Members present:

Chairman Jeffrey
Vice Chairman Robinson
Assemblyman Bennett
Assemblyman Bremner
Assemblyman Chaney
Assemblyman Horn
Assemblyman Sena
Assemblyman FitzPatrick
Assemblyman Rusk
Assemblyman Tanner
Assemblyman Weise

Guests present: See attached list.

Vice Chairman Robinson called the meeting to order at 3:19 p.m. stating that Chairman Jeffrey was testifying in another hearing and would return shortly. He stated the purpose of the meeting was to hear AB 422, 423, 424 and 425, and relating to licensed contractors.

AB 422: Mr. Tom Cooke, attorney for the Nevada State Contractors Board, and Charles Thomas, Secretary for the Nevada State Contractors Board, were present to explain this package of bills to the committee. Mr. Cooke stated that he had just met with Chairman Jeffrey to discuss an amendment to this bill which was necessitated because of a misunderstanding with the bill drafter resulting the in the bill as printed not reflecting accurately their desires. That amendment is attached and included herein and marked as Exhibit "A". He stated that the new language would be substituted for subsections 2 and 3 of the bill as printed and is necessary due to court decision in California (Grimes v. Hoschler, 525 P265). This amendment would make the bill constitutional and also in line with Section 7113.5 of the Business and Professional Code of California. He stated that the language of the bill was redundant and not needed in light of the court decision, relavent to sections 2 and 3.

In answer to a question from Dr. Robinson, Mr. Cooke stated that currently, and constitutionally, the board is not permitted to cancel a contractor's license due to bankruptcy being filed because of the current statutory provisions in the Bankruptcy laws. Mr. Weise pointed out that a contractor filing bankruptcy might not have anything to do with his business and also that he would need his contractor's license to be able to make enough money to continue on in business. Mr. Thomas stated that Section 401 of the Federal Bankruptcy Law would stay any action by any agency so long as the contractor was under the purview of the of the Bankruptcy Courts and that once a contractor was discharged from bankruptcy then the Board could take whatever action they thought necessary based upon the contractor's record in dealing with the public.

AB 423: Mr. Cooke stated that this bill was drafted in order to include bidding on a job as coming under the bonding limit. He stated that this was needed in order to keep people from bidding jobs that they might not have the financial capability to perform.

Mr. Thomas stated that if a licensee knows that he is going to exceed his current limit on a particular bid, he can apply to the Board for a waiver of restriction which is good for that bid only and, if the licensee is successful on the bid, he would then have to post a performance bond. If the licensee wanted to raise his limit permanently, he could apply to the Board to do so and, if he were financially sound, the Board would allow him to do so.

Mr. Cooke stated that this bill was proposed because a licensee had bid on a job above his limit and when the Board had sent him a letter of reprimand, the contractor had taken them to District Court and when the District Court had upheld the decision of the Board on the reprimand, the contractor had taken its appeal to the Supreme Court. He stated that this bill would more clearly define their ability to reprimand and take other disciplinary action when related to bidding procedures.

In answer to a question posed by Mr. Rusk, Mr. Thomas stated that each case is decided individually by the Board based upon each contractor's competence on past work and his financial base within the guidelines set forth in NRS 624.263. He also stated that if a contractor applied for permission to bid over his limit and the Board did not act on the application within the seven day period allowed, the contractor would not be in violation of the law. The committee then discussed with these gentlemen how the limits are viewed when there are several contractors included on a job, i.e. general contractors and sub-contractors, etc. Mr. Thomas stated in conclusion that the Board can ask any contractor to post a specific performance bond with the owner if the Board feels that that might be necessary for one reason or another.

Mr. Cooke stated that a provision such as this helps to slow down the growth of some contractors who might otherwise get into financial or workload trouble due to overeagerness. It was pointed out by Mr. Bennett that the bonds which had been discussed were sometimes very hard to get. Mr. Cooke stated that that was true, but that some help could be obtained through the Small Business Administration.

Assemblyman Bob Price addressed the committee at this point regarding whether the committee would entertain the idea of including in the bill a provision that if a contractor were not actually licensed in Nevada, his bid on any job would be null and void. He stated that this had been part of the law prior to 1969 when the law was changed. He said that this problem with the law had come up recently when a contractor, not licensed in the state, but who had make application for a license using false information, had bid on a job in Las Vegas.

Mr. Thomas stated that this problem only arises when a bid is submitted between the time the contractor makes application for licensing in Nevada and the actual approval of the license.

It was agreed that Mr. Price, Mr. Cooke and Mr. Thomas would meet in order to work on the language for an amendment to AB 422 which would include and take care of the problem raised by Mr. Price.

In answer to a question from Dr. Robinson, Mr. Cooke stated that there is no reciprocity between states regarding contractors licensing.

AB 424: Mr. Cooke stated that the language in this bill would make sure that the Board would have the authority, specifically granted by the Legislature, to reprimand or suspend the license, or increase the cash bond which must be posted with the Board by the contractor. He stated he felt increasing the cash bond would be a very effective tool to use to get the attention of a contractor which they had had trouble with.

He also stated that the warranty provision of section 4, page 2 would help the Board in servicing consumer complaints. He stated that they currently have some power in this area, but that this provisions would clarify those provisions. Mr. Jeffrey asked if there only option at this time was suspension or non-renewal and Mr. Cooke stated that that was the case. He also added that over the years he would guess that 90% of the consumer complaints never got to the Board for action because the contractor took care of the problem when the consumer threatened to turn the problem over to the Board. He also stated that the felt the Contractors Board probably had one of the best agency records in state government when it came to taking care of consumer interests.

In answer to a question from Mr. Chaney, Mr. Thomas stated that there currently is no warranty of work required to be given to the consumer by the contractor.

Dr. Robinson stated that he had purchased a home in Las Vegas from a contractor which was covered by a Home Owners Warranty and that many of the people who had bought homes in that tract had had a great deal of trouble rectifying the numerous problems which they had found with their homes as the contractor, after repeated demands, had not fixed anything. And, he stated, the Contractors Board didn't seem to do anything to the contractor.

Mr. Thomas stated that he knew of the contractor that Dr. Robinson had had the problem with and the reason they had not revoked his license was that they were trying to get him to fix all the things that needed to be redone. He stated that in the case of a contractor who had problems such as these, the Board would require, as a condition of license renewal, that the contractor post a much larger bond.

Mr. FitzPatrick stated that he had had similar problems with an air conditioning unit and that he had tried to get the assistance of the Contractors Board, but that he had not gotten a satfactory response from either the contractor or the Board.

Mr. Thomas stated that work of that nature should also be covered and that he would check into it later.

In answer to a question from Dr. Robinson, Mr. Cooke stated that he did not know why in AB 422 the bill drafter had used the word "substantial" injury on page 1, line 5 and then used the word " material" injury in AB 424, page 2, line 10. He said the intent was the same.

AB 425: Mr. Cooke stated that this bill was simply to limit the contractor by using the aggregate total of all jobs being worked on when reviewing total financial capabilities relative to the contractor's bond. He said that this would make everyone more cognizant of whether or not the contractor might be overextending himself and thus be jeopardizing his financial soundness.

There were no questions relative to this bill.

Mr. Weise asked why all the bills couldn't be grouped into one bill since one of them had to be amended anyway and they all applied to the same chapter of NRS. Chairman Jeffrey stated that this would be considered.

