service

1-19



# NORTHAM

Medication Service

**Buy quality prescription medications  
identical to U.S. standards  
and low low prices**

**SAVE 30% to 60% over U.S. prices  
Call now toll free**

**1-800-363-0436**

Retrovir (AZT) 100 mg  
**\$89.00/100**

Zantac 300 mg  
**\$129.00/100**

Premarin .3 mg	<b>\$17.00/100</b>
.625 mg	<b>\$22.50/100</b>
1.25 mg	<b>\$29.00/100</b>

Vasotec 5 mg  
**\$55.00/100**

Nizoral 200 mg  
**\$148.00/100**

1-20

**For Sale: Black metal tool box for small truck, no trays, \$75.00. 321-5031 after 4:30.**

**SAVE 30% TO 60% on your prescription medications. Prozac \$99/100, Seldane \$45/100, Hismanal \$83.50/100, Eldepryl \$120/100, Premarin .625 mg. \$22.50/100, and Zantac equivalents and most other drugs available. Northam Medication 1-800-363-0436. 11/20**

**Car Batteries as low as \$29.99 at Janney NAPA Auto Parts. c**

**RECEIVED**

NOV 8 1991

KANSAS STATE  
BOARD OF PHARMACY

1-21



# Why Pay High Drug Prices?

Save 30% to 60% on medications through  
NORTHAM Medication Service.

U.S. drug prices are the world's highest ...  
because patents prevent competition.

Some countries do not permit patents on pharmaceuticals; others regulate prices. The U.S. stands virtually alone in allowing drug manufacturers to charge high prices. This means that you could be paying nearly twice as much as needed for costly medication!

## NORTHAM Medication Service.

**NORTHAM** is an international pharmacy, importing from Europe and Canada, where quality is identical to U.S. standards, but prices are lower due to competition.

**NORTHAM** cannot supply all medication, but we try to supply those most widely used and most expensive. All **NORTHAM** products are packed in 100-count packages. A partial list is on the order form. If you are using a drug on the list, order today and we will supply promptly by airmail.

## Your rights

- FDA rules allow you to import drugs for your use.
- You have a right to save money!
- NORTHAM enables you to import to save 30% to 60% over U.S. prices.
- If a drug you use is on our list, order today. Reduce the drug price burden!

**COMPLETE FORM ON REVERSE SIDE AND BELOW AND SEND WITH PAYMENT  
OR ORDER BY PHONE TOLL FREE 1-800-363-0436**

### PAYMENT METHOD

 VISA MasterCard Cashiers Check Money Order

Card #

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Expiration

		/		
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Remember to enclose payment unless this is a VISA or MASTERCARD order.

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_

STATE \_\_\_\_\_

TEL. (\_\_\_\_\_) \_\_\_\_\_

ZIP \_\_\_\_\_

### DOCTOR'S INFORMATION

DR'S NAME \_\_\_\_\_

TEL. \_\_\_\_\_

## NORTHAM Medication Service

International Pharmacy

P.O. Box N-7108, Nassau, Bahamas

or order by phone

Toll Free

1-800-363-0436

The medications are for my personal use and I will use only as directed by my physician.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**ORDER TOLL FREE • 1-800-363-0436**

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Order #

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Credit Auth.

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Auth. Date

1-22

Brand Name	Northam Equiv.	Strength	Quantity	Price /100	Total \$ U.S.
Aldor	Methyldopa	125 mg tab	x100	\$ 11.50	
		250 mg tab	x100	\$ 16.00	
		500 mg tab	x100	\$ 25.00	
Anaprox	Naproxen Sodium	275 mg tab	x100	\$ 45.00	
Anaprox-DS	Naproxen Sodium	500 mg tab	x100	\$ 69.00	
Anasaid	Flubiprofen	50 mg tab	x100	\$ 40.50	
		100 mg tab	x100	\$ 59.50	
Buspar	Buspirone	5 mg tab	x100	\$ 33.50	
		10 mg tab	x100	\$ 57.50	
Calan-Sr or Isoptin-SR	Verapamil-Sr	180 mg tab	x100	\$ 49.00	
		240 mg tab	x100	\$ 62.00	
Capoten	Captopril	12.5 mg tab	x100	\$ 33.50	
		25 mg tab	x100	\$ 36.50	
		50 mg tab	x100	\$ 57.00	
		100 mg tab	x100	\$ 77.00	
Carafate	Sucralfate	1 gm tab	x100	\$ 40.50	
Cardizem	Diltiazem	30 mg tab	x100	\$ 28.00	
		60 mg tab	x100	\$ 39.00	
		90 mg tab	x100	\$ 54.00	
Catapres	Clonidine	.1 mg tab	x100	\$ 9.00	
		.2 mg tab	x100	\$ 12.00	
Cipro	Ciprofloxacin	250 mg tab	x100	\$145.00	
		500 mg tab	x100	\$198.00	
		750 mg tab	x100	\$285.00	
Clinoril	Sulindac	150 mg tab	x100	\$ 62.50	
		200 mg tab	x100	\$ 75.50	
Corgard	Nadolol	40 mg tab	x100	\$ 49.50	
		80 mg tab	x100	\$ 66.50	
Diabeta or Micronase	Glyburide	2.5 mg tab	x100	\$ 22.50	
		5 mg tab	x100	\$ 33.50	
Dolobid	Diflunisal	500 mg tab	x100	\$ 69.00	
Dyazide	Triamterene/HCTZ	50-25 mg cap	x100	\$ 28.00	
Elavil	Amitriptyline	10 mg tab	x100	\$ 12.00	
		25 mg tab	x100	\$ 23.00	
		50 mg tab	x100	\$ 38.50	
		75 mg tab	x100	\$ 51.50	
Eldepryl	Selegiline	5 mg tab	x100	\$120.00	
Feldene	Piroxicam	10 mg cap	x100	\$ 69.00	
		20 mg cap	x100	\$ 99.00	
Flexeril	Cyclobenzaprine	10 mg tab	x100	\$ 58.00	
Hismanal	Astemizole	10 mg tab	x100	\$ 83.50	
Indocin	Indometacin	25 mg tab	x100	\$ 35.00	
		50 mg tab	x100	\$ 53.00	
Imuran	Azathioprine	50 mg tab	x100	\$ 57.50	
Lasix	Furosemide	40 mg tab	x100	\$ 13.50	
Lopid	Gemfibrozil	300 mg tab	x100	\$ 34.00	
		600 mg tab	x100	\$ 62.00	
Lopressor	Metoprolol	50 mg tab	x100	\$ 32.50	
		100 mg tab	x100	\$ 47.00	
Mestinon	Pyridostigmine	60 mg tab	x100	\$ 12.00	
Moduretic	Amiloride/HCTZ	5/50 mg tab	x100	\$ 29.00	
Motrin	Ibuprofen	300 mg tab	x100	\$ 8.00	
		400 mg tab	x100	\$ 12.00	
		600 mg tab	x100	\$ 16.00	
Naprosyn	Naproxen	250 mg tab	x100	\$ 39.00	
		375 mg tab	x100	\$ 59.00	
		500 mg tab	x100	\$ 69.00	
Nizoral	Ketoconazole	200 mg tab	x100	\$148.00	
Nolvadex	Tamoxifen	10 mg tab	x100	\$ 85.00	

