Members present:

Chairman Jeffrey
Assemblyman Bennet
Assemblyman Bremner
Assemblyman Chaney
Assemblyman Horn
Assemblyman Sena
Assemblyman FitzPatrick
Assemblyman Rusk
Assemblyman Tanner
Assemblyman Weise

Members excused:

Vice Chairman Robinson

Guests present: See attached list

Chairman Jeffrey called the meeting to order at 3:07 p.m. and announced the purpose of the meeting was to hear testimony on SB 7, then AB 98 and then AB 101.

SB7: Chairman Jeffrey asked that Mr. Daykin, Legislative Counsel, explain to the committee the need for deletion of the sections relating to commissioned abstractors. Mr. Daykin stated that there are currently no commissioned abstractors on record in the State of Nevada and that the work which has been done in the past by these people is now done primarily by title companies. He also stated that passage of this bill would not preclude a private individual, either for himself or for another party, to do title searches from existing court records.

Next to speak on this bill was Mr. Earl M. Hill of Hill, Cassa, DeLipkau and Erwin, attorneys of Reno. He stated that his primary law practice was in the field of mining and that the was not only speaking as an attorney servicing this type of need but also as a representative of Nevada Mining Association. He stated that although he did agree with Mr. Daykin's remarks, in general, that there was an area in the unpatented mining claims wherein applications are made to the federal govenment for mineral claims where the title companies are either unwilling or unable to do this work for the mininers or mining companies and where the abstractors do do a great deal of work, at a much lower price than would be charged to the client by an attorney doing the work. He said that he felt passage of this bill would take an economical and efficient service out of the reach of these people involed in the mining industry. Mr. Weise asked Mr. Hill if he couldn't use the services of the same people he is now working with if this bill was passed and Mr. Hill stated that the federal govenment required the reports to be submitted by a commissioned abstractor. Mr. Tanner asked Mr. Hill if the BLM would accept a report by one of these people if it were verified by the attorney and Mr. Hill stated that they would. This concluded the testimony on this bill.

AB 98: Chairman Jeffrey asked Assemblyman Coulter if he would

present this bill to the committee, as sponsor. Mr. Coulter stated that this was the third session in which he has introduced it. He stated that there had been a meeting during the day between doctor's representative, the Pharmacy Board, the drug manufacturers, the nurse's association and the AARP and that at the meeting they had been able to work out some compromises on the bill and he submitted a copy of a rough draft of those propsed changes to the secretary for the record and that is attached to and incorporated herein as Exhibit "A". He said that it was estimated that if every state went to this type of program, the consumers would save some $400,000,000.00 per year and that there are some 40 states which have now adopted some sort of generic drug bill. The then reviewed the points covered at the noon meeting with the committee and then stated that he wished Mr. Gene Knapp from the Food and Drug Administration to address the committee.

Mr. Knapp's comments were in text form and are attached hereto and made a part hereof and marked as Exhibit "B". At the conclusion of Mr. Knapp's prepared remarks Chairman Jeffrey asked if the drugs which are dispensed now are coded with a monogram for identification purposes and Mr. Knapp stated that though most of the brand-name drugs are that there are some of the generic drug substitutes which are not and that the FDA really has no authority to demand the tablets and capsules be marked. However, he noted that if said marking was a prerequisite for sale in several states that the smaller manufacturers would probably comply with marking requirements eventually. He also pointed out that the FDA list of substitutable drugs would be completely revised and issued to the pharmacies approximately every three months, but that supplements would be sent out in loose-leaf form each month. The committe then discussed with Mr. Knapp and Mr. Coulter whether or not, if the bill was passed, that there would be any way to insure that the savings in cost between brand-name and generic drugs would ultimately be passed on to the consumer. It was generally agreed that this cost savings would depend for the most part on the individual pharmacist.

Mr. Orvis E. Reil, representing NRTA-AARP, was next to address the issue and his remarks are attached and marked Exhibit "C" and incorporated herein. At the conclusion of Mr. Reil's remarks Mr. Horn asked him how he felt about the pharmacist making a larger profit margin, possibly, on the sale of the generic drugs while only decreasing the cost to the consumer by possibly two or three dollars per perscription. Mr. Reil stated that he knew of no way to keep the pharmacist from doing this type of thing, but that any savings at all to the senior citizen or other consumer would be better than it is now.

Next to speak regarding this bill was Dr. James D. Pitts who was representing Nevada State Medical Association and whose remarks are attached and incorporated herein as Exhibit "D". In response to a question from Mr. Weise, Dr. Pitts stated that he felt that pharmacists were more knowledgeable in the area

of whether or not a drug was a bioequivalent to a prescribed drug than physicians due to the fact that they are more fully and extensively trained in the area of chemical compounding. He did point out, however, that only the physicians should make the dicision whether or not a substitution should be made relative to each patient's personal history. Dr. Pitts stated that he is in favor of each of the drugs being labled for identification purposes as it helps tremendously in diagnosing problems in case of an emergency situation.

In answer to an inquiry from Mr. Sena, Dr. Pitts stated that it is the large drug companies who promote the various drugs and that they spend a great deal of money introducting and promoting these drugs to the physicians. He stated that that is partially responsible for the higher cost of the brand-name drugs and that since the doctor has been exposed to the drug by the brand-name, that he is most likely to prescribe by that name when he wants that particular drug coumpound.

Pat Gothberg of the Nevada Nurses' Association addressed the committee next on this bill. Her remarks in favor of the bill are outlined in Exhibit "E" attached to and incorporated herein and are accompanied by some proposed amendments which are included and attached as Exhibit "F". In regard to the second proposed amendment, Mr. Sena asked Ms. Gothberg if she felt the mailing of the substitution listing should also include the physicians. Ms. Gothberg turned the question over to Dr. Pitts who stated he felt most doctors would not use it if they had it, but that it would be beneficial as a reference material. He did not feel it should be a requirement for them to receive a copy. Ms. Gothberg also emphasized that she felt patients should have the right to be involved in the choice as to whether or not they wished to have generic drug substitutions.

John McSweeney, representing the Nevada Department of Human Resources, Division for Aging Services, was next to speak. He reviewed a letter from Theodore Goldberg which is attached and marked Exhibit "G". He also read from sections of a report by Michael Pertschuk of the FDA. The areas covered are indicated by markings and underlining in the text and it is attached and incorporated herein as Exhibit "H". He also submitted to the committee Exhibits "I" and "J" which have additional information regarding the implementation of this type of program.

Mr. I. J. Sandorf, representing the Advisory Committee to the Division of Aging Services, briefly addressed the committee regarding their support of this bill and pointing our that there is a catalog available for senior citizens through the NRTA/AARP, covering some 10,000,000, which already lists many national brands of non-prescription drug items compared to the generic equivalent (at a much reduced price). Addressing himself to the point brought out by Mr. Horn earlier regarding the amount of discount which will be passed along to the consumer, Mr. Sandorf stated that he felt many of the parmacists would pass a considerable amount on to the consumers and this would be very helpful.

Testifying in opposition to this bill were Mr. Floyd Butler, representing Nevada Pharmacy Association and the Nevada Pharmacists Guild, whose prepared remarks are attached as Exhibit "K" and are incorporated herein, and Mr. Richard L. Shobe of the Nevada Pahrmacists Guild whose prepared remarks are attached as Exhibit "L" and are incorporated herein. During their discussion with the committee Mr. Butler stated that he was not opposed to a "good generic drug bill", but that this bill was not what they thought to be a good bill.

Mr. Shobe stated to the committee that he felt that the increased liability to the pharmacist in the filling of these prescriptions with generic drugs was their primary concern. He stated that when a pharmacist fills a prescription with a brand-name product that they feel very secure, knowing that if anything happens and the patient has a severe reaction to the drug or if he dies, that the manufacturer will stand behind the product. After questioning in this area by Mr. FitzPatrick, Mr. Shobe agreed that if the drug substituted were on the FDA's listing, there would be very little chance of liability because of product failure.

Mr. Bremner and Mr. Chaney asked Mr. Butler and Mr. Shobe why, if they had been aware of this type of legislation for the past three sessions, they had not proposed a bill of their own which would protect the pharmacist and provide the patients with less costly alternatives. Mr. Shobe stated that they had prepared this information and it was submitted to the committee as Exhibit "M" and is attached hereto. They also submitted to the committee a letter from Boehringer Ingelheim regarding patent infringement, which is attached as Exhibit "N" and made a part hereof.

Mr. Chaney asked them also if they currently posted the prices of prescription drugs so that the patient's could look at them. Mr. Shobe stated that they do not post a sign stating the prices are available for inspection, but that the catalog is available if it is asked for. Mr. Shobe also pointed out that the costs of drugs currently is approximately 15% of the total health care costs and though they felt this type of program would help to control health care costs, he did not feel you could impose a cost control program as to generic drug price ceilings.

Upon further discussion, Chairman Jeffrey appointed a sub-committee to discuss amendments to this bill. The subcommittee will be comprised of Mr. Bremner, Mr. Tanner and Mr. Horn who will be working with Mr. Coulter.

There was a brief recess from 5:35 to 5:45 in order to allow Mrs. Hayes to be called.

AB 101: Mrs. Hayes stated that this bill was drafted at the request of one of her constituents whose letter explaining his request is attached and marked as Exhibit "O". She stated that he had a ligitiment point and that this bill would help to alleviate that problem.

Chairman Jeffrey introduced Exhibit "P" into the record which opposes this bill. A brief discussion among the committee members followed. Mr. Bremner moved to Indefinitely Postpone the bill, Mr. Horn seconded the motion and it carried the entire committee, except for Vice-Chairman Robinson, who was excused, and Mr. FitzPatrick who abstained.

Chairman Jeffrey also introduced into the record a petition regarding AB 98 in support of the legislation, and it is attached and marked Exhibit "Q" and incorporated herein.

There being no further business to come before the committee, Chairman Jeffrey adjourned the meeting at 6:05 p.m.

Respectfully submitted,

Linda D Chandler

Linda D. Chandler
Committee Secretary

ASSEMBLY COMMERCE COMMITTEE

ROLL CALL:

Hearing date: February 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 Feb. 1, 1979

PRINT

ASSEMBLY COMMERCE COMMITTEE

GUEST LIST

	NAME (Please print)	REPRESENTING (organization)	WISH TO SPEAK Yes	No.
①	FRANK DAYKIN	LCB	✓	
⑥	James D. Pitts	Nevada State Med. Ass	✓	
④	Gene Kruger	U.S. Food & Drug Administ.		Information only
⑤	Orvis E. Rail	Chairman NRTA/AARP Nevada Joint State Legislative Committee - 424 E. Long St CC	X	
⑨	I.J. Sandorf	Advisory Com. To Div. of Aging	✓	
	Fred Hillerby	Nevada Hosp Assoc		✓
③	Steve Coulter	Assemblyman		
⑧	John McSweeney	Dept. of HR/Div. for Ag. Ser.	✓	
	Bill Cozart	Nev. Assoc. of Realtors	✓	
	Nellie Laird	NRTA/AARP Joint State Leg. Committee		✓
	Claude Evans	Nevada AFL-CIO		X
	Frank Titus	Nev. State Board of Pharmacy		✓
	George Bennett	Nev. State Board of Pharmacy		
	Dorothy Pendleville	Consumer Advocate		✓
	Gerald Pendleville	Amer. Assn Retired Persons		✓
	Ed Gasson	Ciba-Geigy Pharmaceuticals		✓
	John L. Skule III	Hoffmann-La Roche, Inc		✓
	Leo T. Gray	Merck Sharp & Dohme		✓
②	Earl M. Hill	Nevada Mining Assn.	✓	
	Tom Ainsworth	KOLO - KORK - TV & Radio		✓
	Lynn M. Hibbs	Nev. Nurses Assn.		✓
⑦	Pat Gothberg	Nevada Nurses' Association	✓	
	Catherine Loughlin	Leg. Ch - Washoe Co Advisory Bd on Aging		✓
	Alice L. Smith	Nevada State Board of Aging Services		✓
	John Rose	AP		
⑩	Lloyd Gutteridge	State Pharmacy Comm'n & Pharmacy Guild	✓	
⑪	Richard L. Shobe	Nev. Pharmacists Guild	✓	

STEVE COULTER
ASSEMBLYMAN
P.O. BOX 15877
RENO, NEVADA 89507

EXHIBIT A

COMMITTEES
CHAIRMAN
ENVIRONMENT AND PUBLIC RESOURCES
MEMBER
JUDICIARY
TAXATION

Nevada Legislature

PROPOSED CHANGES TO AB98--Generic Drug Substitution

1). Amend Section 1, paragraph 3:

Each prescription will have two lines, one indicating that a substitution is permissible and the other requiring the pharmacist to "dispense as written." The physician would have to sign one line or the other.

2). Amend Section 1, paragraph 4, deleting subsections (a), (b), and (c) and insert ~~two~~ new subsections:

(a) Before a substitution is made, 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.

The name of the Manufacturer must be

~~(b) The directions for the use of the drug dispensed must be indicated on the label;~~ indicated on the prescription label.

3). Add a new section on "Oral Prescriptions."

If an oral prescription is involved, the prescriber shall instruct the pharmacist as to whether or not a generic drug may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

4). Add a new section on "Drug Product Identity."

Each drug sold must have an ~~identity~~ manufacturers or ID code mark on each Tablet or capsule. This would apply to the manufacturer.

EXHIBIT B

STATEMENT

BY

GENE KNAPP

ASSOCIATE DIRECTOR FOR DRUG MONOGRAPHS

BUREAU OF DRUGS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

BEFORE THE

NEVADA LEGISLATIVE ASSEMBLY

ASSEMBLY COMMITTEE ON COMMERCE

CARSON CITY, NEVADA

FEBRUARY 1, 1979

As a representative of the Food and Drug Administration, I am pleased to appear and testify regarding the system by which the Agency assures the quality of the drug supply that reaches the American consumer.

The Federal Food, Drug and Cosmetic Act requires that every drug manufacturer be inspected every two years. Such inspections are done primarily to determine whether the plant is operating in compliance with our Current Good Manufacturing Practice (GMP) Regulations. These regulations specify the basic standards to which a drug manufacturer must adhere, in order to control his production process. Stringent process control is essential to the manufacture of high quality drugs.

A second approach to assuring the quality of drugs is FDA's surveillance program on marketed drugs to determine their adherence to Compendial Standards or standards established in the "New Drug Applications" that FDA approves prior to product marketing. Of the thousands of human drug samples we analyze each year requiring in excess of 250,000 individual assays, we have found only a

small percentage of drug products that are not in compliance with official standards, and thus, require regulatory action. When these monitoring activities reveal problems with an entire class or type of drug, specific intensive programs are established. While some individual products do fail to meet standards, we do not have evidence of any widespread problems in meeting the standards of identity, purity and potency. Although FDA has strong enforcement measures at its disposal, such as seizures and injunctions to remove defective drugs from the marketplace, the usual means is through voluntary recalls by the manufacturer or distributor. A review of the recall lists for the past several years reveals the names of many major manufacturers as well as those that are not so well known. From this FDA is unable to conclude that there is any clear difference between large and small firms or between brand name and generic labeled drugs. There has been a highly publicized recent report on the behalf of large drug firms which purports to refute my previous statement. This I will address shortly.

As any list of recalls reveal, errors do occur and deficient products may on occasion appear on the market.

Therefore, it is important that we have a mechanism for identifying such deficient products rapidly. In 1970, the FDA established a Drug Product Problem Reporting System to accomplish this. The system relies on pharmacists in hospital and community pharmacies to report defects they encounter. To date, over 20,000 such reports on individual products have been received by the Agency. Every one of these reports has been evaluated by the Agency and about one-third result in a special inspection of the firm. The information accumulated through these reports is placed in a computerized file. This file is continually examined on such questions as whether any single firm's product is experiencing any special difficulty with a particular generic drug, or whether a specific firm is experiencing an unusually high number of problem reports for a number of its products.