AB 98: Mr. Bremner, chairman of the sub-committee on this bill, made his report to the committee stating that it had met on two occasions and that he had prepared a written amendment for consideration by the committee as a whole, together with some pertinent information which had been received by the sub-committee, which is attached and made a part hereof as Exhibit "B".

Mr. Bremner stated that he felt the proposed language satisfied most of the concerns of the members of the sub-committee and read the amendment to the committee. It was suggested that section 8 of the proposed amendment be changed by deleting the words "as a reference guide"; adding at the end of that sentence the words "in selecting a generic drug substitute".

Mr. Weise moved the adoption of the amendment with the corrections to section 8 to the bill. Mr. Tanner seconded the motion and it carried unanimously.

Mr. Bremner moved to AMEND AND DO PASS this bill, Mr. Fitz-Patrick seconded the motion and it carried unanimously.

There being no further business, Chairman Jeffrey adjourned the meeting at 4:45 p.m.

Respectfully submitted,

Linda Chandler
Linda Chandler

ASSEMBLY COMMERCE COMMITTEE

ROLL CALL:

Hearing date: March 1, 1979

	Present	Absent	Excused
CHAIRMAN JEFFREY	x		
VICE CHAIRMAN ROBINSON	x		
MR. BENNETT	x		
MR. BREMNER	x		
MR. CHANEY	x		
MR. HORN	x		
MR. SENA	x		
MR. FITZPATRICK	x		
MR. RUSK	x		
MR. TANNER	x		
MR. WEISE	x		

Date of Hearing 3-1-79

ASSEMBLY COMMERCE COMMITTEE

GUEST LIST

NAME (Please print)	REPRESENTING (organization)	WISH TO SPEAK Yes	No.
CHARLES THOMAS	STATE OF NEVADA STATE CONTRACTORS BOARD	X	
TOM COOKE	ATTY CONTRACTORS BOARD	X	
DON GURD	NEV. STATE COUNCIL OF LABORERS		

AB 422

N.R.S. 624.3016 should be amended by deleting Section 2, pertaining to bankruptcy. A new Section 2 should be added, which reads as follows:

2(a). "The avoidance or settlement by a licensee for less than their full amount of the lawful obligations of such licensee incurred as a contractor, whether by (1) a composition, arrangement or reorganization proceeding; or (2) the appointment of a receiver of the property of the licensee under the laws of this State; or (3) the making of an assignment for the benefit of creditors."

2(b). "This section shall not apply to an individual settlement of the obligation of a licensee by such licensee with a creditor, which is not a part of or in connection with a settlement with other creditors of such licensee."

2(c). "No disciplinary action shall be commenced against the licensee for avoiding or settling in bankruptcy, or by composition, arrangement, or reorganization with creditors under federal law, the licensee's lawful obligations incurred as a contractor for less than the full amount of such obligations."

EXHIBIT "A"

SUB-COMMITTEE MEMBERS:

Mr. Bremner
Mr. Horn
Mr. Tanner

The above sub-committee met to discuss AB 98 on two occasions and submit to the committee as a whole the attached proposed amendments to the bill (designated as Exhibit "A").

Also submitted herewith are the various information papers received by the subcommittee during their discussions (designated as Exhibit "B").

Respectfully submitted,

Linda D. Chandler

Linda D. Chandler
Secretary

EXHIBIT "B"

FROM THE SUBCOMMITTEE COMPRISED OF MR. BREMNER, MR. TANNER AND MR. HORN.

AMENDMENT TO AB 98

SECTION 1. Chapter 639 of NRS is hereby amended by adding thereto a new section which shall read as follows:

1. "Practitioner" means: A physician, dentist, podiatrist or veterinarian holding a currently valid license to practice his profession in this state.

2. When a practitioner prescribes a brand name drug and permits substitution, a pharmacist may fill the prescription with another drug having the same active chemical ingredient(s) of the same strength, quantity and dosage and of the same generic drug type as the brand name drug.

3. The pharmacist shall not select and substitute an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product. If a substitution is made, the pharmacist shall notify the person presenting the prescription of the price difference between the brand name drug prescribed and the generic drug proposed for substitution.

4. When a substitution is made pursuant to this section, the pharmacist shall note on the prescription the name of the manufacturer of the dispensed generic drug.

5. Every prescription form in the State of Nevada must contain two signature lines for the prescriber. The left side of the prescription form shall contain under the signature line the phrase "substitution permissible"; the right side shall contain under the signature line the phrase "dispense as written". In the instance of an oral prescription, the pharmacist shall note the prescriber's instructions on the face of the prescription. Prescriptions for federal medical program beneficiaries shall conform to applicable federal regulations. Prescriptions from out of state shall not be substituted.

6. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic drug or substitute any specific generic drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

7. A pharmacist may not make a substitution pursuant to this section unless the manufacturer of the generic drug has shown that:

a. All products have an expiration date on the original package.

b. All tablets or capsules have imprinted upon them a manufacturer's product identification code.

c. The manufacturer maintains recall and return capabilities for unsafe or defective drugs and a statement describing such capabilities is on file with the board of pharmacy.

d. The manufacturer has a liability statement relative to its drug products on file with the board of pharmacy.

8. The pharmacist must use as a reference guide the "F.D.A. List of Therapeutically Equivalent Drugs".

9. A pharmacist who selects an equivalent drug product pursuant to this act assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

EXHIBIT B

13 February 1979

POSITION PAPER: SUBSTITUTION OF GENERIC EQUIVALENT DRUGS WHEN BRAND NAME DRUGS ARE PRESCRIBED (AB98 AND SB137)

SOURCE: STATE WELFARE MEDICAID (TITLE XIX) PROGRAM

CONTACTS: MINOR L. KELSO, CHIEF, WELFARE MEDICAL SERVICES
JEFFREY L. MONAGHAN, PHARM.D., PHARMACEUTICAL CONSULTANT, WELFARE MEDICAL SERVICES

PHONE NUMBER: 885-4775

Background

The federal Maximum Allowable Cost (MAC) Program was implemented in Nevada on June 27, 1977. Because of this, the Nevada Medicaid Program must limit drug payments to the lowest priced generally available brand of a generically equivalent product. These drug price limits are determined by the U.S. Department of Health, Education, and Welfare through pharmacy invoice surveys. Today, there are 14 different drugs affected by the MAC program. Secretary Califano of DHEW has stated there will be 70 drugs on the MAC list by December 1979. When fully implemented, it is estimated the MAC program will save the Nevada Medicaid program approximately $80,000 per year.

Problem

As noted above, the Nevada Medicaid program must limit drug payments to those maximums established by the Dept. of Health, Education, and Welfare. These limits do not apply, however, where a prescriber certifies that a specific brand of a MAC-limited drug is "medically necessary" for a particular patient. Federal regulation (45CFR250.30 (b)(2)(ii)) states this certification must be in the prescriber's handwriting and written directly on the prescription blank or on a separate sheet attached to the original prescription. This certification procedure for prohibiting generic drug substitution is identical to the procedure recommended in the Federal Trade Commission's "Model Drug Product Selection Bill".

EXHIBIT B

Various forms of proposed drug product selection legislation before the Nevada Legislature include the use of a "two-signature-line" prescription form. By signing on one signature line as opposed to the other, the prescriber could indicate to the pharmacist whether or not generic substitution could occur. Presently, the use of the two-line prescription form will not suffice as a means of certification to override MAC limits on multiple-source drugs. The Department of Health, Education, and Welfare has determined that in order to override a MAC limit, a "phrase" indicating the need for a specific brand of medication must appear on the prescription. Obviously a conflict exists between proposed legislation and existing override procedures under the MAC program.