Brand Name	Northam Equiv.	Strength	Quantity	Price /100	Total \$ U.S.
Parlodel	Bromocriptine	2.5 mg tab	x100	\$ 69.00	
		5 mg tab	x100	\$130.00	
Pepcid	Famotidine	20 mg tab	x100	\$ 87.50	
		40 mg tab	x100	\$139.00	
Persantin	Dipyridamole	25 mg tab	x100	\$ 19.00	
		50 mg tab	x100	\$ 28.00	
		75 mg tab	x100	\$ 36.00	
Premarin	Conj Estrogens	.3 mg tab	x100	\$ 17.00	
		.625 mg tab	x100	\$ 22.50	
		1.25 mg tab	x100	\$ 29.00	
Prinivil or Zestril	Lisinopril	5 mg tab	x100	\$ 40.50	
		10 mg tab	x100	\$ 46.50	
		20 mg tab	x100	\$ 54.50	
Procardia or Adalat	Nifedipine	10 mg cap	x100	\$ 24.00	
Proventil or Ventolin	Salbutamol	2 mg tab	x100	\$ 21.00	
		4 mg cap	x100	\$ 29.00	
		Inhaler 16 ml	x100	\$ 13.50	
Prozac	Fluoxetine	20 mg cap	x100	\$ 99.00	
Reglan	Metoclopramide	5 mg tab	x100	\$ 22.00	
		10 mg tab	x100	\$ 30.00	
Retrovir	Zidovudine/AZT	100 mg tab	x100	\$ 89.00	
Seldane	Terfenadine	60 mg tab	x100	\$ 45.00	
Tagamet	Cimetidine	200 mg tab	x100	\$ 39.00	
		300 mg tab	x100	\$ 45.50	
		400 mg tab	x100	\$ 69.00	
		800 mg tab	x100	\$119.00	
Tegretol	Carbamazepine	200 mg tab	x100	\$ 20.50	
Tenormin	Atenolol	50 mg tab	x100	\$ 49.50	
		100 mg tab	x100	\$ 71.50	
Theo-Dur	Theophylline SR	200 mg tab	x100	\$ 14.00	
		300 mg tab	x100	\$ 18.00	
Timoptic	Timol Maleate	.25% 5 ml	x100	\$ 11.00	
		.25% 10 ml	x100	\$ 17.50	
		.50% 5 ml	x100	\$ 13.50	
		.50% 10 ml	x100	\$ 20.00	
Vasotec	Enalapril	5 mg tab	x100	\$ 55.00	
		10 mg tab	x100	\$ 57.50	
		20 mg tab	x100	\$ 79.00	
Visken	Pindolol	5 mg tab	x100	\$ 36.00	
		10 mg tab	x100	\$ 45.00	
Voltaren	Diclofenac	25 mg tab	x100	\$ 27.50	
		50 mg tab	x100	\$ 52.50	
		75 mg tab	x100	\$ 62.50	
Zantac	Ranitidine	150 mg tab	x100	\$ 89.00	
		300 mg tab	x100	\$129.00	
Zovirax	Acyclovir	200 mg cap	x100	\$ 48.00	
Zyloprim	Allopurinol	100 mg tab	x100	\$ 12.00	
		300 mg tab	x100	\$ 28.00	