The quality of our drug supply has been the subject of public debate for the past year. Agencies within the Federal government that buy drugs, such as the Defense Department and Veterans Administration, are trying to cut health care costs without sacrificing quality by purchasing lower cost generic drugs rather than higher

priced and more heavily promoted brand name versions. These agencies, as well as states that are interested in saving money, look to FDA to assure the therapeutic equivalence of drugs made by different manufacturers or marketed under different brand names.

The FDA position is not that all generic drug products can be substituted without concern. FDA's position on generic equivalence is quite simple: we have confidence in all multisource drugs that have gone through our drug approval process and pose no bioequivalence issue. These constitute by far the vast majority of drugs prescribed in this country. As you have probably recently heard, the FDA has developed for the first time, a list of drugs that have passed through our approval process and that are therapeutically equivalent. FDA believes that this list can be used by states, health professionals or consumers who want to save money on health care costs and still be assured of getting quality products. This list has already been submitted to the Nevada State Department of Human Resources, and the State Board of Pharmacy.

During the debate over the generic drug issue, which has been stimulated to a major degree by those with a financial stake in it, there has been much misinformation that may be causing some confusion in the public's mind. For example, one point which is often raised concerns the fact that for drugs which first came on the market between 1938 and 1962 some generic brands have been approved through full New Drug Applications (NDA's) based on a determination of safety and efficacy data, whereas other products are approved through a different type of application called Abbreviated New Drug Applications (ANDA's). On this point, the Agency advises that there is no scientific or medical reason to require generic drug firms to reprove the safety and efficacy of an active ingredient and dosage form which is already firmly established. Rather the approach is to require that generic products be shown in the ANDA to be equivalent to generic products previously approved under a pre-1962 full New Drug Application (NDA).

For this class of generic drug products that were initially introduced on the market between 1938-1962 which are the subject of both NDA's and ANDA's, the standards of

quality and requirements imposed on ANDA application holders are as high and as stringent as those imposed on full NDA's holders for the same generic drugs. One reason for this is that the majority of these products involve full NDA's approved over sixteen years ago, so that new methodology and tests often have not been imposed as a requirement of marketing. On the other hand, because the ANDA was not introduced as a mechanism of drug product approval until the 1970's, additional requirements involving modern instrumental techniques and stringent new special tests (e.g., dissolution tests) have often been imposed.

Concerning the issue of drug equivalence, the bioequivalence of drug products is, of course, of special interest and importance. The term "drug bioinequivalence" is applied to a situation where different brands of a drug involving the same active ingredient, dosage form, and amount of active ingredient produce different sera levels of active ingredient in the body when administered under identical conditions. A significant difference in one brand as compared to another can affect therapeutic performance. Fortunately, there are a limited number of

active ingredients with dosage forms which present actual or potential bioequivalence problems. We use the term "actual" bioequivalence problems to describe bioinequivalence situations identified by studies on volunteer subjects or on patients, or through scientifically documented clinical failures on patients. By studying those active ingredients and dosage forms presenting actual documented bioequivalence problems we have been able to identify factors and characteristics which are common to drugs presenting such problems. We have evaluated other active ingredients and dosage forms to determine which of these possess the apparent combination of factors and characteristics that might cause a bioequivalence problem. Those active ingredients and dosage forms selected on the basis of this evaluation are referred to as presenting "potential" bioequivalence problems. The point I am making here is that because drug products which present potential as well as actual bioequivalence issues are not substitutable in the Agency view, is evidence of our extra effort to remove questionable drugs from consideration for that use. However, even "bioequivalence problem" drugs may be

substituted where the firm has demonstrated the bioequivalence of their product, and this has been done in many instances.

Over the last few months, there has been a highly publicized report issued by a major drug manufacturer indicating that its own evaluation of FDA recall records showed a difference between products made by so-called "research-intensive" firms and those made by the remainder of the companies. The firm has sought a fair measure of publicity for its study, and as a result we have undertaken a thorough analysis of it.

This study has numerous methodological defects. It divides the pharmaceutical industry into two separate categories: "research-intensive" firms and "other" firms. The authors do not state that criteria by which this distinction was made. When analyzing the study, FDA asked an internationally recognized expert on the pharmaceutical industry, to make a similar division, and his list of research-intensive and other firms differs significantly from the corporate authors.

In analyzing the recall data used in the study, FDA discovered that the authors had included recalls that has nothing to do with drug quality and even recalls that did not involve drug products. The study also included recalls of products that would not even be evaluated by FDA as therapeutic equivalents. This last error, in particular, renders the study irrelevant to the issue of the quality of drug products that might be substituted for brand name products. The study included all prescription drug products in its universe for study irrespective of their approval status. FDA would consider only those FDA-approved prescription drug products that are evaluated as therapeutically equivalent.

Within this universe, FDA has no reason to believe that any meaningful quality differences exist among the approved drug products.

To illustrate this, one can look at the FDA data on recalls of prescription drug products in 1977. Of the 94 recalls involving product defects likely to have adverse health consequences, 74 involved drug products that did not have approved new drug applications and therefore

wouldn't even be eligible for evaluation as therapeutic equivalents. Of the remaining 20, a total of 17 were recalls of products that FDA proposes not to evaluate as therapeutically equivalent. Thus, only three recalls in 1977 related to products that FDA would list as being therapeutic equivalents.

In short, we believe the study does not provide any justification for questioning our basic confidence in this nation's drug supply.

The American consumer can be assured that our drug supply is of the highest quality in the world and that drugs will do what they are supposed to in the human body. The 20 more serious recalls on approved drug products I just mentioned resulted from about $4.3 billion wholesale sales volume.

This is not to say that the present system by which drug quality, as well as safety and effectiveness, are assured cannot be improved. The present drug system has served this country very well for the past 40 years, however at this point in time it is to some extent antiquated. On

this basis, the Administration has introduced into Congress legislation that would completely overhaul the drug regulatory system for the first time in 40 years. That legislation is known as the Drug Regulation Reform Act of 1978. Unfortunately, it did not pass last year, but it will be considered again by Congress this year.

Now I would be pleased to answer any questions you have either about my presentation or areas of specific interest to your Committee.

EXHIBIT C

NATIONAL RETIRED TEACHERS ASSOCIATION

AMERICAN ASSOCIATION OF RETIRED PERSONS

NEVADA JOINT STATE LEGISLATIVE COMMITTEE

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TESTIMONY PRESENTED TO THE
ASSEMBLY COMMITTEE ON COMMERCE
Room 240

January 31, 1979 - 3:00 p.m.

A.B. 98 (S.B. 137)

by

Orvis Reil, Chairman
NRTA/AARP
Nevada Joint State Legislative Committee

EXHIBIT C

NRTA-AARP STATEMENT IN SUPPORT OF
STATE GENERIC DRUG SUSTITUTION LAW

Mr Chairman, my name is ORVIS E. REIL and I am the Chairman of the NRTA-AARP Nevada Joint State Legislative Committee. Our two Associations of older Americans have over 40,000 national members in Nevada.

Commomly called generic drug sustitutionlaws are now in effect in 40 states, the District of Columbia and Puerto Rico.

The primary aim of these laws is to stimulate price competition among drug manufacturers and by so doing, to lower prescription costs to all patients. The American consumer has been paying the highest prescription drug prices in the world. Those hardest hit are the elderly who comprise less than 11 percent of the population but purchase one out of every four prescriptions. Expenditures for drugs and drug sundries now represent the second highest out- of- pocket health care expenditure for older Americans. The reasons for this are only a limited number of those over 65 years of age carry private insurance with prescription drug coverage and that Medicare pays for prescription drugs only when the beneficiary is institutionalized in a hospital or skilled nursing facility and intermediate care facilities.

Being old means a person on the average will spend three times more for medication than when he or she was younger. If the older person is chronically ill, as over 40 percent of them are, and has income below the near poverty level classification, as one-fourth of them do, he or she can be spending as much as 10 percent to 45 percent of his or her limited income on prescription drugs, as our Associations learned from a survey of our membership.

What is basically wrong in this country's drug delivery system is that the large drug companies have managed over the years to assume almost total control over their economic envirnment. By this we mean they have in large part been able to prevent real and effective price competition. How do they do so?

First, following discovery of a new drug entity, the innovator firm receives a 17-year exclusive patent right to the drug product. In some cases where the drug rights are envolved in legal action this time can be over a geater period of time. This monopolistic position enables the company to set the price of the

drug product at whatever the traffic will bear.

Prices of brand name drugs usually remain high even after patent expiration because doctors continue to write prescriptions (nearly nine times out of ten) using brand names. And they remain high despite the fact that research and development costs of the new drug are recouped and the company realizes a profit within the first three years of marketing, according to the U.S. Department of Health, Education and Welfare's Task Force on Prescription Drugs.

Second, the major drug companies expend about $1 billion annually on directing advertising, promotion, free samples and detailmen (salesmen) into hospitals, physicians' offices and pharmacies to "educate" health professionals in the importance of prescribing and dispensing only their brand name products.

Third, the major drug firms, in concert with organized medicine and pharmacy during the 1950s were able to convince the states to enact antisubstitution laws and regulations which prevented pharmacists from dispensing any manufacturer' drug product but the one written by its brand name on the physicaian's prescription.

The publicly stated reason for the need for antisubstitution laws was the increasing appearance at that time of "counterfeit" drugs in the marketplace. However, the antisubstitution laws did little to eliminate counterfeit drugs. That was accomplished by the added authority given the Food and Drug Administration by the Kefauver-Harris drug law amendments, finally passed over the vigorous opposition of the pharmaceutical industry. Since those amendments become law in 1962, the FDA has removed some 7,000 ineffective drug products from the market.

We believe the antisubstitution laws have been much more successful in protecting the big drug companies' excessive profits than in protecting patients health. The real consequence of these statutes has been to help shut out any significant competition by generic drug manufacturers, even to this day.

Our Associations do not believe that it as been coincidental that the past 20 some years of antisubstituion laws have also been the period of greatest profit for the large drug manufacturers.

The typical response of the Pharmaceutical Manufacturers Association is that higher profits are necessary for heavy expenditures in research and development. The facts belie that argument. A generous estimate of the drug industry's annual research and development expenditure is about six percent of sales-- mostly development rather than research, and much less than the industry spends on marketing.

Another common excuse of the big drug companies for excessive brand name drug prices and profits is their better quality. No such correlation between higher prices and better quality is either apparent or substantiated.

The plain fact of the matter is that what American consumers are really paying for in higher priced brand name drugs are advertising, promotion, free samples, and excessive profits. Generic substitution laws will simply permit pharmacists and consumers the right to select lower priced equivalent drug products whenever the physician does not insist upon the medical necessity of a paticular manufacturer's product.

Not one of the 40 st te substitution laws interferes with the professional prescribing prerogative of physicians or dentists. Prescribers retain full control over their patient's drug therapy by their right to prohibit sustutution whenever they have a medical reason for doing so.

The following are provisions of a Prescription Drug Selection Law that should be avoided.

1. Any formulary that is tied to HEW's maximum allowable cost (MAC) program.
2. Requiring a formulary with no deadline for the publication of the formulary.
3. Requiring pharmacist to inform doctor of substitution.
4. Requiring pharmacist to obtain prior written consent of patient for substitution.
5. Requiring pharmacist to inform patients of all options for filling prescriptions.
6. Requiring pharmacist to label prescription with both the name of the drug prescribed and the name of the drug dispensed.
7. Requiring patient to request substitution.

EXHIBIT C

8. Permitting prescription forms with preprinted statement, "Dispense as written," or similar words.

9. Allowing doctor to check or initial preprinted statement, "Dispense As Written" or similar words on prescription order.

10. Requiring doctor to sign prescription order on one of the two preprinted lines stating "Substitution Permitted" and Dispense As Written."

11 Requiring physician to write all prescriptions by generic name is unworkable.

I have a copy of a report "ARE GENERICS SAFE?" prepared by the New York State Assembly's Office of Legislative Oversight and Analysis for the First National Conference on Generic Drugs, held at the Mayflower Hotel in Washington, D.C., June 23-24, 1978. I was fortunate enough to have attended that Conference. Although they were invited no one to my knowlwedge attended as representatives of the large drug manufacturers. In the report are 17 pages, double spaced, of a hearing. "WHEN DR. MARVIN SEIFE TESTIFIED UNDER OATH BEFORE THE N.Y. ASSEMBLY'S COMMITTEE ON CONSUMER AFFAIRS AND PROTECTION, HE REMOVED ALL DOUBT THAT GENERICS APPROVED BY THE FDA COULD BE SAFELY SOLD IN NEW YORK STATE. The hearing was held 10:00 A.M. May 31, 1977. The seventeen pages are interesting reading and could answer numerous questions that might come up in a persons mind when anayzing the questions related to the Generic Drug Substitution Laws. I did not make copies of the 17 pages because my service as a representative of the two Associations are not payed for and i do not have a fund to pay for the cost of reproducing the pages. I can make the report available if some one can get them reproduced, and so desires.

A.B. 98 that this hearing is considering contains some of the features we desire to have in a Generic Substitution Law, however, the law would be much stronger and more workable if the text was amended to read as that found in Senate Bill 137; with four minor changes in the text as found in Senate Bill 137.

The four changes are remove the wording "and the board of medical examiners" from lines 20 and 21 on page 2; the wording " and the board of medical exaniners" from lines 30 and 31 on page 2; the words "and the board of medical examiners" from line 36

EXHIBIT C

on page 2; and on line 50 of page 2, change the word "PHYSICIAN" to PHARMACIST.

The text of SENATE BILL 137 contains provisions that have been selected by reviewing the Substitution Laws in the 40 States that now do have such laws. These provisions have proven workable in the various states.

The following is results found in several of the States that now have Substitution Laws.

(From a statement of Fred Wegner, Legislative Representative of NRTA/AARP before Indiana Legislature July 26, 1978)

"The earliest returns on savings are showing up in state medicad programs,

where they are most easily documented. Medi- Cal -- the California Medicaid program -- estimated a $5 million savings two years ago. Florida Medicaid recently estimated $2.4 million savings and the Jack Echerd Drug Store Chain claimed to have saved its patients over $1 million in a year's time. A recent survey in Michigan found actual savings to consumers of about $300,000 while placing potential savings at $18 million.

"A recent 130-pharmacy survey in Delaware of 12 frequently prescribed drugs found that the prices of ten of the drugs did not increase during the study period in contrast with a 7.04 percent increase in the Consumer Price Index. For seven of the drugs stuied, significant savings of from three cents to 13 cents per unit were revealed.

(From a paper "COST IMPLICATIONS OF DRUG PRODUCT SELECTION LEGISLATION" by THEODORE GOLDBERG, Ph.D., presented at the Invitational Dissemination Work shop on Drug Product Selection Legislation, Detroit, Michigan, April 13 an14, 1978. The workshop was co-sponsored by the National Center for Health Servicess Research, Department of H.E.W. and and the Drug Study Project Group of the Department of Community Medicine, Wayne State University School of Medicine, Detroit Michigan.)

"For the first year after the Michigan law became effective, there was approximately a 21 percent savings (or $1.14 savings per prescription) when substitution occured. The second year's savings were remarkably close being approximately 29 percent or $1.15 per prescription. The corresponding figures for Wisconsin for six months of the latter year (which wa the first six months of allowable substitution in Wisconsin) was $.87 a prescription, or 17 percent."

(From a letter of April 1975 sent by Fred Wegner, Legislative Representative of NRTA/AARP to Mr. J. Maternik in Trenton, New Jersey)

"Your physician may believe that in the best interest of your health he must prescribe a brand name drug because drug salesmen spend much time and money in perpetuating the myth that brand names are synonymous with quality and that generic drugs are of inferior quality. Or he may believe he is protecting you by assuring you that the drug he presribed is one produced by a "reliable" manufacturer.