Position

If drug product selection legislation is passed by the Nevada Legislature and it contains a two-signature-line provision, this office will pursue a reversal of present federal policy. If such a drug product selection law is passed and until such a reversal is obtained, it would be necessary for SAMI prescribers to perform an extra step when overriding a MAC price limit. Not only must the prescriber sign the signature line prohibiting substitution, he must also write the phrase "medically necessary" on the prescription blank. If the prescriber signs on the signature line allowing substitution, there obviously is no conflict with present MAC policy.

The Nevada Medicaid program does not believe the federal government's certification requirement for overriding a MAC limit is legally defensible. It is our belief that by choosing which signature line to sign on, the prescriber has made a conscious, binding decision. A prescriber's signature is a significant legal act. As such, it should be binding in terms of overriding a MAC-limited drug.

One of the goals of the Nevada Medicaid program is to keep Medicaid recipients in the "mainstream" of medical care. We will pursue federal acceptance of the two-signature-line prescription form for Nevada Medicaid recipients.

cc: Ralph DiSibio, Director, Department of Human Resources
George E. Miller, Welfare Administrator
Michael Melner, Deputy Attorney General, Welfare Division

Nevada State Board of Pharmacy

GEORGE T. BENNETT, SECRETARY
1281 TERMINAL WAY, SUITE 217
RENO, NEVADA 89502
(702) 322-0691

SUGGESTED AMENDMENTS FOR SB 137
AND AB 98

SECTION 1. CHAPTER 639 OF NRS IS HEREBY AMENDED BY ADDING THERETO THE PROVISIONS SET FORTH AS SECTIONS 2 TO 9, INCLUSIVE, OF THIS ACT.

SECTION 2. "PRACTITIONER" DEFINED. "PRACTITIONER" MEANS: A PHYSICIAN, DENTIST, PODIATRIST OR VETERINARIAN HOLDING A CURRENTLY VALID LICENSE TO PRACTICE HIS PROFESSION IN THIS STATE.

SECTION 3. WHEN A PRACTITIONER PRESCRIBES A BRAND NAME DRUG AND PERMITS SUBSTITUTION, A PHARMACIST MAY FILL THE PRESCRIPTION WITH ANOTHER DRUG HAVING THE SAME ACTIVE CHEMICAL INGREDIENT(S) OF THE SAME STRENGTH, QUANTITY AND DOSAGE AND OF THE SAME GENERIC DRUG TYPE AS THE BRAND NAME DRUG.

SECTION 4. BEFORE A SUBSTITUTION IS MADE PURSUANT TO THIS SECTION, THE PHARMACIST SHALL NOTIFY THE PERSON PRESENTING THE PRESCRIPTION THE AMOUNT OF THE PRICE DIFFERENCE BETWEEN THE BRAND NAME DRUG PRESCRIBED AND THE GENERIC DRUG PROPOSED FOR SUBSTITUTION.

Exhibit B

SECTION 5. WHEN A SUBSTITUTION IS MADE PURSUANT TO THIS SECTION, THE PHARMACIST SHALL NOTE ON THE PRESCRIPTION THE NAME OF THE MANUFACTURER OF THE DISPENSED GENERIC DRUG. ~~SUBSEQUENT REFILLS SHALL BE OF THE SAME MANUFACTURER.~~

SECTION 6. EVERY PRESCRIPTION FORM IN THE STATE OF NEVADA SHALL CONTAIN TWO SIGNATURE LINES FOR THE PRESCRIBER. THE LEFT SIDE OF THE PRESCRIPTION FORM SHALL CONTAIN UNDER THE SIGNATURE LINE THE PHRASE 'SUBSTITUTION PERMISSIBLE'. THE RIGHT SIDE SHALL CONTAIN UNDER THE SIGNATURE LINE THE PHRASE 'DISPENSE AS WRITTEN'. IN THE INSTANCE OF AN ORAL PRESCRIPTION, THE PHARMACIST SHALL NOTE THE PRESCRIBER'S INSTRUCTIONS ON THE FACE OF THE PRESCRIPTION. PRESCRIPTIONS FROM OUT OF STATE SHALL NOT BE SUBSTITUTED.

SECTION 7. AN EMPLOYER OR AGENT OF AN EMPLOYER OF A PHARMACIST SHALL NOT REQUIRE THE PHARMACIST TO DISPENSE ANY SPECIFIC GENERIC DRUG OR SUBSTITUTE ANY SPECIFIC GENERIC DRUG FOR A BRAND NAME DRUG AGAINST THE PROFESSIONAL JUDGMENT OF THE PHARMACIST OR THE ORDER OF THE PRESCRIBER.

SECTION 8. A PHARMACIST MAY NOT MAKE A SUBSTITUTION PURSUANT TO THIS SECTION UNLESS THE MANUFACTURER OF THE GENERIC DRUG HAS SHOWN THAT:

1. All products have an expiration date on the original package.
2. All tablets or capsules have imprinted upon them a manufacturer's product identification code.
3. The manufacturer maintains recall and return capabilities for unsafe or defective drugs and a statement describing such capabilities is on file with the board of pharmacy.

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EXHIBIT B

4. The manufacturer has a liability statement relative to its drug products on file with the board of pharmacy.

SECTION 9. THE PHARMACIST MAY USE AS A REFERENCE GUIDE THE "F.D.A. LIST OF THERAPEUTICALLY EQUIVALENT DRUGS".

HEW proposed language on savings:

> *The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.*

Adding ~~the Arizona language, it might~~ read:

Sec 4

> *The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product. If a substitution is made, the pharmacist shall notify the person presenting the prescription of the price difference between the brand name drug prescribed and the generic drug proposed for substitution.*

HEW language on "Equivalent drug product":

> *"Equivalent drug product" means a drug product with the same established name, active ingredient, strength, quantity and dosage form as the drug product identified in the prescription, and listed as therapeutically equivalent in the current Nevada drug formulary.*

The HEW language on pharmacist liability is similiar to AB98

> *A pharmacist who selects an equivalent drug product pursuant to this act assumes no greater liability for [redacted] selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.*

state of nevada

DEPARTMENT OF HUMAN RESOURCES
WELFARE DIVISION - MEDICAL CARE SECTION
251 JEANELL DRIVE - CAPITOL COMPLEX
CARSON CITY, NEVADA 89710
PHONE 885-4775

M E M O

February 15, 1979

TO: ROGER BREMNER, ASSEMBLY COMMERCE COMMITTEE

FROM: JEFFREY MONAGHAN, PHARM.D.
PHARMACEUTICAL CONSULTANT
WELFARE MEDICAL SERVICES

SUBJECT: SUGGESTED ADDITION TO SECTION 6 OF AMENDMENTS TO SB 137 AND AB 98

PRESCRIPTIONS FOR FEDERAL MEDICAL PROGRAM BENEFICIARIES SHALL CONFORM TO APPLICABLE FEDERAL REGULATIONS.

JLM:dd

cc: Ralph R. DiSibio, Director, Department of Human Resources
George E. Miller, Administrator, Welfare Division
Minor L. Kelso, Chief, Medical Care Services
Michael Melner, Deputy Attorney General, Welfare Division

EXHIBIT B

4. The manufacturer has a liability statement relative to its drug products on file with the board of pharmacy.

Section 9. The pharmacist may use as a reference guide the "F.D.A. List of Therapeutically Equivalent Drugs".