Shipping/Handling \$6.00  
**TOTAL \$ U.S.**

XVII. LICENSURE REQUIREMENTS FOR DRUG DISTRIBUTION

State	Permits/ Licenses Required	New Permit Fee— Pharmacies	Annual Fee— Pharmacies	Annual Inspections	Pharmacist- In-Charge Required	Other Outlets Licensed to Sell Packaged Drugs	
						Saleable Drugs	Annual Fee
Alabama	4	\$100.00 A, Q	\$ 25.00 Q	Yes	Yes	G	None
Alaska	2, 4	\$210.00	\$180.00 M	If possible	Yes	No	None
Arizona	1, 2, 4	\$300.00 M	\$300.00 M	Yes	Yes****	H	
Arkansas	1, 2, 3, 4, 5, 6, 9	\$200.00 A	\$100.00	Yes	Yes		
California	1, 2, 3, 4	\$340.00 A	\$175.00	No	Yes		
Colorado	1, 2, 4	\$225.00	\$125.00	Yes O	Yes	No	
Connecticut	1, 2, 4	\$600.00	\$150.00	Yes	Yes****	OTC	\$70.00/\$50.00
Delaware	1, 2, 3, 4	\$100.00	\$100.00 M	Yes	Yes	R, S	\$200.00/ \$200.00 M
Dist. of Columbia	1, 2, 6	\$100.00 A	\$100.00	Yes	Yes	OTC S	\$65.00
Florida	4	\$220.00	\$175.00 M	Yes	Yes V		No
Georgia	1, 2, 3, 4	\$100.00 A	\$ 85.00 M	Yes	Yes		None**
Hawaii	1, 4	\$165.00	\$165.00 M	Yes M	Yes		\$165.00 M
Idaho	1, 2, 3, 4	\$100.00 A	\$100.00 A	Yes	Yes	H	\$5.00/\$15.00/ \$40.00
Illinois	4	\$100.00	\$100.00 L, M	Yes	Yes	S	\$50.00
Indiana	4	\$ 25.00 B	\$ 25.00	Yes	Yes	G	None
Iowa	1, 2, 3, 4, 8	\$100.00 L, P	\$100.00 L, P	Yes	Yes	S	\$100.00
Kansas	1, 2, 3, 4	\$125.00 N	\$105.00 N	Yes	Yes	E	\$12.00
Kentucky	1, 2, 4, 10	\$100.00 A	\$ 75.00 A	Yes O	Yes	None	None
Louisiana	4	\$100.00 A, F, P	\$100.00 A, P	Yes	Yes	I	None
Maine	1, 2, 3, 4	\$200.00	\$200.00	Yes	Yes	G, S	\$200.00
Maryland	1, 2, 4	\$ 40.00	\$ 25.00	Yes	No		None
Massachusetts	2, 4	\$175.00 B, P	\$175.00 B, L, M	Yes	Yes****		None
Michigan	1, 2, 3, 4	\$ 60.00 B, L	\$ 50.00 L, M	Yes	No		None
Minnesota	1, 2, 3, 4	\$100.00 A	\$100.00	Yes	Yes		None
Mississippi	4	\$150.00 A	\$150.00 M	Yes	Yes		
Missouri	1, 2, 3, 4	\$200.00 A	\$150.00	Yes O	Yes	S	None
Montana	1, 2, 3, 4	\$200.00 A	\$100.00 L	No	Yes		S
Nebraska	4	\$200.00 B, L	\$100.00 L	Yes	Yes		None
Nevada	1, 2, 3, 4	\$300.00 A	\$300.00 M	Yes	Yes****	S	\$200.00 M
New Hampshire	1, 2, 4, 9	\$300.00 A	\$150.00 A	Yes	Yes	S	\$250.00
New Jersey	1, 2, 4	\$200.00 B, L	\$ 85.00	Yes	Yes	G	None
New Mexico	1, 2, 3, 4, 6, 8, 9	\$150.00 A, L	\$150.00 A, L	Yes	Yes	G	Yes
New York	1, 2, 4, 6	\$345.00 D	\$260.00 K	Yes	Yes	H	\$80.00 K
North Carolina	4	\$250.00 B	\$125.00	Yes	Yes		None
North Dakota	1, 2, 3, 4	\$150.00 A	\$150.00	Yes	Yes	H	\$3.00
Ohio	1, 2, 3, 4	\$ 70.00	\$ 70.00	Yes M	Yes		None
Oklahoma	1, 2, 3, 4	\$100.00 A	\$100.00	Yes O	Yes****	G	None
Oregon	1, 2, 3, 4	\$ 75.00 A, N	\$ 75.00 A, N	Yes	Yes	H	\$15.00-\$25.00
Pennsylvania	1, 2, 4	\$145.00 C	\$ 75.00 M	Yes	Yes	G	None
Puerto Rico	4	\$ 3.00 A	\$100.00	Yes	Yes	G	
Rhode Island	1, 2, 3, 4	\$100.00 A, L	\$ 50.00	Yes	Yes	G	None
South Carolina	4	\$100.00 A, L	\$ 50.00 L	Yes	Yes	A	\$50.00
South Dakota	1, 2, 3, 4	\$160.00	\$160.00	Yes	Yes W	G, H	\$10.00
Tennessee	1, 2, 3, 4	\$ 84.00 A, L	\$ 84.00 A, L	Yes	Yes		None
Texas	1, 2, 4	\$132.00 A	\$132.00 A	Yes M	Yes	U	Varies
Utah	1, 2, 3, 4	\$100.00	\$ 40.00 M	Yes	Yes	G	None
Vermont	4	\$ 90.00 M	\$ 90.00 M	Yes	Yes	R	\$90.00 M
Virginia	1, 2, 4	\$200.00*** A	\$200.00***	Yes	Yes		None
Washington	1, 2, 4, 5, 6, 7, 8	\$275.00 A, J, L	\$200.00 J, L	Yes	Yes		\$25.00
West Virginia	1, 2, 3, 4	\$150.00 D, N	\$ 75.00 L	Yes	Yes		None
Wisconsin	1, 2, 3, 4	\$ 50.00 A	\$ 50.00 M		Yes		
Wyoming	1, 2, 3, 4, 6	\$ 50.00 L	\$ 50.00 L	Yes O	Yes	None S	\$100.00/ \$150.00 T

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## XVII. LICENSURE REQUIREMENTS FOR DRUG DISTRIBUTION - (cont.)

## LEGEND

- \* Licensing manufacturers, distributors, and wholesalers located in SC. Also, pharmacies located outside SC whose primary business is mail order prescription service must have a permit to ship, mail, or deliver a controlled substance or dangerous drug or device in SC pursuant to a prescription of a licensed practitioner.
- \*\* The \$100.00 permit fee is for retail pharmacies and hospitals. The permit fee for wholesalers and manufacturers is \$250.00 with a \$150.00 renewal fee.
- \*\*\* Virginia-\$300.00 for manufacturers and wholesalers.
- \*\*\*\* Alternate terms used by the states: AZ-"responsible pharmacist;" CT, MA, OK-"pharmacy manager;" NV-"managing pharmacist."
  
- 1 — License required to manufacture (MT-controlled substances only; WY-legend drugs and controlled substances).
- 2 — License required to wholesale (MT-controlled substances only; WY-legend drugs and controlled substances).
- 3 — License required to ship into state (MT-controlled substances only; WY-legend drugs and controlled substances).
- 4 — Pharmacy permit or license required (VA-\$75.00).
- 5 — Legend Drug Samples Distributors (AR-would require licensure of the company manufacturing the product, but not a separate license).
- 6 — Distributors of controlled substances into state (AR-would also be licensed as either a manufacturer or wholesaler, but not a separate license; WA-legend drug sample distribution fee: \$275.00 for original certificate, \$200.00 for renewal).
- 7 — Poison Distributors.
- 8 — Precursor Chemical Distributors.
- 9 — Public Health Clinics (AR-licensed as a charity pharmacy if they distribute legend drugs).
- 10 — Out-of-state pharmacy permit.
  