If so, his opinion seems to be based on erroneous or misleading information.

EXHIBIT C

For, as you probably know, after a firm's 17-year drug patent has expired, other firms have the right to produce that drug, according to the same chemical specifications, upon approval of its safety and efficacy by the Food and Drug Administrtion. Then strange circumstances begin to take place in the pharmaceutical wonderland, perhaps unknown to your physician, but not to your pharmacist. Drug manufacturers trade brand names; they change product formulas without changing the brand names, the identical drug produced by one manfaturer is sold under different brand names and even its generic name, and a manufacturer's brand name drug might be produced by another manufacturer. In light of these circumstances, does your physician really know which firm produced the brand name drug he presribed?

"The American Pharmaceutical Association (APhA), national professional organization of pharmacists, makes a convincing case that, except when a prescriber specifically writes "no substitution" on a prescription order, the pharmacist, as the health professional with the greatest knowledge of pharmacology, should select the drug product to be dispensed, utilizing as one criterion the relative costs of chemically equivalent drugs. APhA is supported in that position by a unanimous resolution of the Drug Research Board of the National Academy of Sciences/National Research Council, a highly respected group of scientific and pharmacological expert that includes three representative of drug manufacturers.

"The fact that our Associations' concur with the conclusions of these leaders of U.S. pharmacology is evident by one of our 1975 State Legislative Guidelines: "We urge states to repeal antisubstitution laws and regulations and to permit drug product selection by pharmacists as a means to more economical drug dispensing."

" The savings from generic dispensing has been recognized by the federal government as well. The U.S. Department of Health, Education and Welfare (HEW) will soon make final its regulatory proposals that federal drug programs will begin reimbursing providers ony for "the lowest cost drug widely and consistently available in the U.S." in cases where a drug is available from more than one manufacturer, unless the physician presents a proper medical reason for insisting upon a particular

brand name product. In implementing the program, HEW is currently developing guidelines and controls to assure that chemically equivalent drugs have equal bioavailability and therapeutic value within an acceptable range."

"It is ironic that some American doctors insist upon the drug product of a particular manufacturer for office patients, yet relinquish that firm stance for their hospital patients. In nearly 94% of U.S. hospitals, the Chief Pharmacist always or usually has the authority to select the manufacturer of drug products used by patients in that hospital, a power granted him by the Pharmacy and Thera peutics Committee which includes physicians among their members.

"No other country in the world enjoys drug products of higher quality, safety and effectiveness than does our own. For this, we are indebted to the Food and Drug Administration and the pharmaccutical manufacturers. And the citizens of no other country in the world are burdened by higher prescription drug prices than our own. For ths, they are indepted to the pharmaccutical manufacturers alone."

(From a letter sent by Fred Wegner, NRTA/AARP Legislative Reprentative to the other seven Legislative Represent_tives of NRTA/AARP)

"Attached is a case study by a Michigan pharmacist showing the savings to patients and the economies to the pharmaciests from generic substitution.

"Average savings to patients per prescription: $2.09."

EXHIBIT D

Testimony of Dr. James D. Pitts:

Good afternoon gentlemen of the Commerce Committee. I am Dr. James D. Pitts, representing the NSMA to testify on AB 98.

First I would like to state that the NSMA is in full agreement with the intent of AB 98, that is, we feel that the best possible Medical Care should be available at the least expense to the patient.

I hope that with this testimony, I will be able to give you some insight into the whole spectrum of generic prescriptions, so that any bill passed doesn't just seem like a good idea at the time, but reaches the goal intended.

As many physicians, my background in pharmacology in medical school was primarily utilizing the chemical or generic names. I continue to write some prescriptions in this manner.

My first encounter with a break down in this system, was while serving as a physicial in Viet Nam. The government let contracts for generic Tetracycline. The lowest bid came from some firm in Italy. The only problem came when the pills were taken. They came out as they went in, without any absorbtion. We called them "Klinkers", after the sound they made when they fell into one-half of 55 gallon drums we used for toilets.

This one example points out one of the great pitfalls in generic drugs. That is bioequivalency. You could crush the pills up and test them in a laboratory and, yes, they were Tetracycline, but, they did not cause a serum level at all because when taken they did not dissolve.

How many patients were harmed prior to this discovery will never be known. The government didn't ever probably realize that the money it "saved" really increased the cost, because, not only did they buy the "cheap" medications, but we ended up using substitute medications to treat the disease. Plus, an immeasurable amount of lost time for those GI's with Ameobiases who did not respond to the "Klinkers".

So my first point is that it may seem like a good idea to pass a generic drug bill and Mr. Calafonto is pushing for such a bill now, but please realize that the citizens of Nevada may not benefit, if a good system of checks is not placed along with the legislation. A system of checks costs money as will the bureaucracy so formed cost more than the money saved in the first place.

I don't know gentlemen, I'm a physician, not an accountant, you'll have to decide that. Might we not be better off educating the prescribing physicians to true bioequivalent generic drugs as they have primarily the patient's welfare in mind when treating them.

Thank you.

EXHIBIT E

Nevada Nurses' Association

3660 Baker Lane Reno, Nevada 89509 (702) 825-3555

FEBRUARY 1, 1979

ASSEMBLY COMMITTEE ON COMMERCE - AB 98, "GENERIC DRUG BILL"

CONTACT PERSON: PAT GOTHBERG, NNA EXECUTIVE DIRECTOR

The Nevada Nurses' Association supports legislation providing for drug product selection. As proposals are made to this session of the Legislature, we would like to contribute suggestions about those things which we feel are essential to a good workable bill.

1. The entire concept of drug product selection is based upon the assumption that the generic drug is exactly the same as the brand name drug that it replaces. A good bill will contain provisions for a formulary, either positive or negative. This list should be approved by the FDA.

2. Again, using the given assumption that the generic drug is the same as the brand name drug that it replaces, we believe that the consumer is the one person who should make the decision. This element is extremely important to our members. Futhermore, the person most qualified to assist the consumer in his decision is the pharmacist as he is the most familiar with all kinds of available drugs.

3. Drug product selection legislation is only effective if there is a guarantee of savings to the consumer. We would ask that the committee look at possibilities of insuring that the savings be passed on to the consumer. How will this be enforced? We would suggest that one solution might be a requirement that notice be posted at the pharmacy.

AB 98 appears to be a workable bill and we would urge your favorable consideration and action along with possible changes which would place the decision with the consumer and which would provide some sort of enforcement of the cost savings being passed on to the consumer.

EXHIBIT F

Nevada Nurses' Association

3660 Baker Lane Reno, Nevada 89509 (702) 825-3555

PROPOSED AMENDMENTS TO AB 98

1. Delete lines 8, 9, 10 and 11 and replace with:

designated. The pharmacist who dispenses a drug pursuant to this section assumes the same responsibility for dispensing that drug as would be incurred in filling a prescription for a drug prescribed by its generic name.

2. Add to the end of line 14:

The state board of pharmacy shall mail to the pharmacist in charge of each pharmacy the formulary, upon adoption, on or before January 1, 1980.

3. Insert a new section after the above:

Each pharmacy shall prominently display at or near the place where prescriptions are dispensed the following information in block letters not less than 1 inch in height:

> STATE LAW ALLOWS A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG TO BE SUBSTITUTED FOR A DRUG DESIGNATED BY A TRADE OR BRAND NAME UNLESS YOUR PHYSICIAN REQUESTS OTHERWISE. CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG FOR YOUR USE.

4. Delete line 15 on page 1 and lines 1 and 2 on page 2 and replace with:

The patient may request the pharmacist to dispense a generic drug which has the same active chemical ingredients as a prescribed brand or trade name drug unless the prescriber writes "medically necessary" on the prescription.

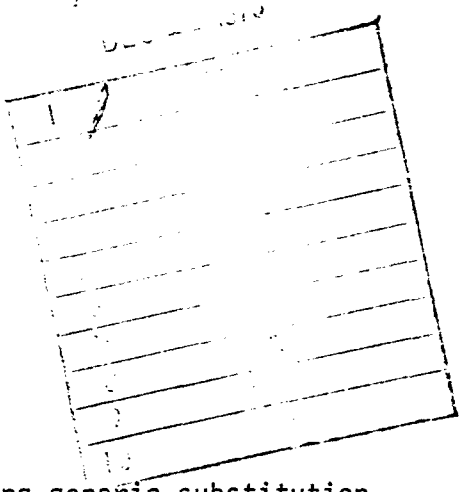
EXHIBIT G

WAYNE STATE UNIVERSITY

SCHOOL OF MEDICINE

GORDON H. SCOTT HALL
OF BASIC MEDICAL SCIENCES
540 EAST CANFIELD AVENUE
DETROIT, MICHIGAN 48201

December 8, 1978



Mr. John B. McSweeney, Administrator
Division of Aging Services
Department of Human Resources
State of Nevada
Kinkead Building, Room 101
505 East King Street
Capital Complex
Carson City, Nevada 89710

Dear Mr. McSweeney:

Your letter, with the enclosure of the Act regarding generic substitution, arrived in my office on December 1st. I have attempted to review its provisions as quickly as possible and to respond to you without delay.

The following comments are intended to raise questions which, in light of our experiences, require further considerations, since the subjects to which they are directed will have important consequences for the achievement of the desired goals of the legislation.

Sec. 2. I would suggest the following language for this section:

> "'Generically equivalent drugs' are drug products having the same active chemical ingredients, finished dosage form and strength."

Sec. 3.1. I would suggest that you use the term "drug product" rather than "drug." As a matter of fact, this suggestion applies throughout the document. Secondly, this section as currently written applies only to prescriptions that are written by brand name. It overlooks the 20 percent of multiple-source prescriptions which are written generically. Therefore, I would suggest an additional clause, probably Sec. 3.3., which would be along the lines of the Wisconsin law, and would say:

> "If a drug is prescribed generically, the prescriptions shall be filled with one of its drug product equivalents having a cost not higher than the average wholesale cost of all of its drug product equivalents."

Sec. 4.2. Should be revised to insert the word "product" after drug in two places.

Sec. 5. This is a very important section in that it deals with the issue of who gets the savings and how they are to be determined. There are several questions that arise about this section:

1. One problem is that the "price" (that is, the retail price) of the generically equivalent substitute may not reflect the lower "cost" (that is, the ingredient cost) of the generic substitute. Thus, unless the Act is specific about how savings are to be calculated, it's possible that the "full savings," whatever that term means in the Act, may not be passed on to the consumer.

   To illustrate: Product "A," which was the one written for in the prescription, may have an ingredient acquisition cost to the pharmacist of $10.00, a mark-up of $5.00, and, thus, a retail selling price of $15.00.

   When the prescription is presented to the pharmacist, he/she, under the provision of the Act, would be required to dispense a product of lower price, but the price can be any amount lower. Thus a pharmacist may dispense Product B, for which the acquisition cost may have been $5.00 but the final selling price may have been established at $13.00. Thus the price of Product B was below that of Product A (by $2.00) which would accrue to the purchaser. But the difference in acquisition costs was $5.00 ($10.00 for Product A and $5.00 for Product B) which could have been passed on to the consumer. If this is what the Act had contemplated and anticipated, then the language of this section would have to be clarified. Language that would require passing on the full difference in the acquisition costs of the two products would be along the lines of the following:

   > "If a pharmacist dispenses a generically equivalent drug product, the pharmacist shall pass on the savings in cost to the consumer. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products."

2. A second problem in this section is what is meant by the term "purchaser." Does it mean the person for whom the prescription is written or the person who pays for the prescription? If the latter, does it mean the patient as well as a third-party payor? If it is meant to apply to third-party payors, as it seems to be, then the language should be changed to reflect

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this (possibly by adding the words "or to whomever pays on his behalf" parenthetically after the term "purchaser" in two places in this section). It should be recognized, however, that the passing on of savings to a third-party payor may reduce the incentive for the purchaser to request, or accept, lower-priced generically equivalent products.

Sec. 6. I assume that there is a state requirement that a record of all prescriptions must be maintained for a minimum three year period. Thus, this section would impose no additional work. What I think this section means is that when a substitution takes place, it must be recorded on the prescription order which in turn must be maintained for a three year period. The language could be as follows:

> "The pharmacist shall note on the original prescription that a different source of the drug entity was dispensed than the one prescribed by showing on the face of the prescription the name of the drug product, or labeler's name for the drug product, dispensed. These prescriptions should be maintained as prescribed by law for all prescriptions."

Sec. 7. This section is another of the most important ones in the Act and involves a number of issues which require clarification.

1. Each pharmacy is required to establish its own individual "positive formulary" which "matches each drug designated by a trade or brand name with all drugs generically equivalent to it." This seems to imply that each pharmacy is required to develop a "positive formulary" of all drug products not included in the "negative formulary" established in accordance with section 8. But, if this is the case, why wouldn't it be simpler to adopt a statewide "positive formulary" which would be adopted by each of the state's pharmacies? (This wouldn't mean that each pharmacy would have to stock all products included in the Formulary, but that substitution could only occur among products included in the Formulary.) The language of the Act could clearly indicate that the pharmacist would have to fill a prescription with a less expensive generically equivalent drug product, among those "stocked in his pharmacy."

If a single statewide Formulary was adopted, then the language of section 7, "The pharmacy may use any source it deems reliable in compiling the formulary." would be unnecessary. If the individual pharmacy formulary is maintained, then this language

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regarding the individual discretion given to pharmacists in adopting their formularies could result in some pharmacies having very limited formularies, if any at all.

In addition, no mention is made of a requirement for pharmacies to file their formularies with the state. Such a provision would be a prerequisite to any intended monitoring of drug product selection legislation.

This is one of the most important sections of the Act and requires a good deal of consideration.

Sec. 8. The intent of this section is clear and the only problem that I see is in its implementation. On what basis does the state board of pharmacy and the board of medical examiners determine that drugs (products) have "been demonstrated clinically not to be biologically or therapeutically equivalent?" I suspect that the law needs to be more specific in directing the state boards. For example, reference could be made to reports published by the F.D.A. as the basis for a determination.

Subsection 3 of section 8 seems fine except that the "negative formulary" should be required to be reviewed periodically. Thus, perhaps this subsection could have the phrase "but not less frequently than every six months." added to it.

This approach may also avoid a possible problem with subsection 4 whereby a complaintant would have the burden of establishing that the state boards had erred in incorrectly listing a product, or drug entity, in the negative formulary. Establishing an objective source for this determination may avoid wide-scale complaints.

Sec. 10. The notice to be posted should add the word "PRODUCT" following each use of the term "DRUG."

Sec. 11. Does the term "standard of care" mean that a pharmacist incurs no greater legal liability when practicing drug product selection than when filling a generically written prescription? If so, why not say that more directly, in language along the following lines:

> "The liability of a [pharmacist] in substituting according to this Act shall be no greater than that which is incurred in the filling of a generically written prescription."

EXHIBIT 6

Sec. 12. This wording would imply greater protection for the prescriber when a substitution takes place than if the prescription was dispensed as written. Why not apply the same approach as is suggested in section 11, which would say simply that no greater liability is incurred in the case of substitution than would have been incurred had the prescription been written generically and the pharmacist had chosen a product to be dispensed.

Two other suggestions that I would make for your consideration are:

1. A provision allowing the state board of pharmacy to review how and to what extent the state's pharmacies are implementing the provision of this Act. The board of pharmacy would be allowed to survey pharmacies to determine the pricing of drug products, which products were being dispensed, and which products were being used in filling generically written prescriptions.

2. A provision requiring the state board of pharmacy to report annually to the legislature on the amount of savings resulting from the operation of the drug substitution legislation. Language for thisprovision could be along the following lines:

> "The department of ( ) shall have the duty of monitoring the cost savings effected by substitutions, and shall issue rules and regulations to effect such monitoring, and shall annually report to the legislative as to cost savings being achieved as well as potential cost savings."