Section 10. A pharmacist who selects an equivalent drug product pursuant to this act assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

AMENDED AMENDMENT FROM THE NEVADA STATE BOARD OF PHARMACY
Re: AB 98

Section 1. Chapter 639 of NRS is hereby amended by adding thereto the provisions set forth as Sections 2 to 10, inclusive, of this act.

Section 2. "Practitioner" means: A physician, dentist, podiatrist or veterinarian holding a currently valid license to practice his profession in this state.

Section 3. When a practitioner prescribes a brand name drug and permits substitution, a pharmacist may fill the prescription with another drug having the same active chemical ingredient(s) of the same strength, quantity and dosage and of the same generic drug type as the brand name drug.

Section 4. The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product. If a substitution is made, the pharmacist shall notify the person presenting the prescription of the price difference between the brand name drug prescribed and the generic drug proposed for substitution.

Section 5. When a substitution is made pursuant to this section the pharmacist shall note on the prescription the name of the manufacturer of the dispensed generic drug.

Section 6. Every prescription form in the State of Nevada may contain two signature lines for the prescriber. The left side of the prescription form shall contain under the signature line the phrase "substitution permissible". The right side shall contain under the signature line the phrase "dispense as written". In the instance of an oral prescription, the pharmacist shall note the prescriber's instructions on the face of the prescription. Prescriptions for federal medical program beneficiaries shall conform to applicable federal regualtions. Prescriptions from out of state shall not be substituted.

Section 7. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic drug or substitute any specific generic drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

Section 8. A pharmacist may not make an substitution pursuant to this section unless the manufacturer of the generic drug has shown that:

1. All products have an expiration date on the original package.

2. All tablets or capsules have imprinted upon them a manufacturer's product identification code.

3. The manufacturer maintains recall and return capabilities for unsafe or defective drugs and a statement describing such capabilities is on file with the board of pharmacy.

Exhibit B

19 Feb. '79
Las Vegas, Nev.

John E. Jeffrey, Chairman
Labor and Commerce Comm.
State Legislative Bldg.
Carson City, Nev. 89701

Subject: AB 98.

Dear Sir,
I was present to testify at the first Hearing of AB 98 on 1 Feb. '79 and since that time have followed it closely. Your appointment of a Sub-Committee to further investigate the subject was most appropriate at the time. I have offered further assistance or discussion to the Sub-Committee, but apparently none has been needed, because my attempts to date have failed. Nevertheless, I am enclosing copies of the Model Drug Product Selection Bill which have been recently released by the F.T.C. You and the Sub-Committee may already have this Model Bill on file, but if not the enclosed is for your disposal as you see fit. I would especially like to emphasize Pages 13, 14, and 15. (References marked).

Pharmacy Groups agree with most of the proposals as set down by the F.T.C., and with us Drug Product Selection is not an "If" question. It is,however, a most important subject particularly in regard to How, When and Why.

We also realize that there is a fundamental hazard in legislation of this type that could emerge from efforts in developing a Model Drug Prod. Bill. The profession of pharmacy and medicine embraces a delicate balance of science and art. Years of study followed by internship and practice uniquely equip these practitioners to serve the patient in a manner best suited to that patient's needs. Efforts to design laws and regulations governing the behavior of these professionals can easily result in denying patients the benefits of the best skills and judgements of their pharmacist and physician.

Some drug product selection laws allow little or no opportunity for professional judgement and artful practice.

EXHIBIT B

This letter and the samples enclosed are sent to you with the very best of intentions, and it is hoped that in some small way it will help your Sub-Committee and the Commerce Committee -- in developing a Bill which will be far ahead of similar type Bills in other States. It is hoped that the Nevada Drug Product Selection Bill will contain provisions for exceptions to the law such as Hospital in-patient formularies and also for pharmacies which serve Nursing Homes or Extended Care Facilities which are provided largely with Unit-Dose Medications. A Drug Recall provision and assurances of return capabilities of out-dated drugs is also an important factor. Lastly, the mail-in prescriptions to the State of Nevada, or the mailing out of prescriptions from the State of Nevada, as I see it, should not be allowed to come under any Drug Product Selection Bill.

If I can be of any assistance, please call.

Respectfully,

E. Floyd Butler, Jr., B.S., Ph.G.
Sahara Rancho Pharmacy (384-4242)
2300 Rancho Dr.
Las Vegas, Nev. 89102

MODEL DRUG PRODUCT SELECTION ACT

Developed for Recommendation
to the States by the

FEDERAL TRADE COMMISSION and the

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

A substantial part of the total annual cost of medical care in America is the cost of prescription drugs. Because many prescription drug products are available from more than one manufacturer and are frequently sold at widely disparate prices, a considerable portion of the expenditure for prescription drugs could be saved if state laws regulating the practice of pharmacy fostered the selection of less expensive generic drug products.

As a means of encouraging and assisting the states in amending their laws to promote the selection of generic drug products, the Federal Trade Commission and the Department of Health, Education, and Welfare have prepared a Model Drug Product Selection Act to recommend to the states. The Model Act would permit pharmacists and consumers to select generic drug products that are lower in cost but therapeutically equivalent to drug products marketed and prescribed by brand name.

In recommending the Model Drug Product Selection Act, the Federal Trade Commission and the Department of Health, Education, and Welfare recognize that most states have repealed or amended

EXHIBIT B

antisubstitution laws prohibiting the selection of generic drug products in place of drug products prescribed by brand name. In their place, many states have enacted laws authorizing generic drug product selection. However, the effectiveness of many state laws is hampered by features that discourage pharmacists from exercising their selection authority.

Accordingly, the Model Act being recommended to the states is designed to be as simple as possible and to avoid unnecessary intrusion into the usual procedures followed by pharmacists in prescription drug dispensing. The Model Act is based on the extensive investigation started by the Federal Trade Commission in July 1976 into the effects of state antisubstitution laws. The findings and conclusions of this investigation, including a discussion of the basis for each section of the Model Act, are presented in the FTC Bureau of Consumer Protection Staff Report on Drug Product Selection. The investigation found that such laws impose substantial costs on consumers by restricting price competition in the multisource prescription drug market. It showed that significant consumer benefits can be achieved through the replacement of antisubstitution laws with effective drug product selection laws. FTC Chairman Michael Pertschuk reported to Congress last July that a Federal Trade Commission economic study estimated an annual potential consumer savings of $341 million from selection of low-cost generic equivalents for 60 popular multisource drugs. This figure, extrapolated to all multisource drugs, produces an estimate of about $400 million a year. The Model Act is also based on the experience

of the Food and Drug Administration in providing assistance to the states in developing formularies of therapeutically equivalent drugs and on that agency's consultation with its state counterparts and other interested organizations to determine the most practicable design for a model state drug product selection law.

Even though a substantial reduction in health care costs can be achieved through the selection of less expensive generic drug products, that goal will not be fully realized unless the public is assured that generic drug products are therapeutically equivalent to brand-name drug products. When testifying before Congress in November 1977, FDA Commissioner Donald Kennedy reported that the Food and Drug Administration, which collects and analyzes thousands of human drug samples each year, has found no evidence of consistent differences between the products of large and small firms, or between brand-name and generic-name products. The Food and Drug Administration is charged with the approval of new drugs for safety and effectiveness and is best able to determine the therapeutic equivalence of drug products. Accordingly, that agency will provide positive assurance to the states that the quality of health care will not be compromised by providing the states a list of drugs that have been determined by the agency to be therapeutically equivalent.