- A — Not transferable.
- B — Transfer fee: same.
- C — Transfer fee: \$15.00.
- D — Transfer fee: \$25.00 (NY-\$345.00).
- E — Only "retail dealers" selling more than 12 different non-prescription drug products are licensed; those selling 12 or less are exempt from licensure.
- F — Administrative fee: \$25.00.
- G — Dangerous drugs saleable designated by law, including vet clinics, rural health center clinics, public health, and outpatient hospitals.
- H — Drugs saleable designated by Board. (AZ-Saleable OTC drug preparations as designated by Board. Up to 15 items, \$100.00 biennial. Over 15 items, \$200.00 biennial).
- I — Louisiana Board of Health license products of manufacturer.
- J — Pharmacy assistant utilization fee (WA-\$60.00).
- K — Triennial.
- L — Additional fee. Controlled Substances Act (IL-\$5.00/yr.; MA-\$75.00; NE-\$10.00; MI-\$60.00 for new C.S. license and \$50.00 for annual renewal; MT-\$35.00 annual C.S. registration fee for pharmacies; NE-\$10.00; RI-\$50.00; WA-\$50.00; WY-\$10.00).
- M — Biennial.
- N — Registration under Controlled Substances Act included.
- O — Twice a year.
- P — Controlled substances permit: \$25.00 (MA-\$75.00).
- Q — Controlled substances permit: \$100.00.
- R — Manufacturing, wholesale, and research outlets.
- S — Wholesalers, manufacturers, and distributors must be licensed (MT-\$100.00 annual C.S. fee for wholesalers, manufacturers, and distributors; WY-has two separate registrations for manufacturers and distributors, and one for prescription drugs and devices only - not for OTC).
- T — In Wyoming - \$150.00 for manufacturers of controlled substances and \$100.00 for distribution of prescription drugs and devices.
- U — Manufacturers and wholesalers licensed by Texas Department of Health.
- V — Prescription Department Manager or Consultant Pharmacist as required.
- W — If pharmacy is not owned by a pharmacist.

Average Annual Fee—Pharmacies \$118.38.

Idaho:

(USP - 27)

Patient Communication. Every out-of-state mail service pharmacy shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

Maine: (The only mention I could find that pertained to telephoning is as follows:)

(USP - 39)

Explanation by pharmacist. With each new prescription dispensed, the pharmacist, in addition to labeling the prescription in accordance with the requirements of the State, must orally explain to the patient or the patient's agent the directions for use; and any additional information, in writing if necessary, to assure the proper utilization of the medication or delivered prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. The section does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

North Dakota

(USP - 58)

Out-of-state pharmacies shall provide accessible telephone counseling service for patients' drug inquiries with a registered pharmacist during regular working hours. Available telephone counseling service must be provided that is consistent with the standard of due care. The pharmacies' telephone number will be prominently identified and affixed on the prescription container label.

Oregon

(USP - 47)

On all new prescriptions, where a danger may exist to the public safety, health and welfare, the pharmacist shall advise the patient or the patient's agent in person as to the possible dangers of taking the medication with alcohol or taking the medication and then operating a motor vehicle or other hazardous machinery. If the medication is delivered or mailed, this information shall be provided the patient in writing.

Utah

(USP - 18)

The only information regarding patient counseling for mail order pharmacies is as follows:)

Each-out-of-state mail service pharmacy shall be licensed by the division if the out-of-state mail service pharmacy provides information to a resident of this state of drugs or devices, including, but not limited to, advice relating to therapeutic values, potential hazards, and use or counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

Arkansas

(USP - 71)

The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.

1-26

controlled substances act of the state of Kansas and applicable regulations, federal drug laws and applicable regulations.

(h) This regulation shall be effective May 1, 1989. (Authorized by K.S.A. 65-1630, as amended by L. 1988, ch. 366, Sec. 16; implementing K.S.A. 1987 Supp. 65-1637, 65-1637a, and K.S.A. 65-1648; effective E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1989.)

**68-7-13. Pharmacist in charge of more than one location.** No pharmacist shall be a pharmacist in charge of more than one full-time pharmacy operation, which is defined as being one where the on-premises pharmacist services total 30 hours or more weekly. (Authorized by and implementing K.S.A. 65-1630; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1988.)

**68-7-14. Prescription labels.** The label of each prescription medication shall be typed or machine printed and shall include the following information:

(a) The name, address and telephone number of the pharmacy dispensing the prescription;

(b) the name of the prescribing practitioner;

(c) the full name of the patient;

(d) the identification number assigned to the prescription by the dispensing pharmacy;

(e) the date the prescription was filled or refilled;

(f) adequate directions for use;

(g) the expiration date of the prescription medication dispensed, if applicable;

and

(h) the brand name or corresponding generic name, the manufacturer or distributor and the strength, unless otherwise specified by the practitioner. (Authorized by and implementing K.S.A. 65-1630; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1980; amended May 1, 1988.)

**68-7-15. Prepackaging or repackaging of drugs.** All prepackaging or repackaging of drugs, whether in a unit dose container or multiple dose container shall conform to the following:

(a) Packaging in advance of immediate need shall be done by a pharmacist or under his or her direct supervision.

(b) This packaging shall be limited to drugs to be dispensed from the premises.

(c) Proper storage conditions shall be maintained so as to preserve the stability of the drug as recommended by the manufacturer.

(d) A proper control system shall be established for lot numbers for recall purposes.

*Kansas State Board of Pharmacy*

LANDON STATE OFFICE BUILDING  
900 JACKSON AVENUE, ROOM 513  
TOPEKA, KANSAS 66612-1220  
PHONE (913) 296-4056

STATE OF KANSAS

HB 3064



JOAN FINNEY  
GOVERNOR

SENATE PUBLIC HEALTH  
AND WELFARE COMMITTEE

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE, MY NAME IS TOM HITCHCOCK AND I SERVE AS EXECUTIVE SECRETARY OF THE BOARD OF PHARMACY. I APPEAR BEFORE YOU TODAY ON BEHALF OF THE BOARD IN SUPPORT OF HB 3064.

THIS BILL WILL REQUIRE THAT THE BOARD OF PHARMACY REGISTER A PHARMACY THAT ADVERTISES, CONTRACTS, AND SOLICITS TO SEND PRESCRIPTION DRUGS INTO AND FOR THE CITIZENS OF KANSAS FROM A PHARMACY LOCATED IN ANOTHER STATE. THIS REGISTRATION WOULD ALLOW THE BOARD TO PROTECT THE HEALTH AND WELFARE OF THE PUBLIC RELATING TO ALL PHARMACIES DISPENSING PRESCRIPTIONS TO SUCH WITHOUT RESTRICTIONS TO LOCATION.

AS AN EXAMPLE OF THE PROBLEM, THERE HAVE BEEN TWO SEPARATE COMPLAINTS IN THE LAST THREE MONTHS WHICH WERE AGAINST TWO DIFFERENT MAIL ORDER PHARMACIES. ONE PHARMACY WAS REGISTERED AND ONE WAS NOT REGISTERED WITH OUR AGENCY. THE PHARMACY REGISTERED WITH US IS BEING CALLED BEFORE THE BOARD, BUT THE BOARD MAY MERELY SEND THE OTHER COMPLAINT TO THE BOARD IN THE STATE OF LOCATION AND A LETTER OF SYMPATHY TO THE COMPLAINANT.