I hope these comments prove to be helpful. If I can be of further assistance by meeting with you in Nevada or by providing other detailed suggestions in writing, just let me know.

Yours sincerely,

Ted

Theodore Goldberg
Professor and Chairman
Department of Community Medicine

TG/mio

EXHIBIT H

STATEMENT OF

MICHAEL PERTSCHUK

CHAIRMAN

FEDERAL TRADE COMMISSION

BEFORE THE

SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

ON H.R. 1963

THE GENERIC DRUG SUBSTITUTION ACT

July 27, 1978

Mr. Chairman, members of the Subcommittee, I am pleased to have this opportunity to discuss the deregulation of generic drug substitution. Consumers have an enormous stake in this issue, and for that reason the Federal Trade Commission has taken an active interest in it.

Within the next few months, our Bureau of Consumer Protection will release a staff report presenting the results of its nearly two-year investigation of generic drug substitution. The staff is working closely with its counterparts in the Food and Drug Administration and the Department of Health, Education and Welfare. In addition to collecting and analyzing published articles, dissertations and surveys, the staff has solicited comments and supporting documentation from representatives of brand-name and generic manufacturers, consumers, pharmacists and physicians. Consultants were hired to estimate the economic impact of substitution laws, and an independent market-research firm conducted a multistate survey of pharmacists' attitudes and behavior to determine the types of provisions that can most effectively encourage pharmacists to substitute low-cost generics. As a result of this investigation, we hope to develop for the states a model substitution law--one that will succeed in bringing prices down.

Although the staff report is not yet completed, we have learned a great deal about both the problem of

substitution--or lack of substitution, to be more precise--and the pros and cons of various solutions to it. First, let me say a few words about the problem.

Consumers spent over $8 billion for prescription drugs in 1977, and the figure will undoubtedly be up in 1978. 1/ A considerable portion of this expenditure--amounting to hundreds of millions of dollars 2/--could be saved if the market fostered the purchase of the lowest-cost equivalent drugs. Unfortunately, as you know, the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay.

Generically equivalent drugs are frequently sold at grossly disparate prices. 3/ Yet it has been demonstrated that physicians often have little knowledge of drug prices. One recent study showed that of 144 physicians responding to a survey, 32% said they had "no idea" of the prices of prescription drugs. 4/ And when the same physicians were asked to rank themselves as to their degree of knowledge of drug prices on a scale of 1 (very informed) to 5 (uninformed), 64% assessed themselves at a 4 or 5.

The reason is simple: there is little incentive for a physician to shop around for the least expensive drug products. First, patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. Indeed, probably only a small percentage of patients currently know enough about comparative drug prices or the availability of less expensive generic equivalents to ask the doctor to prescribe low-cost generic drugs. Second, it is time-consuming, and therefore costly, for physicians to acquire comparative price information.

Drug manufacturers are aware that they would not gain physician loyalty on the basis of price competition. Instead, they spend millions of dollars promoting their brand name products. A 1977 Federal Trade Commission staff report notes that, in 1970, 30 of the largest marketers of prescription drugs spent $682 million on drug promotion, an amount representing 21% of the firms' total sales in the United States or an outlay of more than $2400 per practicing physician. 5/ Not surprisingly, physicians as a group tend to prescribe by these heavily-promoted, easily-remembered brand names: nearly 90 percent of all new prescriptions are written by the brand name of the drug. 6/ The FTC staff report revealed further that physicians

demonstrated a strong preference for the brands that were the first of their kind to enter the market, and were persuaded to prescribe late-entering brands only if they offered some specific therapeutic gain. 7/ The report states,

> Physicians' preferences for a relatively small number of trademarked, brand-name drugs are probably rational responses to the proliferation of trademarked drugs in the industry as a whole. For just one dosage strength of one generic chemical, 20 mg. PETN, the physician faces a bewildering array of alternatives. In 1971, 61 firms offered PETN, 32 under a brand name. To weigh the quality and price alternatives presented by such an array of drugs would involve a notable feat of research and memory. As one pharmacologist has noted, doctors are human beings, not computers 8/

While pharmacists are no less human, they have the capacity to be more efficient in selecting drug products. First, of course, the pharmacist is aware of price differences. Moreover, the pharmacist is intensively trained in drug pharmacology, and is considered technically qualified to dispense generic drug products safely. 9/ Indeed, pharmacists have long been allowed to select drug sources for generically written prescriptions. Yet in some states antisubstitution laws prevent the pharmacist from using his or her expertise to select a less expensive equivalent product to fill a brand-name prescription.

One way to promote price competition, then, would be enactment of less restrictive state laws. About 40 states do now permit some form of pharmacist

selection. The state laws, however, vary greatly in their potential effectiveness; indeed, as I will explain in a few moments, some "substitution" laws impose so many burdens and restrictions on the substituting pharmacist that substitution simply does not take place.

Nevertheless, the most sensible role for the federal government at this stage may not be enactment of preemptive legislation. Because the states are currently in a period of transition--some are beginning to seek actively to make their substitution laws effective--it may be more appropriate to continue to monitor closely the impact of the various state laws, and reserve judgment as to whether federal intervention is warranted. As I mentioned earlier, our staff is currently analyzing the state laws and attempting to determine which approaches work best to encourage pharmacists to substitute low-cost generics. Our report will be finished and made public this fall, but we intend to continue our scrutiny of competition in the prescription drug market as the various state laws make their mark.

Furthermore, there is a serious drawback to enacting federal legislation before we have definitive evidence that it is needed: the difficulty and cost of federal enforcement. An attempt by the FTC--or, probably, any federal agency--to police every sale of a prescription drug would undoubtedly be burdensome.

A better approach, at this stage, would be to observe and evaluate the states' efforts to enforce their laws through the pharmaceutical regulatory bodies and mechanisms already at their disposal.

We do, however, have some specific comments about H.R. 1963, the bill now before the Subcommittee. This bill contains what we believe, based on our studies to date, to be some of the most essential features of a good substitution law. At the same time, we recommend that certain revisions be made, if a determination is made that legislation should be enacted by Congress at this time.

H.R. 1963 permits, rather than requires, substitution of a lower-priced generic drug for a drug prescribed by brand name. That is a wise approach. A pharmacist who is allowed to substitute lower-cost drugs has an economic incentive to substitute and to pass on cost savings to consumers in order to compete with other pharmacists for the consumer dollar. And competition at the retail level is likely to be enhanced by the recently recognized right of pharmacists to advertise drug prices. 10/ If pharmacist substitution does occur, the manufacturers selling higher-priced drugs to the pharmacists will be motivated to lower their prices in order to compete with the substitutes. Thus, competition at these two levels of drug distribution will produce lower prices for consumers.

In short, this is an instance where, according to information available at this time, the market is likely to work well enough by itself that a regulatory mandate is not required.

For the same reason, the best approach to substitution would not attempt to force pharmacists to pass on to consumers all cost savings. H.R. 1963 does not attempt to do this. In those states that have mandatory pass-ons, the pharmacist cannot profit by so much as a penny for costs incurred in using his or her skills to search for, stock and dispense lower-cost generics. Rather than encourage competition, then, mandatory pass-ons provide an economic disincentive for substitution by the pharmacist. A good substitution program should allow the pharmacist to bill at his or her usual retail price for a lower cost generic equivalent, since the marketplace should work to ensure that pharmacists pass on to consumers a healthy portion of the cost savings. Only if the market fails should more restrictive actions be considered.

While H.R. 1963 does not have a mandatory pass-on, it permits a pharmacist to select only the lowest cost product in stock, whether the drug was prescribed by brand name (section 2(a)(1)(B)) or by established name (section (2)(b)(1)). This restriction is probably neither necessary nor workable. It is unnecessary because, as I have outlined, the market is likely to accomplish

the same end unassisted. It is not workable because, first, the pharmacist could technically comply by pricing the least expensive product in stock only 1¢ below the brand name drug prescribed. Second, a pharmacist who did not wish to be forced to sell the substitute at the price of the least expensive drug in inventory could refuse to stock the lowest-cost products at all--so that the effect would be to raise overall retail drug prices. Indeed, with respect to generically-written prescriptions, there is evidence that this type of restriction on the pharmacist does not save consumers money. One study showed that greater savings have been generated in Michigan, which has no such provision, than in Wisconsin, which does have one. 11/

Moreover, to determine whether a violation of the lowest-price-in-stock provision has occurred, the Commission would need to ascertain the various prices of drugs in a pharmacist's inventory at the time a particular substitution took place. This determination might be impossible; it would certainly be costly. Especially in light of this enforcement problem, it makes more sense to test the forces of competition in an unfettered market before authorizing or mandating substitution of only the lowest-priced drug in stock. We therefore recommend that H.R. 1963 be revised to permit pharmacist substitution of any lower-cost equivalent drug product.

A sound approach to substitution also must retain physician control over what drug product the patient buys. H.R. 1963, like current state substitution laws, gives the physician who wishes to prescribe a brand-name drug for a specific medical purpose absolute authority to do so. However, a good substitution law must ensure that the physician who directs that a prescription be filled by a brand-name drug is doing so deliberately, by requiring simply that the physician take a second or two to handwrite "medically necessary." (That is the phrase already used in HEW's Maximum Allowable Cost program.) If the physician fails to take this action, the pharmacist can substitute a generic equivalent. In those states that have repealed anti-substitution laws, the "medically necessary" legend is rarely added, although prescriptions are still frequently written in brand-name language. 12/ So we recommend that H.R. 1963 explicitly require the doctor to write "medically necessary" if he or she wishes to prevent substitution for medical reasons.

Another key element of a workable approach to generic substitution is the adoption of a "positive formulary," a list of generic drug products that are safe, effective and therapeutically equivalent to the brand-name products. (A "negative formulary," a list of nonsubstitutable drug products, might serve the same purpose, but of those pharmacists responding to our

survey who favored a formulary, most preferred the positive formulary approach.) As you know, the FDA is working to develop a positive formulary and has endorsed New York's list. Such lists help the pharmacist, who is the most logical person to search out the lower cost substitutes, to choose safely. And through vigorous FDA enforcement of quality control, the pharmacist can be confident of the continuing reliability of these lists. Thus, we recommend that H.R. 1963 define a "substitute drug" as one which is deemed equivalent by the FDA formulary.

We note that H.R. 1963 includes a provision preempting state law: section 4 of the bill provides that a state may not establish or enforce a law or practice which prohibits a pharmacist from taking an action authorized or required by section 2. It is not clear to us whether a state law would be in violation if, while posing as a "substitution" law, it imposes requirements so burdensome that pharmacists are deterred from engaging in product selection. For example, some state laws include extensive requirements as to the manner in which a pharmacist must notify the patient that substitution has occurred, inform the patient of the exact price savings, and in some cases obtain the patient's affirmative consent. Other laws require that the pharmacist notify the physician by telephone or in writing each time a substitute is dispensed. Some

of these requirements may serve legitimate state interests, but they also may frustrate substitution. If any overly burdensome provisions are to be preempted by federal legislation, the bill may have to address them specifically.

Finally, with respect to pharmacist liability: our study shows that pharmacists are very concerned about what they perceive to be the increased risk of lawsuits arising from the substitution of generic equivalents, and that this fear often deters them from substituting as often as they would do otherwise. In addition, some brand-name manufacturers appear to be magnifying this fear through dissemination of scare stories, so-called "educational" seminars, and so on.

To the best of our knowledge, and according to every brand-name manufacturer and trade association we have contacted, not one lawsuit has been filed against a pharmacist for legally substituting a lower-cost generic drug product or for selecting the source of a generically written prescription. Neither are the major pharmacy insurers we contacted aware of any insurance claims filed. Although the pharmacist may be selecting drug sources more often, the nature of his or her activity remains the same--pharmacists have for years filled generically written prescriptions without incident. Therefore, we see no basis for the exaggerated claims being presented about liability, and we think it

is imperative that pharmacists receive objective information about potential liability, and about the type of protection afforded by the insurance policies of the pharmaceutical manufacturers and by the pharmacists' own policies.

This brings me to my closing point. A substitution law, even one which embodies all of the features we have identified as essential, will only be effective if it is accompanied by adequate educational programs. Pharmacists must be provided with the facts about liability and with comparative source information. Physicians must be assured that they retain absolute authority to insist upon a particular drug source when they think it medically necessary. And consumers must be informed about the availability of generic drugs and the savings they make possible. Federal programs to support these educational efforts could help to ensure that a substitution law, at the state or federal level, will work.

At the FTC, we will continue to monitor carefully the success of substitution, and stand ready to take whatever action is necessary to ensure the health of price competition in the prescription drug market.

Thank you. I will be glad to answer any questions.

Goldberg, supra. In Ontario, "No Substitution" is indicated on less than 1% of prescriptions. Allan E. Dyer, "Implementation and Implications of Applying Drug Product Selection to Selected Populations," presented at Invitational Dissemination Workshop on Drug Product Selection, Detroit, Michigan, April 13, 1978. The FTC pharmacist survey shows similar results.

Moreover, it has been demonstrated that if preprinted prescription blanks requiring the physician to sign one of two lines--"D.A.W." or "Substitution Permitted"--are used, doctors preclude product selection in most cases. In Delaware, 62.1% of prescriptions were signed on the "D.A.W." line. Fink and Myers, "Effectiveness of Drug Product Selection Legislation in Delaware," adapted from presentation to the American Pharmaceutical Assn., Montreal, Canada, May 17, 1978. A New York Board of Pharmacy survey showed 74% of the preprinted forms were signed on the "D.A.W." line. N.Y. Times, June 2, 1978 at B6. The FTC survey shows similar results.

FOOTNOTES

1 / Pharmacy Times, April 1978, p. 41. The figure increased by 13% between 1976 and 1977, according to pharmaceutical industry figures.

2 / Our Bureau of Economics staff estimates the potential savings for 60 popular multisource drugs at $341 million.

3 / For example, HEW recently found that wholesale prices for 100 capsules of generic drug ampicillin in 250 mg doses varied from $6.00 to $18.74. Address by James T. Doliuso, "A Perspective of Bioavailability/Bioequivalence," 23rd National Meeting of APLA Academy of Pharmaceutical Sciences, Phoenix, Arizona (Nov. 14, 1977). Similar disparities exist for other drugs. See, e.g., Vol. 2, Wisconsin Drug Formulary (Feb. 1977).

4 / Presentation by Joseph L. Fink, III and Daniel J. Kerrigan, "Physicians' Knowledge of Drug Prices," 23rd National Meeting of APLA Academy of Pharmaceutical Sciences, Phoenix, Arizona (Nov. 14, 1977).

5 / Bond and Lean, "Sales, Promotion, and Product Differentiation in two Prescription Drug Markets," a Bureau of Economics Staff Report to the Federal Trade Commission, Feb. 1977, p. 1. Some more recent trade estimates have put total pharmaceutical advertising and promotion outlays at $1 billion for 1977. Advertising Age, Feb. 13, 1978, p. 68.

6 / Bond and Lean, supra, p. 76; see also Pharmacy Times, April 1977, p. 38.

7 / Bond and Lean, supra.

8 / Bond and Lean, supra.

9 / Goldberg, et al., "Evaluation of Impact of Drug Substitution Legislation," Vol. NS16, No. 2, Journal of the American Pharmaceutical Ass'n. (1976).

10/ See, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

11/ Theodore Goldberg, "Cost Implications of Drug Product Selection Legislation," presented at Invitational Dissemination Workshop on Drug Product Selection Legislation, Detroit, Michigan, April 13-14, 1978.