Based on the collaborative efforts of the Federal Trade Commission and the Department of Health, Education, and Welfare, the major features of an effective drug product selection law are the following:

- A provision permitting pharmacists to select a lower-cost generic drug product from a "positive formulary" listing drugs that have been determined by the Food and Drug Administration to be therapeutically equivalent.
- A provision recognizing the absolute authority of the physician to prohibit drug product selection upon the determination that a specific brand-name product is medically necessary.
- A provision assuring that pharmacists who choose to select lower-cost generic drug products will share these savings with consumers, without eliminating pharmacists' incentives to dispense generic drug products.
- An optional provision to assure pharmacists that no greater liability is involved in generic drug product selection than would be involved in filling a prescription for a drug product prescribed by its generic name.
- A provision permitting consumers to choose whether they wish to receive a less expensive generic drug product selected by the pharmacist or the prescribed brand-name product.

The Model Drug Product Selection Act being recommended to the states is set out in the attachment.

We will continue to monitor carefully the effectiveness of drug product selection laws in providing savings to consumers,

and stand ready to take appropriate action to ensure the health of price competition in the prescription drug market.

State officials that wish additional information or assistance in the legislative consideration of the Model Act may contact:

Division of Professional Services
Bureau of Consumer Protection
Federal Trade Commission
6th St. & Pennsylvania Ave, N.W.
Washington, D.C. 20580

State Services Branch
Division of Federal-State Relations
Office of the Executive Director
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EXHIBIT B

MODEL DRUG PRODUCT SELECTION ACT

Section I. [DEFINITION.]

(a) "Established name" has the meaning given in section 502(e)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352(e)(3)).

(b) "Equivalent drug product" means a drug product with the same established name, active ingredient strength, quantity and dosage form as the drug product identified in the prescription, and listed as therapeutically equivalent in the current [name of state] drug formulary.

(c) "Prescriber" means a person licensed by the state to prescribe drug products.

Section 2. [DRUG PRODUCT SELECTION.]

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select an equivalent drug product listed in the current [name of state] drug formulary.

(b) The pharmacist shall not select an equivalent drug product if the prescriber handwrites "medically necessary" or words of the same meaning on the written prescription, or when ordering a prescription orally, the prescriber specifies that the prescribed drug product is medically necessary. The designation of medical necessity shall not be preprinted or stamped on the prescription. This subsection does not preclude a reminder of the procedure required to prohibit selection of an equivalent drug product from being preprinted on the prescription.

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(c) The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.

(d) The pharmacist, or the pharmacist's agent, assistant or employee shall inform the person receiving the drug pursuant to the prescription of the selection of a lower-cost equivalent drug product and of the person's right to refuse the product selected.

Section 3. [PRESCRIPTION LABEL.]

Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established name and the name of the manufacturer, packer or distributor, using abbreviations if necessary.

Section 4. [PRESCRIPTION RECORD.]

The pharmacy file copy of every prescription shall include the trade or brand name, if any, or the name of the manufacturer, packer or distributor of the drug product dispensed.

Section 5. [DRUG FORMULARY.]

(a) The [state health department, board of pharmacy or drug formulary commission] shall establish and maintain by regulation a [name of state] drug formulary of equivalent drug products. The formulary shall list all drug products the Commissioner of Food and Drugs, United States Food and Drug Administration, has approved as safe and effective, and has determined to be therapeutically equivalent. The formulary shall list all drug products that were not subject to premarketing approval for

safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, that are manufactured by firms meeting the requirements of that Act, are subject to pharmacopoeial standards adequate to assure product quality, and have been determined by the Commissioner of Food and Drugs to meet any other requirements necessary to assure therapeutic equivalence. The formulary may list additional drug products that are determined by the [department, board or commission] to meet requirements adequate to assure product quality and therapeutic equivalence.

(b) The [department, board or commission] shall provide for revision of the formulary as necessary but not less than annually.

(c) The [department, board or commission] shall provide for distribution of the formulary and revisions to all pharmacies and prescribers licensed in this state and to other appropriate individuals.

(d) The [department, board or commission] shall assess the need and if appropriate provide for public education regarding the provisions of this act and from time to time shall monitor the effects of the act.

Section 6. [PHARMACIST LIABILITY.] (Optional)

A pharmacist who selects an equivalent drug product pursuant to this act assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

Section 7. [ENFORCEMENT.]

Section 8. [EFFECTIVE DATE.]

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MODEL DRUG PRODUCT SELECTION ACT

PREPARED AND ISSUED BY FTC/FDA STAFF

SECTION-BY-SECTION ANALYSIS

Section 1 [DEFINITIONS]

(a) "Established name" has the meaning given in Section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(3)).

(b) "Equivalent drug product" means a drug product with the same established name, active ingredient strength, quantity and dosage form as the drug product identified in the prescription, and listed as therapeutically equivalent in the current [name of state] drug formulary.

(c) "Prescriber" means a person licensed by the state to prescribe drug products.

Section 1 adopts standard definitions of "established name" and "prescriber," and defines "equivalent drug products" in terms that assure that drug products eligible for selection are therapeutically equivalent.[1]

Section 2 [DRUG PRODUCT SELECTION]

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select an equivalent drug product listed in the current [name of state] drug formulary.

Section 2(a) permits rather than requires pharmacists to

select lower-cost equivalents, because, based on our experience and analysis, mandatory laws appear to be both unnecessary and unworkable. They appear to be unnecessary if pharmacists' economic incentive to select lower-cost products is not eliminated (see discussion of Section 2(c) below). They appear to be unworkable because costly enforcement efforts are necessary to overcome pharmacists' resistance to such government intrusion.[2] The FTC study, for example, found a significantly lower rate of product selection in Pennsylvania, which has a mandatory law, than in several other states with permissive laws.[3] Similarly, other evidence indicates a lack of compliance with mandatory laws.[4] Permissive product selection laws can therefore be expected to produce a greater savings to consumers without unnecessary government regulation.

Section 2(a) also recognizes the right of the person receiving the drug pursuant to the prescription to insist upon the brand prescribed by the physician (see discussion of Section 2(d) below) and limits product selection to those equivalent drug products listed in the state's positive formulary (see discussion of Section 5 below). The phrase "person receiving the drug pursuant to the prescription" refers to a person (who may or may not be the actual patient) who brings the prescription to the pharmacy and receives the drug after the prescription has been filled, or to a person to whom the drug is delivered (at the pharmacy or elsewhere) after the prescription has been telephoned to the pharmacy by the prescriber.

(b) The pharmacist shall not select an

equivalent drug product if the prescriber handwrites "medically necessary" or words of the same meaning on the written prescription, or when ordering a prescription orally, the prescriber specifies that the prescribed drug product is medically necessary. The designation of medical necessity shall not be preprinted or stamped on the prescription. This subsection does not preclude a reminder of the procedure required to prohibit selection of an equivalent drug product from being preprinted on the prescription.

Section 2(b) recognizes the absolute authority of the prescriber to insist upon a particular drug source he or she judges medically necessary. The term "medically necessary" is suggested for two reasons: it is identical to the phrase required by HEW's Maximum Allowable Cost program and thus does not require prescribers to use a different term for Medicaid patients,[5] and it best describes the justification for insisting upon a more expensive product.

Numerous studies show that prescribers rarely (generally less than five percent of the time) find it necessary to use the "medically necessary" designation.[6] The Model Act's use of a positive drug formulary of FDA approved drugs to assure the equivalence of substitutable products (as well as its reliance on the pharmacists' professional judgment) should make prescriber concern about the medical need for a particular brand even more infrequent.