THE BOARD OF PHARMACY RESPECTFULLY REQUESTS THE FAVORABLE PASSAGE OUT OF COMMITTEE OF HB 3064.

THANK YOU.

*Senate P. How*  
*Attachment #2*  
*4-6-92*

**Statement of  
Baxter Healthcare Corporation, Prescription Service Division  
Opposing House Bill No. 3064  
to the  
Senate Public Health and Welfare Committee**

**April 1, 1992**

Mister Chairman and distinguished Members of the Joint Committee on Administrative Regulation Review, my name is Clifford Berman and I am speaking on behalf of Baxter Helthcare Corporation's Prescription Service Division. Our division is one of the nation's leading mail service pharmacies, with facilities located in Illinois, Texas and Virginia. By way of background, I am a pharmacist registered in the state of Illinois and an attorney licensed in the state of Illinois. I serve as Director of Professional Services with Baxter's Prescription Service Division.

**Baxter Opposes Enactment of HB 3064**

Baxter opposes enactment of HB 3064 because, in requiring mail service pharmacies to follow the pharmacy and controlled substance laws of the state of Kansas, it sets up an unreasonable burden to the continuing ability of Baxter and other mail service pharmacies to serve Kansas patients.

**HB 3064 Is Unnecessary**

Before discussing these burdens, it is essential to realize that HB 3064 is unnecessary. It is unnecessary because every mail service pharmacy is already licensed both by the state in which it is located and federally and must comply with the relevant laws of its home state and the federal government. This involves compliance with the State Pharmacy Practice Act, Controlled Substance Act and Food, Drug and Cosmetics act and the Federal Controlled Substance Act and Food, Drug and Cosmetics Act.

**HB 3064 is Unreasonably Burdensome**

Just keeping abreast of and complying with the intricate and ever changing laws of one state alone is itself a full-time task. Multiply this times 50 states and the burden placed upon pharmacies such as

*Senate P. H&W  
Attachment  
4-6-92 #3*



Baxter, which practice on a nationwide basis, becomes apparent. The sheer magnitude of this endeavor would virtually insure instances of noncompliance with formalities of the law, which, although not threatening to the health of patients, would put the pharmacy's license and thus its ability to do business in jeopardy. Further, costs to our patients would be unnecessarily increased to cover the additional administrative expenses necessary to undertake educating our employees as to the laws of 50 states and attempting to ensure compliance with those laws.

### Suggested Amendment

Baxter recognizes and shares the legitimate interest of the state of Kansas in seeing that its citizens receive the highest quality pharmacy services, whether from retail, institutional or mail service pharmacies. As to mail service pharmacies, this can only be achieved if the state of Kansas knows the identity of mail service pharmacies serving their citizens, has a means of monitoring the practice of those pharmacies, and is able to follow through with the appropriate agencies of the pharmacy's home state in the event of practices potentially harmful to citizens of Kansas.

We feel that each of these goals is met through the provisions of statutes like that recently enacted in California. A copy of that law, commonly referred to as the "California Disclosure Law", is appended hereto. The features of that law are:

1. Requires disclosure of the location of the pharmacy and the identity of corporate officers and pharmacists.
2. Provides for access to necessary information by the California patient (through toll-free telephone services) and by the California Board of Pharmacy (through record availability).
3. Subjects the pharmacy to disciplinary action by the California Board of Pharmacy for failure to register or in the case of harm to a California patient, if the matter was referred to the home state Board of Pharmacy and that Board has not taken timely action.

California achieved its objectives while still recognizing the ultimate authority over the pharmacy by the pharmacy's home state Board of Pharmacy and home state pharmacy laws. The pharmacy is not, however, required to follow California law. California's disclosure

law has served as the model for similar legislation or rules in numerous states across the nation, including Minnesota, Missouri, Kentucky, Virginia and Maine.

In light of these existing laws which do not require multiple state legal compliance by mail service pharmacies, regulation such as HB 3064 is particularly suspect under the United States Supreme Court's "least restrictive means" test for determining whether a law is an unreasonable burden on interstate commerce. Pike v. Bruce Church Inc., 397 U.S. 137,142 (1970). Simply put, when a state attempts to place burdens on interstate concerns, such as mail service pharmacies, it must use the least restrictive means possible. The California law and its progeny serve as ready "yardsticks" by which to gauge other state's laws under the "least restrictive means" test.

In order for mail service pharmacies to be able to continue offering their services to Kansas citizens, we urge the board to take a middle ground approach represented by the many "disclosure laws". In this regard, it is important to realize that mail service pharmacies have been serving the citizens of Kansas for decades, with no requirement that they follow the laws of Kansas and with no demonstrable threat to the safety of Kansas citizens. Rather than going from the present situation of no regulation to the most burdensome form of regulation in one fell swoop, we urge this Committee to consider the middle-ground approach typified by the California disclosure law. It is only in this manner that Kansas will truly achieve its underlying goal of knowing who the mail service pharmacies are and being able to monitor their practice. This is so because history dictates that few, if any, mail service pharmacies would choose to seek registration under the type of restrictive regulation represented by HB 3064 in its present form.

By choosing the middle-ground approach represented by the laws of California, Minnesota, Missouri, Kentucky, Virginia and Maine, Kansas will have a law which is constitutionally sound and acceptable to the mail service industry. Should the suggested "disclosure" legislation prove undesirable in practice, the legislature is of course always free to seek an amendment at a later date. We are confident that this will never be necessary.

Again, Baxter's Prescription Service Division thanks this Committee for the opportunity to present its views in oppositon to HB 3064.

**CALIFORNIA**

**4050.1. Nonresident Pharmacy**

(a) Any pharmacy located outside this state which ships, mails, or delivers, in any manner, controlled substances or dangerous drugs or devices into this state shall be considered a nonresident pharmacy, shall be registered with the board, and shall disclose to the board all of the following:

(1) The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing controlled substances or dangerous drugs or devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist.

(2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(3) That it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(b) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(c) The registration fee shall be the fee specified in subdivision (a) of Section 4416.

(d) The registration requirements of this section shall apply only to a nonresident pharmacy which only ships, mails, or delivers controlled substances and dangerous drugs and devices into this state pursuant to a prescription.

(e) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists.

**4350.6. Nonresident Pharmacy Violations**

(a) The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4363 or for any failure to comply with Section 11164 of the Health and Safety Code.

(b) The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within 45 days of the referral. The board shall obtain and maintain a record of referrals pursuant to this subdivision and any action taken thereon and shall report its findings to the Legislature on or before March 31, 1991.