12/ In Michigan, "D.A.W." (Dispense as Written) was written on 6.4% of prescriptions in the first year of product selection, and decreased to 4.0% the second year. Similarly, it was indicated only 3.6% of the time in Wisconsin. It was applied as frequently to single- source prescriptions as to multisource. Theodore

EXHIBIT I

SELECTED CHARACTERISTICS OF DRUG PRODUCT SELECTION LEGISLATION IN FIVE WESTERN STATES*

prepared by W.M. Dickson for the Invitational Dissemination Workshop on Drug Product Selection Legislation, Seattle, Washington, September 21-22, 1978.

*Taken from a compilation by the Drug Product Selection Legislation Study Group, Department of Community Medicine, School of Medicine, Wayne State University, Detroit, Michigan 48201.

	Arizona	California	Colorado	Oregon	Washington
10) PRESCRIBER LIABILITY					
Specifically Exempt	X	X		X	X
No Specific Provision			X		
11) DPS CRITERIA					
Bioavailability and Therapeutic Equivalence	X				
Therapeutic Equivalence		X	X	X	X
12) PERIODIC REPORTS ON SAVINGS TO GOVERNMENT AGENCY					
Report Required					
Not Required	X	X	X	X	X

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	Arizona	California	Colorado	Oregon	Washington
1) FORMULARY					
Positive	X				
Negative		X			X
None			X	X	
2) FORMULARY DEVELOPMENT					
State guidelines	X	X	N/A	N/A	
Federal guidelines					X
3) PRESCRIBER OPTION					
DAW/NS		X	X	X	
Signature Lines	X				X
4) SELECTED OPTIONS					
Mandatory Substitution					
Extra Labeling	X	X	X	X	
Extra Records			X		X
Must Inform Prescriber					
Must inform Patient	X	X	X	X	X
5) SAVINGS DISPOSITION	N/A				
Pass to Consumer		X	X	X	X
Pass to Third Party		X			
Pass to Social Asst. Agency		X			
6) SAVINGS CALCULATION					
Based on Retail Price				X	
Based on Wholesale Cost		X			X
Method Not Mentioned	X		X		
7) GENERIC PRESCRIPTIONS				(lowest retail)	
Specific Provisions				X	
No Provision	X	X	X		X
8) POSTING REQUIRED					
To 100 Drugs		X			
DPS Availability Notice				X	X
Not Required	X		X		
9) PHARMACIST LIABILITY					
Liability Not Greater than Generic RX	X		X	X	
Protected by Positive Formulary					
Both of the Above		X			
No Specification					X

EXHIBIT J

COST IMPLICATIONS OF DRUG PRODUCT SELECTION LEGISLATION*

BY

THEODORE GOLDBERG, Ph.D.**

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* Presented at the Invitational Dissemination Workshop on Drug Product Selection Legislation, Seattle, Washington, September 21-22, 1978.

** Professor and Chairman, Department of Community Medicine, Wayne State University School of Medicine, and Principle Investigator, Evaluation of Impact of Drug Substitution Legislation Study, Wayne State University.

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EXHIBIT J

Invitational Dissemination Workshop
on Drug Product Selection Legislation
Seattle, Washington - September 21-22, 1978

COST IMPLICATIONS OF DRUG PRODUCT SELECTION LEGISLATION

Theodore Goldberg, Ph.D.

The primary objective of the close to forty laws currently enacted which deal with the subject of drug product selection (sometimes called generic drug substitution laws) is to save money. It also is undoubtedly true that there were, and are, many other particular interests involved in encouraging and supporting the passage of the various state laws. Pharmacists wanted greater professional responsibilities and recognition. Consumers wanted greater participation in the control of health care costs.

But the most basic, underlying motive for the enactment of the legislation was the desire to find ways to contain the ever-escallating costs of health care -- in other words, to save money.

As a matter of fact, some state laws even go so far as to require that a responsible state agency report to the legislation each year on the extent to which savings have actually occurred. The state of Illinois, for example, requires that:

> "The Department of Public Health shall have the duty of monitoring the cost savings affected by substitution and shall issue rules and regulations to affect such monitoring, and shall annually report to the legislature as to cost savings being achieved."

Neither Michigan nor Wisconsin requires that there be an annual accounting of the economic impact of the drug product selection laws. However, the current study of the impact of the legislation in those

states considers the question of cost implications to be a key element in the impact of the legislation. Thus, we have not overlooked this area which we know is of crucial importance to legislators and researchers alike.

The potential for cost savings as a result of drug product selection, or product substitution, exists whenever two condition are met:

1. First, two or more products must be available for the particular drug entity prescribed; and

2. Second, the price of the alternative product must be lower than the price of the product prescribed.

While these may sound like very simple and easily met conditions, it is important that we keep in mind the meanings of the terms used such as drug entity, drug product, generic equivalent, and the like, and to appreciate their implications.

It is important to understand these distinctions because the first requirement to achieve savings from drug product selection is that there exist multiple source drug entitites -- the greater the number of prescriptions for multiple source drug entities, the greater the potential for savings.

But meeting these two conditions does not mean that there will necessarily result in cost savings. Having multiple source products of varying prices is essential for cost savings, but it is not sufficient. Before savings can occur a number of other conditions must be met. The first of these is that the prescribing physician must not forbid

substitution by requiring the pharmacist to "dispense as written" the drug product prescribed. The next, and perhaps most crucial condition to be met, is that when offered the opportunity to substitute, the pharmacist will in fact choose to dispense a generically equivalent product which is less costly than the one which has been prescribed.

The final condition necessary to achieve savings is that the less costly product dispensed must be acceptable to the patient.

Each of these conditions not only influences whether drug product selection is possible, but the extent to which each of these conditions exists or is exercised determines the degree to which savings result.

Our study has looked at each of these factors in considerable depth in both the states of Michigan and Wisconsin. We now have possibly the most extensive data available anywhere to answer the questions of what the potential is for savings from drug product selection legislation as well as to estimate the actual extent of savings which have occurred as the direct result of the introduction of the legislation. What is perhaps most important, we now have the data to discuss reasons for the gap between actual and potential savings, whether that gap is narrowing, and what factors impact on widening or narrowing the gap.

The data upon which we base our conclusions were derived from a stratified probability sample of about 31,000 prescriptions in the State of Michigan for the year immediately prior to and 33,000 and 22,000 in each of the two years following the implementation of the

legislation in Michigan. A comparable data base was developed in Wisconsin with a slightly smaller sample of 25,000 prescriptions in the first and second years, and 18,000 in the third year of the study. These numbers are the sample sizes for the completely recorded sample, and do not include additional scanned prescriptions, which constitute approximately an additional half a million prescriptions per year in each of the states.

Thus, we have generated and have computerized a data base from which to analyze and answer questions related to drug product selections covering a three-year period and containing completely recorded information regarding over 154,000 prescriptions. We believe this is the largest, most carefully compiled and most useful data set available anywhere in this country. Most important, however, is the fact that this data has allowed calculations to be made on actual prescribing and dispensing information, not merely on the basis of some arbitrary schedule of prices which may or may not accurately reflect what is actually charged.

We now are in a position to analyze the process described above and to answer questions about the effectiveness of drug product selection legislation to date. The specific questions which flow from the description of the process by which savings ensue from drug product selection legislation are as follows:

1. What proportion of prescriptions fall into the category of "multiple source drug entities?" The answer to this question determines the perimeter of the area in which product selection can be effective.

2. Is there a significant differential in the prices of products within the same drug entity? The answer to this question determines whether there is the potential for significant savings to be achieved even if the number of multiple source drug entities is large.

3. Based on the answers to questions 1 and 2, what is the range of potential savings from drug product selection, assuming a number of possible alternatives, such as substitution of the lowest priced generically equivalent product; or substitution of the median priced product, or various other alternatives?

4. To what extent is the option to substitute foreclosed by the actions of prescribers in requiring the pharmacist to dispense the specific product which was identified in the prescriptions? The answer to this question will disclose the extent and degree of restriction imposed upon the dispensing pharmacist and thus will identify the area in which the pharmacists may exercise discretion.

5. To what extent do pharmacists actually exercise the option to select less costly products within the scope of prescriptions for multiple source entities and for prescriptions which do not contain any prohibition? A subsidiary question relates to the

choice of products selected when substitution does occur. The answer to these questions produces the final answer to the question of the extent of actual savings and allows a determination to be made of the size of the gap between potential and actual savings.

6. Is there a change over time of any of the following conditions: The proportion of prescriptions for multiple source drug entities; the price range of products within drug entities; the proportion of prescriptions which are written generically; the extent to which physicians require that drugs be "dispensed as written"; the rate of drug product selection exercised by pharmacists?

I am sure that there are many other questions which could be asked; some even for which we have the data to answer. But the questions listed here are the ones which we believe most directly affect the process of drug substitution and thus the resulting savings impact. I am sure that our subsequent discussion will indicate the extent to which the questions we raised are the relevant and significant ones.

Now to answer the questions that were raised:

There are a very substantial number of entities for which there are two or more generically equivalent products. In each of the years studied the proportion of multiple source drugs was over 51% in Michigan and 52% in Wisconsin. Thus, the answer to the first question of whether there are enough prescriptions for multiple source entities to provide the opportunity for savings from drug product selection -- the answer is definitely and emphatically yes.

Knowing that many products exist from which choices can be made is one thing. Knowing whether there are price variations among the products which could result in savings is quite another./

The fact of the matter is that there is a substantial variation of the prices of products within many entities. Our analysis looked at the difference in prices between the drug product actually prescribed and the price of the drug product actually dispensed. Thus, our estimates show the minimum amount of savings. There may very well have been lower priced products which could have been dispensed in substitution for the product prescribed. However, we calculated the prices of the products actually dispensed. But, we have the data which would allow further analysis to determine whether any additional savings could have occurred if a less costly product had been dispensed instead of the one actually selected.

For the first year after the Michigan law became effective, there was approximately a 21 percent savings (or $1.14 savings per prescription) when substitution occurred. The second year's savings were remarkably close being approximately 20 percent or $1.15 per prescription. The corresponding figures for Wisconsin for six months of the latter year (which was the first six months of allowable substitution in Wisconsin) was $.87 a prescription, or 17 percent.

Savings from substituting a lower priced generically equivalent drug product for a higher priced prescribed one within the same drug entity is directly attributable to the introduction of the drug product selection legislation.

But an important and related issue is the question of price differential, or price savings, as a result of drug product selection which has been practiced for years before the recent acts became effective and which has never really been thought of as drug product selection -- that is, what happens when prescriptions are written generically. In these cases -- and our findings that between 20 and 25% of prescriptions are written generically is much more than had previously been thought -- a choice has to be made by the pharmacist as to which product to dispense. Thus in more than one out of five of all prescriptions for drug entities in which there is more than one product, pharmacists must make a choice among two or more products to be dispensed. The importance of this practice to cost savings is in terms of the choice of the product to be dispensed -- is it the most expensive, the average priced or the lowest priced, of products which could be dispensed? Whichever the choice, will have a substantial impact on drug costs, particularly since we now know that generically written prescriptions account for a very substantial proportion of all multiple-source entity prescriptions.

Interestingly enough, the Michigan law is silent when it comes to generically written prescriptions. The Michigan law states that:

> "When a pharmacist receives a prescription for a brand name drug product...." (emphasis added) and then procedes to define what is to happen, totally ignoring the cases of generic prescribing."

The Wisconsin law, on the other hand, directly deals with the issue of generic prescribing by requiring that:

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"If a drug product listed in the formulary is prescribed generically, the prescription should be filled with one of its drug product equivalents having a cost not higher than the average wholesale cost of all its drug product equivalents."

The key issue, though, is how the price of the product actually dispensed compares with the average price of products within the same drug entity, any one of which legally could have been dispensed in filling the prescription.

Our results provide very satisfying evidence to demonstrate that pharmacists filling generically written prescriptions do, in fact, choose products whose price is below the median price and thus are lower priced than would be the case of a prescription in the same drug entity which was dispensed as written. However, the difference in price between the price of the product dispensed and the average price of the products in that drug entity is not as great as the difference between the price of the drug dispensed and the price of the drug prescribed, when substitution takes place.

The comparisons in Michigan are: $.65 "saved" per prescription for generically written prescriptions during the first year compared to $1.14 actual savings when substitution was involved. Comparable figures for the second year in Michigan are $.68 "saved" and $1.15 actually saved by substitution. This means that while lower than median priced drug products are dispensed when prescriptions are written generically, this does not result in as great a savings as when the process of

substitution is actually involved and a drug product different from the one specifically prescribed is dispensed.

The pattern of savings from generic prescribing also prevails in Wisconsin. The cost of the products selected to fill generically written prescriptions is below the average price of drug products within the same drug entity. However, an interesting finding is that the amount of difference in the price of products dispensed and the average price of products within that entity was much smaller in Wisconsin than in Michigan. For the first six months of the Wisconsin legislation, $.14 was "saved" in dispensing generic prescriptions compared to $.74 for the corresponding year in Michigan.

The two conditions necessary to achieve savings from drug product selection obviously are present to the extent that the potentials for savings not only exists but is substantial.

The next question to be asked is what possible barriers exist to achieving the maximum potential savings.

One possible impediment to achieving potential savings is if prescribers frequently exercized their option to require the pharmacist to dispense the specific product ordered in the prescription. Such a restriction would only be meaningful for multiple source prescriptions. An order to "dispense as written" for a single source product would have little meaning since there would only be the one product which could be dispensed.

Both in Michigan and Wisconsin, as in almost all other jurisdictions, physicians specifically retain the right to order that

the specified drug be dispensed as written (or some other terminology having the same effective meaning). And yet the option to exercise their restraint is practiced very infrequently. Whether or not this comes as a surprise reflects one's preconceived notions. But the facts are that in the first year of the operation of the legislation in Michigan only 6.4 percent of prescriptions bore the handwritten order that the prescription be dispensed as written and the following year the proportion had dropped to 4.0 percent. (As an aside, it's interesting to note that the requirement that the prescription be "dispensed as written" was applied just as frequently to single source prescriptions for which no substitution was possible, let alone whether it was advisable, and even to generically written prescriptions which in no way could be "dispensed as written.")

The experience in Wisconsin followed the same general pattern with 3.6 percent of the prescriptions requiring that there be "no substitution" during the one year in which the legislation was effective.

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Based on the foregoing process of analysis it is possible to now calculate the potentials for savings from drug product selection. In other words, the information we now have allows us to project accurately and precisely the area of possible savings and to measure the projection of actual savings against the potential.

In order to calculate the savings from substitution, as well as the potential savings from substitution, it is necessary to know the price of the product dispensed as well as the price that would have been

charged if the product that was prescribed had been dispensed. When a substitution takes place, however, only the price of the dispensed product is known. Therefore, a method had to be designed which would allow an estimate of the price of the prescribed product to be made.

The comparison thus would be between the actually known price of the product dispensed and the price of a comparable, randomly selected prescription that was dispensed as written. If each substitution is matched with another prescription which was dispensed as written randomly sampled from a group similar to the substituted prescription, then the average price differences can be computed for all the resulting matched pairs to obtain an estimate of the average savings due to substitution.

This technique requires that the "matched" prescription must be reasonably comparable to the substituted prescription. Three characteristics have been identified as important for comparability. The "matched" prescription should be from the same time period, it should be for approximately the same quantity, and it should be from the same pharmacy or from a pharmacy with similar characteristics. (Any of these matching characteristics could be relaxed, or other criteria could be introduced. However, any such criteria affect only the strength of the statistical test for a difference in prices; the validity of the text flows from the random selection of the substituted or generically written prescriptions, and their matches).

The question of whether the prices of dispensed and prescribed products differ when substitution takes place, can be answered by matching each actually substituted prescription with a

comparable prescription for the same product that was dispensed as written and then comparing the prices of the matched pairs.