This approach--requiring that the prescriber take a couple of seconds to handwrite "medically necessary"--works better than the use of preprinted signature lines on the prescription. Studies show that when prescribers are required (whether they have strong concerns about the medical necessity of a particular brand or not) to sign either a line designated "dispense as written" or one designated "substitution permitted," they prohibit substitution half the time or more.[7] Studies also indicate that prescribers prohibit substitution with relatively uniform consistency for all drugs, regardless of their therapeutic category, and equally often for single-source drugs (for which no substitution is possible) as for multisource drugs and even for generically-written prescriptions (when the pharmacist must choose some brand to dispense).[8] It seems that prescribers more often exercise their "veto" because they oppose product selection as an intrusion into their professional automony than because of possible medical concerns about a particular drug product.[9]

Although the Model Act (and similar statutes) does not prevent the prescriber from writing "medically necessary" on every prescription, it does require an affirmative act indicating the prescriber's conscious decision. The additional cost of an expensive brand-name product should not be imposed on the consumer without ensuring that the decision is made consciously.[10] Preprinted prescription forms are far more likely to be signed by habit on the same line initially chosen, with the initial decision being based on general support or opposition to product selection.

The American Medical Association argues[11] that physicians may fail to make the "medically necessary" designation because they are not in the "habit" of doing so. A study by Dr. Theodore Goldberg in Michigan, however, provides some evidence to refute this explanation: although one might expect the influence of past habit to decrease as prescribers became more familiar with a new product selection law, the percentage of prescriptions designated "dispense as written" decreased from 6.4 percent during the first year of the Michigan law to 4.0 percent during the second year.[12]

Prescribers must be informed, of course, of the law's provision for designating a particular brand as medically necessary. The agency responsible for the state drug formulary could provide this information as part of its functions (see Section 5 below). And the section permits a prescriber concerned about forgetting the provision to preprint a reminder on the prescription. A physician survey prepared for Roche Laboratories indicates that prescriber awareness of the law's provisions may not be a problem: of 200 Florida physicians interviewed in October 1977, 99.5 percent said they knew about the 1976 Florida product selection law, and 97.0 percent also knew that the only way to prevent substitution was "to write 'medically necessary' on a prescription."[13] Although this survey was imperfect, there is no contrary evidence indicating that prescribers are unaware of the procedure to prevent substitution. Moreover, brand-name manufacturers have substantial economic incentives to ensure that prescribers are continually reminded about the procedure required to limit the prescription

to a particular brand.

(c) The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.

Section 2(c) requires that a pharmacist who engages in drug product selection share cost savings with the purchaser by dispensing a less expensive product than the brand prescribed. A mandatory pass-on of all cost savings to consumers is not recommended, because that provision diminishes pharmacists' economic incentive to engage in product selection. By denying pharmacists additional profit for costs that may be incurred in searching for, stocking and dispensing lower-cost generics, mandatory pass-ons may even provide an economic disincentive for product selection. Many pharmacists responding to a survey conducted by the FTC, especially pharmacy owners and managers, said that mandatory pass-ons of all cost savings would deter them from substituting as often as they would otherwise.[14] FDA consultation with its state counterparts confirmed the preferences of pharmacists for the type of provision recommended.

The marketplace should work to ensure that pharmacists pass on a large portion of the cost savings to consumers. Moreover, increased pharmacist selection of lower-cost products should eventually produce additional savings by motivating brand-name manufacturers to lower their prices to compete with less expensive generics.

Not only are mandatory pass-ons unnecessary, but they may be unworkable. It is difficult to draft language specifying

the savings that must be passed on because pharmacists' pricing systems vary and because an actual event (the sale of the dispensed product) must be compared with a hypothetical event (the sale of the brand prescribed but not dispensed).[15] To enforce and monitor pass-on provisions would require ascertaining the prices of the prescribed and dispensed drug products at the time a particular selection occurred. This determination would certainly be costly and might be impossible.[16] The fact that the FTC study found one-third to one-half of the pharmacists in states with mandatory pass-ons unaware of those provisions indicates that the mandate often may not be complied with.[17]

> (d) The pharmacist, or the pharmacist's agent, assistant or employee shall inform the person receiving the drug pursuant to the prescription of the selection of a lower-cost equivalent drug product and of the person's right to refuse the product selected.

Section 2(d) makes the purchaser's right to insist upon the brand prescribed (see Section 2(a)) more meaningful by requiring that the person receiving the drug pursuant to the prescription be notified of the selection of a lower-cost generic and of his or her right to insist instead upon receiving the brand prescribed. (A refusal may affect the patient's right to reimbursement under third-party payment plans.) This notice not only alerts the purchaser to expect to pay a lower charge, but also encourages pharmacists to help educate consumers about the cost benefits of drug product selection. Responses to the

FTC study indicate that the increased time spent with patients because of such provisions does not unduly burden pharmacists.[18]

The Model Act does not require that pharmacists inform the purchaser of the difference in prices of the brand prescribed and the generic dispensed because that calculation may be sufficiently burdensome to discourage product selection (the purchaser, of course, may ask the pharmacist the amount of price savings).[19] Similarly, the Model Act does not require that pharmacists notify the purchaser of the availability of a generic equivalent prior to filling the prescription because prior notice is inconvenient, particularly when the prescription is telephoned in by the physician.[20]

Section 3. [PRESCRIPTION LABEL.]

Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established name and the name of the manufacturer, packer or distributor, using abbreviations if necessary.

Section 3 requires that prescription labels include the dispensed product's name or its generic name and the name of the manufacturer, packer, or distributor. The requirement applies to all prescriptions because the information is just as useful (in an emergency, for example) for generic prescriptions as for substituted prescriptions. Further, the extra labeling and record-keeping requirements imposed on substituted prescriptions should be reduced as much as possible to minimize the difference

in administrative requirements between practicing drug product selection and not practicing it.

Section 4. [PRESCRIPTION RECORD.]

The pharmacy file copy of every prescription shall include the trade or brand name, if any, or the name of the manufacturer, packer or distributor of the drug product dispensed.

Section 4 requires that the file copy of all prescriptions identify the product dispensed by including its brand name or the name of its manufacturer, packer, or distributor.[21] As with labeling, the requirement applies to all prescriptions because this information should be equally necessary when a prescription is written generically as when an equivalent product is selected to fill a brand-name prescription. The FTC study indicates that these labeling and record-keeping requirements will not unduly increase pharmacists' paperwork.[22]

Section 5. [DRUG FORMULARY.]

(a) The [state health department, board of pharmacy or drug formulary commission] shall establish and maintain by regulation a [name of state] drug formulary of equivalent drug products. The formulary shall list all drug products that the Commissioner of Food and Drugs, United States Food and Drug Administration, has approved as safe and effective, and has determined to be therapeutically equivalent. The formulary shall list all drug products that were not subject to premarketing

approval for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, that are manufactured by firms meeting the requirements of that Act, are subject to pharmacopoeial standards adequate to assure product quality, and have been determined by the Commissioner of Food and Drugs to meet any other requirements necessary to assure therapeutic equivalence. The formulary may list additional drug products that are determined by the [department, board or commission] to meet requirements adequate to assure product quality and therapeutic equivalence.