This section shall be operative until January 1, 1992, and as of that date, is repealed unless a later enacted statute deletes or extends that date.

**4350.6. Nonresident Pharmacy Violations**

The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4363 or for any failure to comply with Section 11164 of the Health and Safety Code.

This section shall become operative on January 1, 1992.

**4363. Unlicensed Nonresident Pharmacy Advertising**

It is unlawful for any nonresident pharmacy which is not registered pursuant to Section 4050.1 to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

Added by Ch. 1034 Stat. 1988.

## **OBJECTIVE FINDINGS ON THE SAFETY OF MAIL SERVICE PHARMACY**

Following is a chronological sampling of statements on the safety of mail service pharmacy from a variety of objective observers, including federal agencies, state legislative committees, professional associations and educators:

- **University of Tennessee, College of Pharmacy (1986)** -- In 1986, the College of Pharmacy at the University of Tennessee conducted a study to determine the satisfaction of customers of using mail service pharmacies compared to customers of local retail pharmacy services. The report concluded:

*"Most mail order users report few problems and the overall rating of the service was excellent or good. In fact, the rating for mail order services was slightly better than the rating for community pharmacy services."*

[*"Evaluation of Consumer Opinions of Prescription Drug Services from Community and Mail Order Pharmacies,"* conducted by The Center for Pharmacy Management and Research, College of Pharmacy, The University of Tennessee, 1986]

- **American Medical Association (1987)** -- In 1987, the House of Delegates of the American Medical Association found that:

*". . . MSPs [mail service pharmacies] are less vulnerable to drug diversion than retail pharmacies.... Presently the practice of obtaining drugs from mail service pharmacies appears to be relatively safe."*

[Resolution adopted by the House of Delegates, American Medical Association, 1987]

- **Michigan State Legislature (1988)** -- In 1988, a Joint Committee of the Michigan State Legislature reported that:

*"Mail order pharmacy appears to be a safe and convenient method of obtaining pharmaceuticals for millions of Americans and hundreds of thousands of Michiganians.... There is anecdotal information reciting problems with MOPs [mail order pharmacies] but little or no documentation to support alleged problems."*

[Joint Study Report, Michigan State Legislature, 1988]

- **Maine State Legislature (1989)** -- In 1989, a Joint Committee of the Maine State Legislature reported that:

*"The Committee found no evidence that there was any difference in safety between having a prescription filled by mail and through an in-state pharmacy."*

[Joint Standing Committee Report, December 1989]

- **Brandeis University, Bigel Institute for Health Policy (1989)** -- In 1989, the Institute, under a grant from the federal Health Care Financing Administration (HCFA), conducted a study to evaluate mail service pharmacy, finding that:

*"Concerns expressed by community pharmacies have generally reflected their apprehension of a new competitor.... The quality of both the drug products dispensed and the pharmacy services provided by the mail service pharmacies studied appears to meet generally accepted pharmacy standards of practice.... Overall, the data obtained as part of this study indicate that mail service pharmacies provide a viable alternative system for the delivery of maintenance or chronic-prescribed medicines."*

[Horgan, et al., "Study to Evaluate the Use of Mail Service Pharmacies" Bigel Institute for Health Policy, Brandeis University, Waltham, Massachusetts, September 12, 1989]

- **Office of Inspector General, Department of Health & Human Services (1990)** -- In 1990, the Office of Inspector General reported that:

*"[T]he differences in clinical services provided by MSPs [mail service pharmacies] versus other retail settings may be more theoretical than actual.... [G]iven the relatively low level of services that are actually provided in community settings, there may be little difference in interventions received by patients, and in some cases, the information provided by MSP package inserts may be more than patients receive from their neighborhood pharmacist."*

["The Clinical Role of the Community Pharmacist," Office of Inspector General, November 1990]

- **Food & Drug Administration (1990)** -- In 1990, FDA, following an inspection of six mail-order pharmacies, rejected a petition requesting that it regulate mail order pharmacies, stating:

*"FDA . . . must deny the petition at this time because the agency does not have sufficient evidence to conclude that the practices of mail-order pharmacies pose a danger to the public health or that such practices go beyond the traditional practice of pharmacy and thus warrant CGMP [Current Good Manufacturing Practice] enforcement."*

[November 29, 1990 Response Letter of Ronald G. Chesemore, FDA Associate Commissioner for Regulatory Affairs]

- **The Milbank Quarterly (1990)** -- In 1990, three Professors from the University of Michigan, College of Pharmacy reported in a peer-reviewed publication that:

*"Pharmacy organizations have expressed concerns about the quality-control procedures used by MPS [mail pharmacy services]. A number of anecdotal cases have been gathered about patients who have experienced problems.... Despite the concerns raised by these reports, there are no controlled studies which demonstrate the MPS have higher drug-dispensing error rates than community pharmacies. While only a few limited studies have compared error rates, these findings suggest that MPS are as safe as community pharmacies."*

[Kirking, Ascione & Richards (University of Michigan), "Choices in Prescription-drug Benefit Programs: Mail versus Community Pharmacy Services," The Milbank Quarterly, Vol. 68, No. 1 (1990)]

Testimony Presented to Senate Public Health and Welfare  
April 1, 1992  
Proponent of Hb 3064

My name is Mary Holmoran. I am a pharmacist and I am employed at Super-U in Topeka. I am here to speak in favor of Hb 3064.

Mail order pharmacy differs greatly from other mail order businesses, in that the health and welfare of the pharmacy patron is at stake. I believe that the Kansas consumer who obtains medication through the mail should be provided the same protection and services as the local patron. I would like to comment on two areas: profile monitoring and telephone access to the pharmacist.

1. Profile monitoring. Kansas law requires profile monitoring. A look at the combination of oral contraceptive and certain antibiotics provides a good example of how this monitoring can help the consumer. Many antibiotics decrease the effectiveness of oral contraceptives. If one of these antibiotics is prescribed to an oral contraceptive patient, she can be advised to use extra protection while on antibiotics, or the physician can be called, and a different antibiotic requested. When no monitoring is provided, pregnancy or abortion can be the result, unless the patient is sophisticated enough to know when to exercise caution with certain antibiotics.