To answer the question of whether the price of the product dispensed was lower than the average price of all products within that entity, it is necessary to match each actually substituted prescription with a randomly selected comparable prescription for any product within that entity, and then compare the prices of the two.

A third important question relates to the price of the products that are selected in filling generically written prescriptions. This can be examined by matching each generically written prescription with a randomly selected comparable prescription for any product within that entity, and then comparing the prices of the two.

Comparisons have been made to answer all three of these questions. This was done in two different ways: First, by matching prescriptions within the dispensing pharmacy where such matches could be found, and second, by matching substituted prescriptions with those which had been "dispensed as written" in any pharmacy in the sample.

The latter method yields the largest number of matched prescriptions and thus the method we used for our calculations. Tables A, B, and C show the prices and their differences, using this method and the t-tests of the hypotheses that the differences are zero. (Comparison of these prices with those found by matching within pharmacies showed no meaningful differences between the two methods.)

The results displayed in the tables show that a statistically significant price reduction was obtained by substitution. The price of

TABLE A

Prices of Substituted vs Non-Substituted Prescriptions,
Michigan Years 2 & 3 (First Two Years of Allowable Substitution),
Comparing Similar Prescribed Products

	Number of Matched Prescriptions	Average Price of Dispensed Product	Average Price of Matched Prescriptions	Average Price Difference	Standard Deviation of the Difference	Paired t-Statistic
Year 2	463	$4.37	$5.51	$-1.14	2.41	-9.92*
Year 3	521	4.72	5.87	-1.15	2.54	-10.34*

*Significant at P< .00005

TABLE B

Prices of Substituted vs Non-Substituted Prescriptions,
Michigan Years 2 & 3 (First Two Years of Allowable Substitution),
Comparing Prescriptions Within Entity Classes

	Number of Matched Prescriptions	Average Price of Dispensed Product	Average Price of Matched Prescriptions	Average Price Difference	Standard Deviation of the Difference	Paired t-Statistic
Year 2	565	$4.56	$5.49	$-.92	2.21	-9.94*
Year 3	653	4.79	5.75	-.96	2.46	-9.93*

*Significant at P< .00005

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TABLE C

Prices of Generically Prescribed Entities Compared to
Prices of Products Within That Same Entity,
Michigan Years 1, 2, & 3

	Number of Matched Prescriptions	Average Price of Dispensed Product	Average Price of Matched Prescriptions	Average Price Difference	Standard Deviation of the Difference	Paired t-Statistic
Year 1	708	$3.83	$4.43	$-.60	1.97	8.05*
Year 2	615	3.90	4.53	-.64	2.05	7.65*
Year 3	404	4.07	4.81	-.74	2.25	

* Significant at P< .00005

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the substituted item also was significantly below the average price for all drug products dispensed for the same entity. The average price reduction for a matched substitution pair within the state was $1.14 (or 21%). This shows that substantial savings were realized by substitution.

The price of the substituted product dispensed was $.92 (17%) less than the price of other products within the same entity for matched pairs within the state. This shows that pharmacists do dispense lower priced products (i.e., products in the lower half of the price range for the entity) when substituting one product for another.

For generically written prescriptions, the price of the product dispensed was $.64 (14%) and $.72 (15%) less than the price of prescriptions for all products within the same entity, dispensed in the state during three years. This demonstrates that when filling a generically written prescription pharmacists dispense a product in the lower half of the price range for products in that entity. Savings incurred when prescriptions are written generically, however, were not as great as the savings resulting from substitution.

To calculate the potential savings from substitution reliable estimates of the following information is required:

1. The total number of prescriptions dispensed during the year.
2. The proportion of this number which involve multiple source drugs.
3. The average savings if substitution was exercised.

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The calculation would thus utilize the following formula:

Total Potential Savings = No. of Substitutable Prescriptions x Estimate of Average Savings

The estimate of the number of prescriptions dispensed in Michigan during the year ranges between 26 and 34 million. If the proportion of these which involve multiple source drugs is approximately 51 percent, this means that the prescriptions which are susceptible to drug product selection are between 13.3 and 17.3 million prescriptions per year.

Our findings indicate the approximately 20 percent of these prescriptions for multiple source drug entities are written generically and even though these may be influenced by drug product selection legislation, for our present purposes these generically written prescriptions will be considered separately.

If we further reduce the number of the pool of prescriptions for which potential savings are possible by the proportion of them for which the prescriber forbids substitution, then the total must be reduced by a further 4 percent (the current rate of D.A.W.'s).

The final range thus becomes between 10.2 and 13.3 million prescriptions per year.

The average savings from substitution amounts to approximately $1.15 per prescription or a total potential annual savings in Michigan of between $11,730,000 and $15,295,000. If to this were added the savings from dispensing lower priced products when filling generically written prescriptions, then the total potential annual savings would amount to between $13,538,800 and $17,647,800. This, of course, is just

for Michigan. Comparable data could be developed for each of the other states, whether or not drug product selection law exist.

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But just because savings, and very substantial savings at that, are potentially available does not mean that they necessarily will be realized. The final element in the process which must be satisfied before potential savings become actual savings is that substitution must occur or that prescriptions must be written generically and filled with "lower" cost products. The potential for savings may be substantial but may never be realized if the actual process of substitution does not occur.

The experience in Michigan does not provide the basis for any degree of confidence that the potential for savings is being realized to anywhere near the extent which is possible. Nor does the evidence indicate that the trend toward achieving a greater degree of the potential is increasing at anything other than a snailspace even though admittedly the legislation has only been in operation for three years which is a relatively short period on which to base projections.

All the evidence we have gathered and received, and which we have already summarized in this report, seems to indicate that pharmacists have a substantial, largely unkindered, opportunity to choose among generically equivalent products. Reports by the professional association of Michigan pharmacists seem to indicate that pharmacists look forward to the opportunity to exercise their professional judgment in selecting a less costly product to dispense

when given the opportunity. In fact, a recent survey conducted by the Michigan Pharmacists Association of Michigan pharmacists indicated that:

> "Fifty-five percent of community pharmacists responding to a membership opinion survey . . . report that they practice drug product selection 'frequently' or 'whenever possible.'"

But, despite these indications that the process of drug product selection should be occurring frequently, and thus generating substantial savings for consumers, the facts do not support this conclusion.

During the first year of the operation of the legislation in Michigan, only 1.49% of all prescriptions for multiple-source entities (.67% of all prescription orders written) were actually substituted. During the second year of the legislation only 1.50% of all prescriptions for multiple-source entities were substituted. Thus, during this first two-year period, not only was there little use of the opportunity to substitute but there is no indication that the rate of substitution increased very rapidly, if at all.

One reason given for the low rate of substitution in Michigan was that the original act required a "purchaser request" before the pharmacist could exercise his/her option to select a product to dispense different from the one prescribed. There was considerable controversy over the meaning of this requirement, which was argued as being ambiguous at best, but the issue was brought to a head by a declaration of the State's Attorney General who found that the language of the act clearly required the prior request of the purchaser before the pharmacist could

exercise any option. As a result of this decision, a campaign was waged to amend the legislation in order to allow pharmacists the option to initiate the process of drug product selection. This was accomplished by an amendment, which became effective on January 11, 1977, and eliminated the requirement that ". . . . the purchaser request . . . ." The amended version of the law states: "When a pharmacist received a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not a higher cost generically equivalent drug product . . ."

We have attempted to measure the effect of removing the requirement for the purchaser's request on the rate of substitution. During the period covered by the data collected for the second year there were only four months when the amended law applied. Thus, it may be too early to measure the impact of removing this condition. Nevertheless, we applied what is known as a "time series" analysis to the data to see whether any difference occurred at or after the point in time when the amendment became effective. Our analysis failed to indicate any effect on the rate of substitution other than that which could be explained by the very slight increase in the rate of substitution over time.

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What we have tried to do in this paper is to present the picture of the potential impact of drug product selection legislation and to compare it with the actual record of performance. Obviously there is

a wide gap between the two. However, it would be both inaccurate and misleading not to acknowledge the extent of savings which has resulted from the operation of this legislation.

Based on the range of estimates of the volume of prescribing in Michigan as being between 26 and 34 million prescriptions per year, applying the difference in prices actually found between the prescribed and dispensed products and applying the actual rate of substitution experienced in Michigan, we calculate that the actual reduction in the cost of prescribed drugs, as the result of drug product selection, falls somewhere within the range of $200,000 and $300,000 a year

We don't suggest that this amount of savings isn't significant. It is and should be acknowledged to be. However, when one compares this amount to the amount of potential savings, which we have calcualted to be between 16 and 21 million dollars a year in Michigan, one is left with the uneasy feeling that time alone may not achieve the desired goals. However, I should tell you that while we have not yet completed our collection and analysis of data from our third field survey, which will provide us with a fourth year of data from which to project trends, our very sketchy and preliminary observation of the data as they are coming in seems to indicate that there is a very substantial increase in the extent of drug product substitution, our impression being that it may even be as high as 10 to 15 percent of multiple source entity prescriptions. If this impression is confirmed when we analyze the complete data, then it may be that the low rate of drug product selection during the first couple of years may be only a temporary phenomenon until the provisions of the law become better known. We certainly will make this analysis available as soon as it is completed.

On the other hand, if we continue to observe substantial and continuing and only very slowly diminishing gap between actual and potential savings

resulting from the low rate of utilization of the opportunities afforded by the legislation, it may be necessary to consider changes in the legislation which would encourage greater utilization of the process of drug product selection in order to assure that its potential benefits are to be realized. Encouragement probably can take many forms. The two most obvious ones can be characterized as incentives or directives. The legislation can build in greater incentives for pharmacists to exercise the option to dispense less costly products more frequently, or the legislation can build in provisions that pharmacists are required to dispense in conformity with certain conditions specified in the legislation. There are examples of variations and combinations of both these approaches which could be considered.

As examples of provisions which would provide greater incentives for pharmacists to practice drug product selection would be the following:

1. By providing legal protection against additional liability for practicing drug product selection.

2. By minimizing in every way the difference in administrative requirements between practicing drug product selection and not practicing it:

   (a) Reduce extra labeling, recordkeeping, and receipt provision requirements to a minimum, when drug product selection occurs. It would seem appropriate (when not specifically forbidden by the prescriber) to label the product dispensed with its generic name, and the name of the manufacturer (or distributor).

   (b) Any dispenser of drug products to the public must meet all requirements of drug product selection as does a dispensing pharmacist.

(c) A non-pharmacist can be the individual who informs the purchaser that drug product selection can occur, as well as the options available.

3. By assuring the pharmacist that he will not stand to lose financially from exercising drug product selection. In fact, the legislation should provide the incentive to share in the savings so as to encourage the practice of drug product selection. The dispenser should not be expected to financially underwrite any aspect of drug product selection, and any increase in work associated with drug product selection should have the work's associated cost paid by the person (or third-party payor) for whom the service is provided.

Examples of possible regulatory provisions are much more difficult to find, but two fairly recent illustrations come to mind. The first is of the PAR COST program in Ontario which establishes maximum reimbursable costs for the drug entities contained within the PAR COST Manual. This provincial government program applies mainly to prescription drugs dispensed to persons covered for benefits under the provincial welfare program or programs for the elderly, but the agreements to participate in the program extend to most retail pharmacists in the province.

The other example of a regulatory program is the Maximum Allowable Cost ("MAC") program operating at both the federal and state levels in the United States. The significance of these programs is that they provide a schedule of maximum payments to pharmacists for specifically identified drug entities dispensed under programs covered by the MAC regulations. The federal

MAC program has identified a number of multiple source drug entities for which it will pay a maximum ingredient cost plus dispensing fee when a product within this entity is dispensed. The incentive is thus for the pharmacists to dispense a product within the entity which has a cost at or below the limit paid by the MAC program.

The state MAC programs are similar to the federal program except that they also include maximum reimbursable costs for single source as well as multiple source drug entities.

A summary of the main conclusions of this paper could be briefly stated as follows:

1. Over half of all prescriptions written are for entities within which there are choices of products which may be dispensed.

2. There are substantial differences in prices of drug products within drug entity categories.

3. Prescribers do not to any significant extent, exercise their option to deny substitutions.

4. The potential for savings from drug product selection is very substantial.

5. The achievement of the potential, up to the present time, has been very modest.

6. Efforts to reduce the gap between actual and potential savings will require social policy (political) decisions.

EXHIBIT K

Mr. Chairman, I am Floyd Butler representing the Nevada Pharmacy Ass ., and the Nev. Pharmacy Guild.... I have been a Pharmacist for 25 years. I am the Chief Pharmacist, Sahara Rancho Pharmacy, Las Vegas, Nevada.

I would like to go on record that we are not Opposed to the concept of Drug Product Selection, or as it is also called, Generic Substitution. The fact that we are not opposed perhaps indicates that we are half-way there.....

What I would like to do, Mr. Chairman, is to address subjectively A.B. 98, Any comment that I should make in regard to A.B. 98 is not intended as a reflection on the credibility of any of its co-signers.

However,..we do strongly, collectively, absolutely oppose A.B. 98 which is in most of its structure a gross mis-carriage of what its all about, not only in what it says, but what it doesn't say as well.

I have with me today a copy from the Bureau of Consumer Protection, a Staff Report to the F.T.C. which embraces every aspect of Drug Product Selection. This report is 360 pages long and required 3 years to complete. It has just now been released, January'79.

A.B. 98 pretends to cover all the bases in a few short paragraphs, 15 lines on Page 1 and less than 14 lines on Page 2.

I don't personally feel that we are to the point in time when we are expected to accept or approve a Bill of this magnitude especially if it meets very few or none of the sustaining requirements involved.

Take the Bill from the top. This is the 3rd attempt from the same source to sponsor a Drug Substitution Bill. Hopefully it will meet the same fate as its predecessors. I will assume that its many indorsements simply indicates an approval for the concept of the Bill and not the Bill itself.

From the Bill, 1st. paragraph, quote

"A prescription for a drug designated by a trade or brand name my be considered as an order for the drug by its generic name."

This is not true..... There are many trade names, or Brand Names which do not have a Generic Equivalents.

The Bill goes on to state, "And may be used as an authorization for dispensing a drug which is listed in the formulary."

We, as pharmacists, already have the authorization to dispense, in fact, we are licensed by the State of Nevada to do just that. We need no further authority to dispense dangerous drugs.

Why not state it thusly? "In the pharmacist's professional judgement he may select a generic equivalent if all criteria is met."

EXHIBIT K

From the Bill again, Under first part of Paragraph 2, quote, "Which will cost the patient less than the Drug designated." Answer to this statemen which denotes a Mandatory application is simple. I cannot at the moment think of any other industry which is Mandated by Law that its product wi cost less if they want to stay in business. Can you think of one???? It should be clearly understood that as more good Generic equivalents become available, and that as we have the right to greater utilization, prescription prices should decline to some degree. The free enterprise system, and the market-place, as well as increased competition will solve what the Bill is trying to accomplish. Any Mandatory stipulation in a Drug Product Selection Bill will serve as a disincentive for the Pharmacist to wisely employ his expertise.

From the Bill, 2nd. part Paragraph 2, quote, "The Pharmacist who selects etc., assumes the same responsibility, etc." This is most assuredly false and could only be true providing the Manufacturer whose product was selected carried a Liability Statement in behalf of the Pharmacist as well as on the product itself not to mention the physical responsibility of the Pharmacist having to be above any questionable doubt. (Liability of the Pharmacist will be more clearly revealed to you in a few minutes by another person who will address the subject in detail.)

Section 2, Quote, "The State Board of Pharmacy shall adopt by regulation a formulary which lists equivalent drugs which as been approved by the Food and Drug Administration." Precisely this provision is not enough. By that I mean the State Board should by Mandate of this Legislature regulate the whole subject of Drug Product Selection and investigate every aspect of its nature in the best interests of the Consumers it represents. A formulary either positive or negative, in my opinion, is not the answer. An approved list by a Federal Agency updated and used as a Reference List only,...yes,,,,,provided those drugs on the Reference or Approved List are by reputable manufacturers, and that they have a good track record, and most importantly a statement of liability on file with the State Board

EXHIBIT K

of Pharmacy.