Section 5(a) requires that a state agency (whose composition is to be determined by each state) maintain a positive formulary listing those equivalent drug products eligible for selection by pharmacists. The formulary automatically includes all drug products determined therapeutically equivalent and approved as safe and effective by FDA. It further includes all products not subject to FDA approval for safety and efficacy (drugs approved only for safety prior to 1962 and drugs marketed prior to 1938)[23] if they otherwise meet requirements FDA finds necessary to assure therapeutic equivalence.[24] FDA previously has announced that it will be providing states with a list of approved drug products that it has determined are therapeutically equivalent.[25] FDA has no current plans to review unapproved drug products for therapeutic equivalence; however, such evaluations may be feasible at some time in the future for certain classes of these

drugs. This section of the Model Act provides a legal mechanism to incorporate any such evaluations into state formularies should they be made in the future. The section also permits the state agency to list additional drug products it determines to be therapeutically equivalent.

There are two principal reasons for recommending a drug formulary in the Model Act. First, some problems with therapeutically significant variations in the performance of chemically identical drug products in the body have occurred in the past.[26] While the potential for such problems is small, a sound law should rely on the best scientific information available to ensure that such drug products are not selected. Second, several studies, including the one conducted for the FTC, have found the greatest degree of product selection in states with a drug formulary.[27] A researcher with the Goldberg study similarly concluded that "provision of lists (formularies) is associated with higher rates of substitution."[28] For example, that study's preliminary analysis of 1977-78 data in Wisconsin, which has a positive formulary, indicates an 18 to 20 percent rate of product selection compared to a 1.5 percent rate in Michigan, which has no formulary.[29] The evidence of this and other studies[30] indicates that the product information and guidance provided by drug formularies appears to encourage pharmacists to engage in product selection more frequently than they might otherwise.

The recommendation of a positive formulary, listing all substitutable drugs, rather than a negative formulary, listing all nonsubstitutable drugs, is a more difficult decision. However,

the positive formulary offers several advantages. When asked in the FTC study under which system they would substitute most often, four times as many pharmacists preferred a positive formulary as preferred a negative formulary.[31] This response indicates that formularies are most useful to pharmacists when they provide guidance in the form of a comprehensive list of substitutable products. In addition, a positive formulary can exclude the substantial number of drug products that have never been approved by FDA but still remain on the market[32] and thus prevent their use in product selection. Finally, a positive formulary, combined with price information and a list of available sources of generic drugs (should states elect to add such a requirement to the Model Act) could be used as a comparative guide to prescription drugs. Publicized through the media and made available wherever prescription drug products are sold to the public, a properly designed guide would facilitate price shopping by consumers and consumer groups.[33]

Administrative costs for the establishment and maintenance of positive formularies, however, generally are greater than those for negative formularies.[34] And delay in adding new products to the positive formulary poses a potential competitive barrier. The Model Act minimizes administrative costs by relying on the FDA to supply a list of drug products that have been determined by the agency to be therapeutically equivalent. By making costly and duplicative efforts by 50 states unnecessary, FDA preparation of a single drug list ensures that the list's benefits outweigh its costs. Further, the Model Act assigns primary responsibility

for determination of product equivalence to the agency that is the single best source of drug information and scientific expertise. Most states, faced with limited resources, already rely on FDA for assistance in preparing their formularies.[35] Establishment of a formulary of FDA-approved equivalent products also is consistent with the Office of Technology Assessment Panel's recommendation of a federal compilation of interchangeable products[36] and with FDA's responsibilities for premarket drug approval,[37] bioequivalence requirements,[38] and Good Manufacturing Practice regulations.[39]

Finally, the Model Act authorizes the state agency to list additional products it determines to be therapeutically equivalent. This should be necessary only if the states feel that significant barriers to competition are resulting from what it perceives to be a significant need to add new products to the formulary. To further minimize the possibility of unnecessarily impeding competition, states might wish to consider a "sunset" provision, which would eliminate the formulary after allowing some reasonable period of years for FDA to assure the therapeutic equivalence of all marketed products.

(b) The [department, board of commission] shall provide for revision of the formulary as necessary but not less than annually.

(c) The [department, board of commission] shall provide for distribution of the formulary and revisions to all pharmacies and prescribers licensed in this state and to other appropriate individuals.

Section 5 (b) and (c) require that the state agency "provide for" revision and distribution of the drug formulary. The term is intended to allow for the possibility that the board or commission might be able to arrange for the actual revision and distribution to be performed by another agency, rather than directly by the board or commission itself.

(d) The [department, board or commission] shall assess the need and if appropriate provide for public education regarding the provisions of this act and from time to time shall monitor the effects of the act.

Section 5(d) requires that the state agency assess the need and where appropriate provide for public education about the product selection law. For example, the agency could examine the extent to which retail pharmacies provide the necessary consumer information and, as needed, supplement those efforts through the mass media or at retail outlets.[40] Most consumers are unaware of the availability of generic equivalents and of the ability of pharmacists to select a less expensive equivalent in lieu of the more expensive brand prescribed. The FTC study, for example, found that few consumers ask their pharmacists about the possibility of dispensing a lower-cost generic.[41] Particularly during the first few years of a new product selection law, it is important that consumers be informed about the cost savings provided by generic equivalents, about their right to be informed when product selection occurs, and their right to refuse the product selected. Informed consumers may encourage pharmacists to select lower-cost generic drug products more

frequently.[42] Pharmacists and prescribers also need to be informed about their responsibilities under the law.

This section also requires that the state agency periodically monitor the effects of the product selection act. Because of the limited amount of information available, there are still some unresolved questions concerning the effectiveness of certain provisions in motivating pharmacists to select generic equivalents and to provide cost savings to consumers. It is therefore a useful allocation of resources for each state to examine the effectiveness of whatever law it adopts in this area and to recommend modifications as necessary.

Section 6. [PHARMACIST LIABILITY] (Optional)

A pharmacist who selects an equivalent drug product pursuant to this act assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

Section 6 is an optional provision assuring pharmacists that their liability for product selection will not exceed the liability incurred when filling a generically-written prescription.

The results of the FTC study[43] and other surveys[44] indicate that pharmacists are concerned about the liability risks of product selection and that many therefore are deterred from selecting drug sources as frequently as they otherwise would. A thorough search by the FTC, however, has failed to identify a single lawsuit or insurance claim filed against a pharmacist for legally substituting a lower-cost generic for the prescribed

brand name. Nor has there been any report of a pharmacist ever being held liable for selecting the source used to fill a generically-written prescription.[45] Accordingly, there is no reason to believe that drug product selection will create new liability problems.[46]

The FTC survey found that most pharmacists in states with provisions limiting or defining their liability for product selection were unaware of those provisions.[47] Therefore, it has not been possible to determine whether such provisions are effective in encouraging pharmacists to engage in product selection. Whether or not a state specifically addresses the liability issue in its law, it must provide objective information about liability to pharmacists, who otherwise may be presented only with misleading and exaggerated statements.[48]

Although most liability provisions are more a restatement than a limitation of the legal standard likely to be applied by common law, the mere existence of a liability provision in the state law may serve to reassure pharmacists that they will not be subjected to an unreasonable standard. Joseph Fink, a professor at the Philadelphia College of Pharmacy and Science who has conducted a study of the Delaware product selection law and has written extensively on liability, concludes that a state law should include a liability provision:

> On balance, it is probably better for a legislative body to make a good effort to insulate or indemnify the pharmacist who engages in drug product selection to encourage cost savings than not to address the issue at all.[49]

If a liability provision is adopted, it should limit the liability from product selection to that incurred in filling a generically-written prescription. Pharmacists have been filling generic prescriptions for years and may be more reassured by a reference to that familiar activity than by a law limiting the evidential impact of drug product selection (for example, a law stating that substitution shall not constitute evidence of negligence if made within the reasonable and prudent practice of pharmacy).[50]

Section 7. [ENFORCEMENT.]