2. Telephone access. The proposal before you requires an 1-800 telephone number be provided to ensure accessibility to the pharmacist. On one day of this week, I had 4 patron telephone calls for additional information after visiting our pharmacy. One had received a special dosage form of an antibiotic that is rendered ineffective when chewed. She could not swallow the capsule, and wanted to chew the medication. We gave her advice as to how to administer it. Another patient wanted elaboration on the drowsiness side effect. A third wanted further affirmation that there were no interactions or contraindications. A fourth wanted to know what the medications were to be used for. State law requires counseling in the pharmacy, but sometimes people need to hear the advice twice, or they think of additional questions when they are at home with the medication in hand.

Hb 3064 provides needed protection for the consumer of prescription medicines obtained through mail order. I urge your consideration and support of this proposal.

*Senate P. HCU*  
*Attachment #*  
*4-6-92 4*

9995 Bluejacket Drive  
Overland Park, Kansas 66214  
April 1, 1992

Senator Bud Burke  
Kansas State House  
Topeka, Kansas

Your Honor :

As a Senior Citizen of the State of Kansas I oppose House Bill 3064 on pharmaceutical legislation. I am the spouse of a retired member of Western Auto Supply. Daily I require two Cardizems capsules 90 mg; one Hydrochlorothiazide tablet 25mg; Zantac 150 mg. They cost as follows- At the local pharmacy the Cardizem costs \$18.69 for 30 capsules; Hydrochlorothiazide cost \$2.67 for 30 tablets and Zantac \$2.67 for 30 tablets. With a doctors prescription I pay \$5.00 for 180 Cardizem capsules; \$5.00 for 90 Zantac tablets and there is no charge for the Hydrochlorothiazide tablets for 90 tablets because they are generic.

I paid \$56.97 to the local pharmacy per month. For three months I paid \$170.91. The insurance company paid back \$42.71 per month. For three months- \$128.13. In time I would get \$42.78. Baxter HealthCare Corporation charged \$10.00 for the three prescriptions for 90 days. The amount totals \$40.00 a year. Through the local pharmacy total for the year would be \$171.12.

There has never been any problems receiving the ~~prescriptions~~ prescriptions by mail. Everyone I have know has had no problems. One man who has to take much medicine said he would never afford to buy all the medication he has to take if he couldn't depend on Baxter.

Respectfully,

*Mrs. Geneva B. Watkins*  
Mrs. Geneva B. Watkins

*Sen. P. Now*  
*Attachment #5*  
*4-6-92*



Hon. Roy M. Ehrlich, Chairman  
Senate Public Health & Welfare Committee  
State Capitol Building  
Topeka, Kansas 66612

SUBJECT: H.B. NO. 3064

Mr. Chairman and Committee Members:

My name is Frank Lawler, I am a resident of Leawood, Kansas. I appreciate this opportunity to speak in opposition to H.B. 3064 whereby Kansas would prohibit the sale and delivery of out-of-state mail order prescription drugs by a pharmacy not holding a Kansas pharmaceutical license.

My friends, Geneva Watkins, Mr. and Mrs. Clarence Arndt and I were alarmed to read for the first time on Saturday, March 28, an article (photocopy attached) concerning proposed H.B. No. 3064 which you are considering this morning.

What has prompted this bill; is the purpose to limit competition in prescription drug sales? It would seem that limiting competition will only increase drug costs as the main reason for individuals ordering drugs by mail is to obtain the most affordable price. I feel I can speak to this issue as I take prescription drugs which cost in excess of \$100.00 per month. Therefore, I shop for the best price, as do most seniors who are on fixed incomes. Consequently, we fail to see how this proposed bill qualifies as a consumer protection measure?

Specifically, what is it that the supporters of this measure feel needs fixing? My friends and I each order prescription drugs from out of state pharmacies. We have had no problems with these pharmacies, therefore what hard facts dictate the need for this proposed measure?

It would seem H.B. No. 3064 would constitute undue restraint of trade if adopted. Furthermore, how is the bill going to be enforced when agencies such as the Veterans Administration mail drugs to veterans all over the country? Also, how is the licensure requirement be met by those pharmaceutical companies which mail orders for prescription drugs to third party retirees of a number of large corporations? Corporate contracts with these companies to provide drugs to retired workers at reduced prices benefit the retiree and the corporation. Any elimination of such sources or increased overhead expense to them is bound to impact adversely by increased costs to the consumer thus benefiting neither the retiree or the corporation. In fact their out of pocket expense can only increase--the opposite of what the state should consider as a priority.

Senate P. NEW  
Attachment #  
4-6-92 6

The American Association of Retired Persons Pharmacy in Kansas City, Missouri sells and mails prescription drugs to over a hundred thousand patrons in Kansas. As one of that 100,000-plus, the proposed bill offers no consumer protection that I can detect. Unless the sponsors have hard evidence to the contrary, it appears that the ultimate impact of the bill will be increased prices for many who can ill afford any additional out-of-pocket expense from their fixed income.

I have attached to my testimony a photocopy of a survey of the prices pharmacies in Johnson county were charging several years ago for a number of the drugs common to most senior citizens. The main point of the exhibit is to show the wide range in prices among the Johnson county area pharmacies and that by shopping around retirees and many others can hold down out of pocket expense. The survey did not include the American Association of Retired Persons' Pharmacy in Kansas City, Missouri. Had their prices been included the saving would have been all the more obvious.

In conclusion we see no need for H.B. No. 3064 and urge the Committee to forgo approval the bill.

A handwritten signature in cursive script, appearing to read "Frank J. ...". The signature is written in dark ink and is centered on the page.

# Pharmacy legislation hailed as protection, but is it necessary?

By JIM SULLINGER  
Staff Writer

Rep. Arthur Douville can't put his finger on it, but something in House Bill 3064 bothers him.

The bill would prohibit the delivery of out-of-state or mail-order prescription drugs without a Kansas pharmaceutical license.

For example, if you order medicine in Missouri and have it delivered to your home in Kansas, the Missouri pharmacy must have a Kansas license or it could not legally deliver the medicine under the bill.

It also would require out-of-state pharmacies to keep separate records on deliveries to Kansas customers.

The proposed law is being sought by the Kansas Pharmacists Association.

Douville, an Overland Park Republican, said supporters have hailed the bill as a consumer-protection measure even though there is no evidence that anyone has been harmed without it.

Douville worries that the real target may be out-of-state competition.

"Is the objective to cut down on competition and help pharmacists in the state of Kansas?" Douville asked.

Yes. Could the result be higher state-induced prices for prescription drugs? Douville said he was worried this might prove to be the practical outcome.

The Kansas Senate approved a bill earlier this week requiring motorcycle riders to wear helmets.

The measure was placed into another bill on the Senate floor and now goes to a joint House-Senate conference committee.

The proposed law wouldn't be very strict, however.