Section 3, A.B. 98, Quote, "The Pharmacist may not fill a prescription using another drug of the same generic name if the prescriber indicates on the prescription that a substitution is not allowed."

I question the application of the mechanics involved to avoid substitution as stated in Section 3. By what means,...by what line,..by what words does the physician indicate to us what direction we may take in filling the prescription if substitution is denied?? Should this not have a standardized procedure of some type? Such as,.."Medically necessary, or some such connotation added to the prescription, or perhaps a D.A.W. signature line on the prescription form per se, which I feel personally is another undesirable attachment.

The most glaring omission in Section 3 is the fact that the Physician should retain control over the whole process, and that he and he alone, in his Professional judgement, will decide which direction we take in the application of Drug Product Selection.

Another omission in A.B. 98,the patient seems to have nothing to say about the process either with the Physician or the Pharmacist. He is not allowed to make a choice, that is, according to the Bill. I personally feel that the choice should be given somewhere along the line and that it should be discussed with the Physician before the patient leaves the office.

Another omission in A.B. 98 provides nothing for an Oral Prescription by telephone in regard to Generic possibilities, nor does the Bill touch on the recording requirements necessary on information received from the physician. Lack of recording provisions enhances liability of all concerned.

Still another omission. No provision made for prescriptions mailed into or out of the State of Nevada, and as to how the Law would apply.

A.B. 98 allows no exceptions in the process of Drug Product Selection, which could mean that Hospital adopted formularies might be affected,

EXHIBIT K

or Pharmacies which service Nursing Homes might equally as well be handicapped in providing services. Provisions are necessary for this type of Health-Care in our Hospitals and Nursing Homes. There must be exceptions provided, and it must be spelled out.

Section 4, A.B. 98, quote, "The cost of the drug to the patient must be reduced by at least the difference between the wholesale prices (?) of the drug designated by a brand or trade name and the drug dispensed."

I am still trying to figure out this formula for price fixing which is indicated in that quotation. Prescription pricing has already been discussed previously in this presentation. I won't elaborate any further on this point.

Section 4, sub-section (b) quote, "Directions for use of the drug dispensed must be communicated to the patient." Any reputable Pharmacist will,when asked by the patient, offer advice about the medication or answer any question within the realm of practicality. If we mandate this in every case, extra costs of hiring another Pharmacist will delete any possible savings hoped for in this Bill. Another point is A.B. 98 does not say how we will communicate, by what method, etc. A busy Prescription Case would be hard pressed to have a Pharmacist communicate with every patient.

Section 4, sub-section (c), quote, "The name of the dispensed drug must be indicated on the prescription label except where the prescriber orders otherwise." Now,...it is already a Law that the name of the drug shall appear on all prescription labels. The prescriber has no choice one way or another and neither do we.

Section 5 No further comment.

My personal convictions about this Bill, A.B. 98.

Leave it right where it is either in Committee or in Limbo, and I do not feel that it is even amendable.

EXHIBIT K

Summing up:

There are four necessary ingredients for a good Drug Product Selection Bill They are as follows:

1. Absolute control and authority of the physician to decide if Drug Produc Selction shall be employed or not, and defined properly in the Law.
2. Adopt the FDA approved Generic Equivalent list not as a formulary, but as a reference list only based on the liability statements of the manufacturers involved.
3. No Mandatory Pass-Ons of,or formulas for Cost Savings. Allow the market place and compatitive sources to seek its level of lowering prescription prices. This is the American Free Enterprise System.
4. Assurance to Pharmacists on the matter of Liability,and the subject spelled out in the Law including liability statements from each Manufacturer whose product is used.

John Board

Thank you Mr.Chairman, I would like now to refer you to the next person on the Panel.

EXHIBIT L

DISTINGUISHED MEMBERS OF THE ASSEMBLY COMMERCE COMMITTEE:

I am here to present several views on A.B. 98 concerning drug product selection as relates to liability and the practicing pharmacist. A number of considerations have been set forth by a number of sources presenting the pros and cons of extending liability protection within the act of establishing drug product selection.

Simply stated, a pharmacist in filling a prescription is under a duty to use that degree of care and skill which is expected of a reasonable competent practitioner in the same or similar circumstances. This is the legal definition by which a pharmacist's conduct would be judged in assesing whether he had incurred liability as a result of his professional activities.

To be a professional in this society means perils as well as responsibility. The word "pharmacist" connotes special skill and talent. The pharmacist has numerous exposures which include a professional liability to his patient. And, of course, the patient is the public. So--the pharmacist in discharging his professional skills exercises a special degree of responsibility and is held to the highest degree of care in today's courts.

The modern day pharmacist is an expert on the comparison of different versions of generically equivalent drugs, produced by different manufacturers. That poses special problems for their special skills and talents. It is well known, for instance, that 0.1 milligram of digitoxin, a cardiac drug, from different manufacturers may have wide physiologic effects. Different brands of this drug vary in their adsorption characteristics leading to different blood levels and tissue levels. They also vary in the amount of active drug present in an individual tablet or dosage. The pharmacist as an expert on the individual variations among drugs has the capacity to pick the drug which has the greatest physiologic activity, the best quality control, and to understand the other qualities of the drug which is being generically dispensed.

The legal duties on the matter of generic dispensing are still ill-defined, and the practices of the pharmacist at this time are not yet sufficiently uniform to indicate a standard. The pharmacist is faced with a high liability potential for his failure to intervene in the

doctor-patient relationship and advise the patient of the inherent dangers in the use of a particular drug. To cover these provisions, some states have enacted sections within the product selection legislation which indicate that if the pharmacist dispenses a generically equivalent drug or a medication from a "Positive" formulary, and for some reason, injury results, there is no liability.

However, several considerations must be examined for the above indicated situation. In New York, for example, health department attorneys rejected a request from the National Association of Retail Druggists that liability protection be extended to pharmacists forced by state law to substitute lower cost drugs. In a letter to NARD executive Vice President William E. Woods, they indicated "the controversial state substitution law does not create any new liability for pharmacists who, are in case, usually protected by manufacturers product warranties."

According to APHA associate general counsel, Carl Roberts, a pharmacist liability protection clause is useful in any state substitution law, but only to a point. Robert's opinion is that such a clause is likely to have a psychological effect and deter litigation. However, once a case is presented in court directly challenging the liability protection, there is doubt that the clause will be able to stand up, on constitutional grounds.

Pharmacist Attorney Joseph L. Fink III of the Philadelphia College of Pharmacy supports the view and believes this type of special legal protection to pharmacists is simply unconstitutional. Such protection clauses could all be thrown out on a single ruling that one state's clause is unconstitutional. More than that, careful consideration should also be made of such protection given to physician's liability under the same type of clause. Here again a legal question could arise under litigation as to the constitutionality of such protection.

Further, in respect to manufacturers product liability warrants, statements are generally contained in the various policies which must be carefully evaluated for what is or is not covered by such protection. Despite the prominence which some firms have been giving their statements, a number of manufacturers either do not have such protection of product or do not have policies making them available. The Kansas Pharmaceutical

Association requested certification of such policies from 107 firms and only 32 responded. The Portland Retail Druggists Association corresponded with 111 drug manufacturers and received replies from only 38. Of the 38, 25 had insurance which afforded protection to pharmacists as well as the manufacturer. The 13 remaining companies had only protection for themselves. Most policies place specific conditions and restrictions upon the pharmacist as to the care and performance of his specialized duties.

The impact of modification of state antisubstitution laws is evident in language of the policy statements. If a drug is prescribed by generic name, many companies will protect the pharmacist when their product is dispensed. In the case where the product is prescribed by trade name but, pursuant to state law, the pharmacist dispenses the involved firm's product, some firms will provide automatic protection, while others reserve the right to review all the facts before providing protection.

In the recently published FTC model substitution law formula, FTC Chairman Pertschuk outlined what should be contained in a substitution law. He indicated " a good substitution program should be simple. It should be self-enforcing. And, it should interfere as little as possible in the pharmacist's management perrogatives." He went on to explain that it should contain assurance to pharmacists on liability. Pharmacists "fear" of lawsuits from generic substitution often prevent them from substituting as often as they would otherwise. Pertschuk assured in his presentation that the FTC sees "no basis for the exaggerated claims being presented about liability." he further emphasized that the pharmacist should receive "objective information" about potential liability and about the type of protection afforded by insurance policies of pharmaceutical manufacturers and by the pharmacists own liability coverage.

While we are acutely aware of the many ramifications remaining in this type of legislation, we are also equally aware that we can't possibly address all the issues and problems. However, as far as the liability issue, remember any provision which reduces the pharmacists liability exposure in drug product selection would serve to encourage pharmacists to exercise that authority. The question to keep in mind is whether the public is willing to trade some protection in the

liability area for the expected benefits of drug product selection.

If any drug product selection were to be mandatory in form, in other words were to require pharmacists to engage in drug product selection, then clearly the pharmacist must not be subjected to potential liability for having complied with the explicit mandatory requirement of the statute. I would in closing ask that you keep in mind the APHA position on any mandatory drug product selection. It is their position that mandatory drug product selection will destroy not only the prfession, but more importantly the public health protection function which the pharmacist is intended to serve.

EXHIBIT M

NEVADA PHARMACISTS GUILD
STEWART E. PAQUETTE, R.PH.
EXECUTIVE SECRETARY
1113 SOUTH 15TH STREET • LAS VEGAS, NEVADA 89104

January 29, 1979

Gentlemen:

We recognize the responsibility of the Legislature to insure the citizens of the State that they are offered the benefit of quality pharmaceutical products at competitive prices in the marketplace.

We propose in this regard, in order for pharmacies to be able to operate with accountability and effectiveness, that AB98 be withdrawn along with anyother Bill similar, dealing with Drug Product Selection, (DPS) and that an Enabling Act i.e., enabling legislation be passed delegating the Nevada State Board of Pharmacy, to develop regulations to cover DPS in ALL respects.

Further that an outside committee be appointed compromised of Pharmacists, Consumers and representation from Allied Health Groups to assist and advise in promoting these Regulations regarding DPS.

The enabling act could stipulate areas of action and specify an effective date when initial regulations shall be completed.

By using this method of enacting legislative intent, the regulations could be updated to comply with changes in State and Federal needs and possible re-alignment with FDA recommendations.

Respectfully

STEWART E. PAQUETTE R Ph.,
executive secretary

We're building a reputation, not resting on one.

NEVADA PHARMACI

4712 Heidi Circle
LAS VEGAS, NEVADA 89102

ALL NEVADA PHARMACISTS. "WHAT DOES THE 1979 NEVADA LEGISLATURE HOLD?!"

While we have no insight into the 'halls of the legislature' nor do we possess 'crystal balls' or other methods of predicting what 'disinterested parties will do'....One can be 'sure' that the 1975 and 1977 Legislative sessions saw attempts to pass a "PRODUCT SUBSTITUTION BILL"....and we need - no insight - to know that we can expect another attempt in 1979.

We feel we must be 'realistic' - We must prepare for any eventuality... We feel that if "WE - DO NOT PRESENT A PRODUCT SELECTION BILL"..prepared by us, it will be prepared by others, and possibly less to our liking., and while we would prefer less legislative action involving pharmacy and the health-care professions, we hope you feel as we do and that our efforts meet with your approval.

1. We have contacted most states that have PRODUCT SELECTION LAWS and have received copies of these laws.
2. We have met with manufacturers representatives also interested in PRODUCT SELECTION LAWS and were informed of pit-falls to watch for.
3. We have studied these laws and chosen those parts which we feel WE CAN LIVE WITH and which will BE ACCEPTABLE (in most part) by the Medical Community and finally,
4. We have prepared a PRODUCT SELECTION BILL which we hope will meet with your approval.
5. Attention invited to US Map...more states are passing generic laws each month...

THE WAVE OF THE FUTURE IS NOW...EITHER WE PARTICIPATE...WITH OUR EFFORTS OR WE WILL BE REQUIRED TO COMPLY...WITHOUT BENEFIT OF OUR EFFORTS....

☐ Generic states today...plus Alaska
(And additional states passing generic laws month by month)

EXHIBIT M

Drug Product Selection — E. Floyd Butler Jr., B.S.,Ph.

The Pharmaceutical Profession accepts the responsibility to the citizens of Nevada to offer the benefits of quality pharmaceutical products at the lowest possible cost or at reasonable competitive prices. It shall be understood th in providing this concept that there will be no MANDATORY CLAUSE which prohibits the pharmacist or the physician in exercising his professional judgement. The pharmacist shall have the right to practice Drug Product Selection only under the guide lines as prescribed.

Explanation and requirements of Drug Product Selection:

1. Product Selection shall refer to the pharmacist's selection of a Generic Drug Product which is pharmaceutically and therapeutically equivalent and may be dispensed in place of the Brand Name or Drug Product specified by the prescriber.

2. Generic name shall mean the official title of a drug recognized in the most current USP or NF and one which meets the standards of strength, quality and purity as determined by the FDA, and shall be considered pharmaceutically and therapeutically equivalent.

4. Pharmaceutically equivalent products refer to products with the same activ ingredient, dosage form, and strength and can be considered therapeutically equivalent providing they are marketed under approved new drug applications, are manufactured under the same standards, meet identical or comparable specifications, and in those instances where positive evidence of bioequivalence is necessary, in fact are shown to be bioequivalent.

5. A pharmacist may not exercise Drug Product Selection under the provisions of this bill unless the product is contained in the FDA'S Therapeutically Equivalent Drug List which shall be termed as a REFERENCE FORMULARY to be updated within reasonable periods of time and made availble to all pharmacist in the State or Nevada. A pharmacist may not exercise Drug Product Selection if indicated to the contrary by the prescriber.

6. A pharmacist may practice Drug Product Selection, dispensing a Generic Dru on all written prescriptions unless the prescriber indicates otherwise in writing "Medically Necessary" or "Brand Name Necessary" on the prescription for the Brand Name or Drug Product which has been prescribed.

7. A pharmacist may practice Drug Product Selection on all oral prescriptions unless it is expressly denied by the prescriber. A statement to the effect that Product Selection has been denied to the pharmacist will be recorded on the face or back of the prescription by the pharmacist receiving the oral prescription.

8. Contained in NRS 639..."No person who owns a pharmacy licensed under this chapter may require a pharmacist in his employment to dispense a specific drug when a choice of drugs is available." NRS 639 to be amended to specify, "It shall be unlawful for any employer, within the meaning of this bill to coerce, intimidate, or force any pharmacist to dispense a specific drug for another drug, and it shall be punishable as a misdemeanor."

9. The State Board of Pharmacy may adopt any necessary Regulations, may delete, change or add to any Regulation such as Regulation 5.01 for the continuation of this bill.

10. Exceptions to Drug Product Selection. In every case where the application of a formulary or a drug list is prepared for use within the confines of a Hospital or Nursing Home which has been prepared by the Pharmacy Committee, or by the Pharmacy Consultant and approved by the staff physician.

11. Manufacturers whose Generic Drug Products meet all FDA Regulations shall also be requested to-

a. Mark products with an I.D. or monogram.

b. Label products with expiration dates.

c. Provide reasonable return goods services for expired products.

d. Maintain complete resources for product information.

e. Maintain recall capabilities for any unsafe or defective drug.

12. The practice of Drug Product Selection shall apply to all prescriptions, including those presented by or on behalf of persons receiving State or Fed. assistance payments.

13. The Liability of a pharmacist practicing Drug Product Selection under the prescribed guide lines herein stated shall be no greater than that which is incurred in the filling of a GENERICALLY WRITTEN PRESCRIPTION. The failure of a prescriber to specify that no PRODUCT SELECTION is authorized does not constitute evidence of negligence.