Section 8. [EFFECTIVE DATE.]

Section 7 and 8 defer to each state the determination of the appropriate enforcement provision and effective date of the Model Act.[51] Violation of pharmacy laws generally are classified as misdemeanors and cause for revocation of the violator's professional license.

1 See discussion of chemical equivalence in "Staff Report to the Federal Trade Commission: Drug Product Selection" (January 1979) (hereafter FTC Report), Ch. VI.A.4.

2 See discussion of pharmacists' opposition to mandatory laws in FTC Report Ch. VII.B.1.

3 See discussion of FTC Study in FTC Report Ch. VII.C.3.

4 See discussion in FTC Report Ch. VII.B.1. See also New York Times article-discussing reports of "widespread non-compliance" with New York's mandatory law. The New York Times, Dec. 26, 1978, at B-1.

5 See discussion of Maximum Allowable Cost program in FTC Report Ch. VI.B.

6 See discussion of state surveys regarding the use of the "medically necessary" designation in FTC Report Ch. VII.B.3. and C.

7 See discussion of state surveys regarding the use of pre-printed prescription forms. Id.

8 See discussion of Delaware and Michigan studies. Id.

9 See discussion of Delaware and Michigan Studies and a University of Mississippi survey of physician attitudes in FTC Report Ch. VII.B.3.

10 For this reason, the section prohibits the use of preprinted forms, which otherwise might be supplied to prescribers by brand-name manufacturers in an attempt to limit competition from lower-cost generics.

11 Letter from Dr. James H. Sammons, Executive Vice President, American Medical Association, to Peter Holmes, FTC, Feb. 7, 1978.

12 See discussion of Michigan study in FTC Report Ch. VII.B.3. and C.1.

13 Rx/OTC, "Florida Physicians Survey: Substitution," November 1977, at 3-4. Such states as California and Colorado permit but do not require preprinted designations of medical necessity as long as they are initialed personally by the prescriber. This alternative avoids the need to enforce the required use of a particular prescription form (see discussion of the percentage of invalid perscription forms used in New York City, FTC Report Ch. VII.B.3.) California studies show that this provision has not resulted in a large number of prescriptions prohibiting product selection. See California studies cited in FTC Report Ch. VII.B.3 and C.4.

14 See discussion of mandatory pass-ons and the results of the FTC study in Ch. VII.B.6. and C.3., supra. For a discussion of the potential inventory savings from product selection, see Ch. IV.B.

15 See discussion of cost savings provisions in FTC Report Ch. VII.B.6.

16 See for example, comment of a Michigan State Representative that the Attorney General's office admitted the unenforceability of such provisions, FTC Report Ch. VII.B.6. For similar reasons, provisions are not recommended that would limit selection for either a brand-name prescription or a generically-written prescription to the lowest-cost product in stock. The Goldberg study's comparison of the savings (14 cents per prescription) from generic prescribing in Wisconsin, which has such a provision, with the savings (74 cents per prescription) in Michigan, which does not, indicates that these provisions may be ineffective. See FTC Report Ch. VII.B.6. Moreover, a pharmacist can comply with such provisions merely by pricing the least expensive product in stock only a penny below the brand-name item, or by refusing to stock lower-cost products at all.

17 See FTC Report Ch. VII.C.3.

18 See discussion of FTC study in FTC Report Ch. VII.B.4. and C.3.

19 See FTC Report Ch. VII.B.4.

20 See Ch. VII.B.4.

21 It is unnecessary to record the generic name of the drug dispensed because its identity is provided by the brand name for which the prescription was written.

22 See FTC Report Ch. VII.B.5.

23 See discussion of FDA premarket drug approval in FTC Report Ch. VI.A.1.

24 This provision avoids the problem presented by the New York formulary, which limits eligible products to those with approved new drug applications. See Ch. VII.B.2.

25 Donald Kennedy, FDA Commissioner, Statement Before the Sub-Committee on Consumer Protection and Finance, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, July 27, 1978.

26 See discussion of bioavailability in FTC Report Ch. VI.A.4. and Ch. IX.E.1.

27 See discussion of surveys in FTC Report Ch. VII.C.

28 Carolee DeVito, Wayne State University, "Drug Product Selection Legislation: Issues and Alternatives," Presented at the Invitational Dissemination Workshop on Drug Product Selection Legislation, Seattle, Washington, Sept. 21-22, 1978, at 11.

29 Id. at 5.

30 See FTC Study, FTC Report Ch. VII.C.3., and Fink study of Delaware, FTC Report Ch. VII.C.2.

31 See discussion of FTC Study in FTC Report Ch. VII.C.3. An approximately equal number of pharmacists preferred no formulary as preferred a positive formulary. FDA's consultation with state agencies also failed to establish a clear preference. Higher rates of product selection, however, generally were reported in states with drug formularies States without positive formularies could experiment to see if dissemination of the FDA list of equivalent drug products to all pharmacists serves much the same function as establishment of an official statewide positive formulary.

32 See discussion of FDA premarket drug approval in FTC Report Ch. VI.A.1. FDA is in the process of removing these unapproved products from the market, but is likely to require several years to complete the process. It would be difficult, if not impossible, to identify and list all these products in a negative formulary.

33 The FDA drug list may in the future be combined with drug price information. See FTC Report Ch. VII.B.2.

34 See Letter from Patrick B. Donoho, Director of State Government Affairs, National Association of Chain Drug Stores, to Peter D. Holmes, FTC, Sept. 18, 1978.

35 See discussion of state formularies in Ch. VII.B.2.

36 See discussion of the OTC Panel's Report in FTC Report Ch. IX.E.1. Several scientists also have recommended establishment of a positive formulary by FDA. See FTC Report, id.

37 See FTC Report Ch. VI.A.1.

38 See FTC Report Ch. VI.A.4. Although the Model Act establishes a positive formulary of equivalent products, the formulary also could specifically identify those drug products FDA determines to be therapeutically inequivalent.

39 See FTC Report Ch. VI.A.5.

40 See discussion of pharmacy advertising in FTC Report Ch. IX.D.

41 See discussion of FTC study in FTC Report Ch. VII.B.4. and C.3.

42 Two surveys of pharmacists and "pharmacy leaders" found that they expected consumer demand to be an important factor in encouraging more product selection. See FTC Report Ch. VII.B.4.

43 See FTC Report Ch. VII.C.3.

44 See FTC Report Ch. VII.B.4. and Ch. IX.E.1.

45 See FTC Report Ch. IX.E.1.

46 See discussion of potential liability in CH. IX.E.

47 See FTC Report Ch. VII.C.3.

48 See, e.g., "Pharmacy and the Law," a Roerig-Pfizer film of a Dade County, Florida sumposium on Pharmacy and the Law (final script dated Aug. 11, 1977).

49 Joseph L. Fink, III, Associate Professor of Pharmacy Administration, Philadelphia College of Pharmacy and Science, Statement before the Subcommittee on Consumer Protection and Finance, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, July 27, 1978, at 6.

50 See discussion of liability provision in FTC Report Ch. VII.B.7.

51 Although the Model Act is intended to apply only to community pharmacies, a state may wish to consider whether in light of its other health laws it needs to expressly exempt hospitals, nearly all of which have their own controls on source selection, from the drug product selection law.