It's like the state's seat belt law. Police cannot stop someone just because they aren't wearing a seat belt. But if an unbelted motorist is stopped for another traffic infraction, police can give the driver a ticket for not wearing a seat belt.

The same theory would apply to the motorcyclist who hasn't donned a helmet. The fine would be \$10. The measure passed on a vote of 21 to 19.

★ ★ ★

A bill to certify deaf interpreters was approved Friday by the House and now goes to the Senate.

It was sponsored by Rep. Ruth Ann Hackler, an Olathe Democrat. Olathe has a large deaf community and is the home of the Kansas School for the Deaf.

Hackler said the legislation would establish several levels of interpreters, based on ability. They would be certified by the Kansas Commission for the Deaf and Hearing Impaired.

Another bill would change the name of the commission to the Kansas Commission for the Deaf and Hard of Hearing.

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Rep. Tim Carmody, an Overland Park Republican, has been appointed to the Kansas Public Employment System Study Commission.

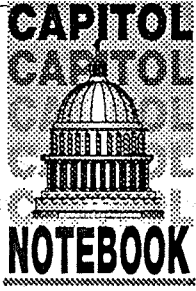
The 11-member commission was created in the wake of charges that KPERs retirement funds were invested improperly, resulting in huge losses.

"On this commission, we will review the big picture of KPERs, determine how well it works and what could be done to make it work better," Carmody said.

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Quilts were on display around the second-floor rotunda this week.

Quilters from Johnson County displaying their work were Rosie Grinstead of Mission Hills, Elaine Sparlin of Lenexa, Connie Dudziak of Olathe and the Quilters Guild of Greater Kansas City.



COMMUNITY PHARMACY SURVEY RESULTS

GENERIC	BRAND	GENERIC	BRAND	GENERIC	BRAND	BRAND	GENERIC	BRAND	GENERIC	BRAND	GENERIC	BRAND		
POTASSIUM		HYDROCHLOR-			CARDIZEM		TENORMIN		ATENOLOL		TAGAMET		Pharmacy	
Chloride TR	HYDRODIURIL	RATHIAZIDE	ISORDIL	ISOSORBIDE	(tablet)	LASIX	FUROSEMIDE	(tablet)	(tablet)	INDERAL	PROPANOLOL	(tablet)	Services*	
(tablet)	(tablet)	(tablet)	(tablet)	(tablet)	*100 pills,	(tablet)	(tablet)	*100 pills,	100 pills,	(tablet)	(tablet)	* 100 pills		
ills, 600 mg.	100 pills, 50 mg.	* 100 pills, 10 mg.	* 10 mg.	* 100 pills, 40 mg.	* 50 mg.	* 50 mg.	50 mg.	* 100 pills, 40 mg.	* 300 mg.					
*	*	*	*	*	*	*	*	*	*	*	*	*	*	
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14	N/A	14.87	1.98	13.27	2.14	32.78	8.89	2.20	38.55	N/A	18.13	6.71	32.03	* Generic
														* Drug Sub.
										No				* Records, easy caps,
15	6.30	11.95	2.95	12.25	2.95	34.95	11.95	5.95	41.60	Generic	14.75	9.95	39.95	* after hrs. code phone
														* free delivery
														* Weekend records
2	-	10.61	2.59	11.26	3.69	36.99	10.37	4.69	44.06	-	19.56	7.99	42.89	* disc. older people
														* easy caps
														* Weekend
9	-	11.69	4.89	13.77	6.79	40.59	11.39	6.89	46.89	-	20.29	11.09	40.89	* Discounts
														* easy caps
														* Sat. 9-2 free
0	-	12.85	2.50	15.87	4.85	41.55	12.15	-	48.95	-	22.60	12.10	45.40	* delivery, records
														* easy caps
														* Humana Sr. disc.
7	-	12.01	3.06	11.24	4.18	39.49	10.90	4.70	41.90	-	20.90	9.30	39.23	* Sat. 9-2, Records
														* Easy caps
														*
2	-	10.61	2.59	11.26	3.69	36.99	10.37	4.69	44.06	-	19.56	9.99	42.89	* Same as
														* above
														* Weekend. 24 hr.
9	-	12.69	3.69	14.89	3.69	42.49	13.74	8.29	54.99	-	24.29	15.99	44.99	* after hr., records
														* disc. easy caps
														*
														*
														*
														*
	6.29	11.94	2.94	12.24	2.94	34.94	11.94	5.94	N/A	19.74	9.94	39.94	39.94	* Records,
						from								* Easy caps,
						to 44.39*								* Weekends
						*mfg. price								*
						*increase								*

6-9

Mr. Chairman, Members of the Committee: My name is Clarence Arndt, and I am a resident of Overland Park.

I am a member of the Johnson County Aging Commission; an ex- Silver Haired Legislator; and local legislative officer for AARP Chapter No. 2333 of Overland Park.

Thank you for the opportunity of testifying against HB 3064. I believe this bill is a group program to regulate and stifle out- of -state competition; and I worry that the net result will be higher prices for prescription drugs, state-wide.

I am a retiree from Farmland Industries, and a policy holder in their insurance program; and as such I could be affected by this bill. Since 1987 Farmland has had an optional benefit to its medical plan, and that is the Baxter Prescription Drug Program. This plan allows members to save money, time, and paperwork on their prescriptions. A 90 day supply can be ordered with just one \$8.00 copayment for each prescription. To fill this same 90 day supply at the local pharmacy would require payment at the full retail price, and filing for eligible reimbursement. There is a big advantage to the health plan, also, in the reduction of administrative costs due to decreased claim submissions.

My wife is subject to migraine headaches, for which, she takes the prescription drug, Blockadren. A 90 day supply is 270 pills which retail at \$120.00. I have the option of placing this prescription with Baxter Prescription Service of Lincolnshire, IL, and paying \$8.00 copayment; or buying locally at \$120.00; filing a claim and being reimbursed at 70% with a \$200.00 deductible. With this option, the expense to me is 30% or 36.00. By mail my cost is \$8.00, or a savings of \$28.00 to me on this one prescription. Prescriptions are received at my home by first class mail or UPS.

This bill is designated a consumer protection measure, but where is the evidence that anyone has been harmed without it?

Please consider that if out-of-state suppliers are burdened with additional expense by this bill, many older Kansans will be paying more for their prescription drugs.

Thank you,

*Clarence Arndt*

Clarence Arndt

4-1-92

*Senate P. H&U*  
*Attachment #*  
*4-6-92*      *7*