14. Liability of the pharmacist shall be further considered in that all Manufacturers of Generic Drug Products will be required to file a complete LIABILITY STATEMENT relative to its Drug Products with the Nevada State Board of Pharmacy within a reasonable length of time following adoption of this Bill.

15. Prescriptions filled outside the State of Nevada and mailed into the State of Nevada by any pharmacy or mail-order house outside the State Lines shall contain only the Drug Product prescribed. No Drug Prod. Selection shall be made.

16. Any legal prescription brought into the State of Nevada from other States shall be filled according to the Laws or Regulations of the State of Nevada.

EXHIBIT M-__

Drug Data

FTC

Summer 1978

	1. Drug Product Selection Prohibited	2. Drug Product Selection Permitted /Mandated	3. State Positive Formulary	4. State Negative Formulary	5. No Formulary	6. Refill Limitation	7. Generic Rx Provision	8. Physician Consent (Preprinted Rx Blanks)	9. Physician Veto (D.A.W., D.N.S., etc.)	10. Purchaser Consent	11. Purchaser Veto
Alabama	S										
Alaska		S			X			X		X	
Arizona		S	X					X			
Arkansas		S		X					X		X
California		S		X					X		
Colorado		S			X				X		
Connecticut		S			X				X		X
Delaware		S		X				X			
D. C.		S	X	O					X		X
Florida		S/M	X 5	X					X		X
Georgia		S			X		X	X			X
Hawaii	S										
Idaho		R			X			X			X
Illinois		S	X					X		X	
Indiana	S										
Iowa		S		X					X		X
Kansas		S		X 7				0	X		
Kentucky		S/M	X						X		X
Louisiana	S										

12. Physician Notification	13. Purchaser Notification	14. Pharmacist Recordkeeping for Drugs Dispensed	15. Selected Drug Must be Lower in Cost	16. Pass-on of Entire Cost Savings to Consumers	17. Other Cost Savings Provisions	18. Pharmacist Liability	19. Physician Liability	20. Consumer Information Posted	21. Rx Container Labeling	22. Manufacturer's Labeling	23. Date Fully Effective	
												Alabama
X	X		X					X 1			9/76	Alaska
	X					X	X		X		1/79	Arizona
	X		X		X				O		12/75	Arkansas
	X		X	X		X	X		X		5/76	California
	X	X	X	X		X 2			X	X	4/76	Colorado
	X	R	X	X		X 3		X	X		10/76	Connecticut
	X	X		X					X		9/76	Delaware
		X	X 4			X	X	X	X		12/77	D. C.
	X	X	X	X 6		X	X	X			74,A 6/76	Florida
		X			X						1/78	Georgia
												Hawaii
		X	X	X				X	X		7/78	Idaho
	X	X	X			X	X				6/78	Illinois
												Indiana
	X	X	X	X						X	7/76	Iowa
			X		X						7/78	Kansas
					X			X	X		72,A 6/76	Kentucky
												Louisiana

	1. Drug Product Selection Prohibited	2. Drug Product Selection Permitted/Mandated	3. State Positive Formulary	4. State Negative Formulary	5. No Formulary	6. Refill Limitation	7. Generic Rx Provision	8. Physician Consent (Preprinted Rx Blanks)	9. Physician Veto (D.A.W., D.N.S., etc.)	10. Purchaser Consent	11. Purchaser Veto
Maine		S			X				X		
Maryland		S		X					X		
Massachusetts		S/M	X					X			
Michigan		S[8]			X				X		
Minnesota		S			X				X[9]	X	
Mississippi	S										
Missouri		S		X				X			X
Montana		S			X		X		X		X
Nebraska		S		X			X		X		X
Nevada	R										
New Hampshire		S	X					X[11]		X	
New Jersey		S/M	X					X			X
New Mexico		S	X						X		
New York		S/M	X					X			
North Carolina	S[14]										
North Dakota	S										
Ohio		S	X[15]						X		
Oklahoma		S[16]			X						
Oregon		S			X		X		X		

EXHIBIT M

12. Physician Notification	13. Purchaser Notification	14. Pharmacist Recordkeeping for Drugs Dispensed	15. Selected Drug Must be Lower in Cost	16. Pass-on of Entire Cost Savings to Consumers	17. Other Cost Savings Provisions	18. Pharmacist Liability	19. Physician Liability	20. Consumer Information Posted	21. Rx Container Labeling	22. Manufacturer's Labeling	23. Date Fully Effective	
	X		X 4						X		76,A 7/78	Maine
	X	X	X	X							7?A 75 1/78	Maryland
			X						X		71,A 1/78	Mass.
	X		X	X					X		75,A 1/77	Michigan
	X		X 4	X					X	X	8/75	Minnesota
												Mississip
		X 10	X			X			X	X	1/79	Missouri
	X		X	X		X	X	X			7/77	Montana
			X		X	X	X	X	X	X	1977	Nebraska
												Nevada
											8/73	N. H.
X 12			X		X			X	X		1979	New Jerse
X 13			X						X		5/76	New Mexic
			X					X	X		4/78	New York
												N. C.
												N. D.
	X	X	X	X	X		X		X	X	1/78	Ohio
											1961	Oklahoma
		X	X 4			X	X	X	X		9/75	Oregon

EXHIBIT M

	1. Drug Product Selection Prohibited	2. Drug Product Selection Permitted/Mandated	3. State Positive Formulary	4. State Negative Formulary	5. No Formulary	6. Refill Limitation	7. Generic Rx Provision	8. Physician Consent (Preprinted Rx Blanks)	9. Physician Veto (D.A.W., D.N.S., etc.)	10. Purchaser Consent	11. Purchaser Veto
Pennsylvania		S M	X			R		X			X
Rhode Island		S M	X					X			X
South Carolina	S R										
South Dakota		S			X			X			
Tennessee	-	S	X					X			
Texas	S										
Utah		S	X 17						X	X 18	
Vermont		S M	X			X			X		X
Virginia		S	X					X 19			
Washington		S		O				X			
West Virginia		S M		X				X			X
Wisconsin		S	X			X	X		X		
Wyoming	S										

12. Physician Notification																								
13. Purchaser Notification	X																							
14. Pharmacist Recordkeeping for Drugs Dispensed	X	X																						
15. Selected Drug Must be Lower in Cost	X	X				X																		
16. Pass-on of Entire Cost Savings to Consumers		X				X																		
17. Other Cost Savings Provisions	X																							
18. Pharmacist Liability	X	X				X																		
19. Physician Liability	X	X				X																		
20. Consumer Information Posted	X																							
21. Rx Container Labeling	X					X																		
22. Manufacturer's Labeling						X																		
23. Date Fully Effective	5/77	76,A 5/78		7/78	6/77																			
	Penn.	R. I.	S. C.	S. D.	Tennessee	Texas	Utah	Vermont	Virginia	Washington	W. Virginia	Wisconsin	Wyoming											

EXHIBIT M

CODES FOR CHART

M - Mandatory, R - Regulation, S - Statute, X - Affirmative Provision, O - Optional Provision, A - Amendment

FOOTNOTES FOR CHART

1/ Required only during first 2 years of Act.

2/ Same liability as incurred in filling a generic Rx, but pharmacist charged with notice of FDA bioequivalence problems list.

3/ Posting of sign and absence of purchaser veto are no defense.

4/ Selected drug must be of lower or equal cost.

5/ Each pharmacy is to prepare its own positive formulary.

6/ Pass-on of difference in retail price.

7/ Product selection prohibited for drugs FDA determines to be bioinequivalent.

8/ Purchaser can mandate product selection.

9/ Pharmacist can override veto if selected drug is made by same manufacturer as prescribed drug.

10/ Name of manufacturer must be on Rx label or in pharmacist's records.

11/ Physician must write in words "or its generic equivalent drug listed in N.H. drug formulary."

12/ Physician notification required only if physician so indicates on Rx.

13/ Physician notification required only if pharmacist changes the drug dispensed at some time after product selection has occurred (e.g. refills).

14/ Except for Medicaid Rx's, for which product selection is mandatory, absent D.A.W.

15/ Each pharmacy is to prepare its own positive formulary. Drugs cannot be considered generically equivalent if listed by FDA as having a proven bioequivalence problem.

16/ Product selection upon authority of prescriber or purchaser.

17/ Utah Board of Pharmacy empowered to adopt FDA list. Selected drugs may not be in any Drug Bioequivalence Problems List such as FDA list.

18/ Purchaser must specifically request product selection.

19/ Rx blanks required after 1/1/79. Prior to that time, physicians may handwrite "Voluntary Formulary".

20/ Product eligible for selection only if manufacturer's name appears on label.

Copy received [illegible]

EXHIBIT N

Note: Prime example
1. Patent infringements, another reason why every prescription cannot be filled or even considered generically.
2. A Mandatory Substitution Law would produce a situation of breaking the law in one respect to fulfill another.
3. Most dangerous as a liability factor for the Pharmacist.

Boehringer Ingelheim

Boehringer Ingelheim Ltd.
90 East Ridge
P.O. Box 368
Ridgefield, Connecticut 06877

Dear Pharmacist:

RE: Patent Infringement - PERSANTINE® (dipyridamole)

We have recently learned that generic substitutes for Persantine are being marketed in the United States.

As we trust you are aware, dipyridamole is the subject of a patent (Patent No. 3,031,450) issued to Boehringer Ingelheim GmbH and is distributed in the United States under an exclusive license by Boehringer Ingelheim Ltd. Accordingly, any generic substitute for Persantine that you may encounter has been manufactured in violation of the patent laws.

We ask you to help to ensure the integrity of our patent and take this opportunity to alert you to the very important insurance considerations incidental to the dispensing of generic substitutes for Persantine. Only the sale of Persantine entitles you to rely upon the quality synonymous with the Boehringer Ingelheim name and the protection afforded by Boehringer Ingelheim's broad product liability insurance coverage. You are, therefore, urged to keep detailed and accurate records with respect to the dipyridamole prescriptions you fill.

Please see the reverse side of this letter for full prescribing information.

Very truly yours,

Norman Hacking

Norman Hacking
Vice President, Marketing

Telephone: (203) 438-0311
Telex: 137318 Answer back: BILUSA Rigd.
Cable: BILUSA Ridgefield Ct. 06877

EXHIBIT O

January 19, 1979

To: John Jeffery, Dob Robinson, Marion Bennett, Roger Bremner, Loni Chaney, Nick Horn, Nash Sena, Mike Fitzpatrick, Bob Rusk, Darrell Tanner, and Bob Weise.

Reference, AB-101

First, please pardon the dittoed letter but I'm a teacher and it's a busy weekend coming up. Also, apologies for any mis-spellings--got your names from the Review-Journal.

I'm the person who asked Karen Hayes to introduce abill to outlaw people, firms, and/or advertising agencies from leaving papers and pamphlets laying in driveways or hanging on doorknobs unless the person receiving them has signed a paper saying he wants the stuff.

This goes for the L.V. SUN's "Advertiser," the Avon lady, and any and all firms that contract with furniture stores, etc., to place their advertising around town.

First of all, it's litter. Secondly, it's an open invitation to any would-be burglar that no one's home. I admit to being a little paranoid--we've been hit twice--but when we go away we notify the police, stop what can be stopped, arrange with neighbors to keep an eye out, set timers on lights, and can have all this negated by papers in the drive or hanging on some part of the house as a flag saying "Hey, fellers, looky--nobody's home!"

Third--I don't want the stuff. And I consider it an invasion of both property and privacy for people to leave it. I also consider it trash, because it goes right into the garbage can--and wonder if it would be all right for me to take my trash over and dump it on Mr. Greenspun's lawn, as he's dumping what I consider his on mine???

For businesses, and for those people who want it, door-to-door advertising is fine, but there are those of us who don't want it and what I'm asking is protection from it. It should be no more of a problem for a company to get signatures of people who want the material than it is for a newspaper to get subscriptions.

Finally--I heard of a case in Florida where a homeowner who was burgalarized when such material was hanging on his door sued both the advertiser and the company who placed it and won--so AB-101 is also protection for the firms involved.

I truly hope you will consider it favorably.

Sincerely,

George T. Appleton
3400 Florrie Avenue
Las Vegas, Nevada 89121

EXHIBIT P

JANUARY 25, 1979

JACK JEFFREY
Chairman
Commerce Committee
NEVADA STATE ASSEMBLY
Carson City, Nevada

DEAR JACK,

I am writing to protest against AB 101, the bill to prohibit hanging of advertising flyers on residential doorknobs.

I am outraged that this bill has even been drafted since there is no evidence of substantial public outcry against door hangers.

If news reports are correct, Karen Hayes has introduced this bill by request of one of her constituents. We all know Karen has the largest district by population and voter registration. How much of a problem can door hangers be if ONLY ONE of her constituents complained about them?

This absurd bill should have been referred back to its originator by the entire Assembly. But since that did not happen, I hope you will vote against it in committee.

I have campaigned twice for Assembly. Nick Horn beat me by 153 votes in the 1976 primary and Jan Stewart beat me by 38 votes in the 1978 primary. I'm going to run again and will keep running until I win.

Door hangers have been an indispensable part of my campaigning and hopefully will be in the future.

In 1976, not one of the 4,200 registered Democrats in AD 15 who got my doorhangers complained about them. In 1978, not one of the 5,500 registered Democrats in AD 14 complained about my doorhangers.

In fact, many lonely people (senior citizens especially) welcome the doorhangers because it gives them an opportunity to call up a candidate and chat on the telephone and/or invite them back to their homes for a personal visit.

There will be one inescapable result if AB 101 is passed into law: it will be even more difficult for common people like me to make a serious attempt to run for Assembly.

EXHIBIT P

It is still possible to run a fairly economical campaign and work like hell and have a chance to win. One economy measure is to limit the number of mailings and compensate with doorhangers.

Nick spent $5,000 against my $3600 in the 1976 campaign. Stewart spent $8600 against my $4100 in the 1978 campaign. If it becomes illegal to use door hangers to help cut costs, then people like me will be priced out. Then only the wealthy or the few with wealthy connections will be able to mount serious election races.

Again the bottom line: Where is the public demand for the passage of this bill? If none exists, let's bury the bill now.

Thank you for your considerations.

Sincerely,

ART RADER

4923 Colorado Avenue
Las Vegas, Nevada 89104

PS: If residents placed small "post no bills here" warning signs on their homes, as many now post "no peddlers" or "no trespassing" signs, would this not have the same effect as AB 101? It would keep doorhangers away from residents who don't want them and allow them where they are welcomed.

EXHIBIT Q

January 18, 1979

Assemblyman Jack Jeffery
~~Senator Joe Neal~~
Legislative Building
Capitol Complex
Carson City, N.V.
89701

Dear Mr. Jeffery:

We the undersigned, as registered voters and senior citizens living on fixed incomes, urge you to support legislation requiring pharmacists at the customers request, to fill prescriptions with generic equivalent drugs when they are less costly and available.

We thank you very much for your attention in this matter.

Sincerely,

1. [signature]
2. Carole Arnold
3. Ernest A Bartlett
4. Teresa Gidor
5. David Lemke
6. Joyce R. Lawton
7. Ken D. Lemke
8. Diane Colehour
9. [signature]
10. Jan Moore
11. Janet Hadley
12. Pat Moore
13. Eleanor Barnett
14. Joyce C. Walker
15. Mary E Austin
16. Sharon Garland
17. Kathleen Clayton
18. Geraldine L. Virgil
19. Clifford J. Baker
20. Jerry Hanning
21. Jean Eggers
22. Lula Bissell
23. [signature]
24. Evelyn Salzberg
25. [signature]
26. Kenneth Kimball
27. Martha Hussain
28. Lavieta L. Marchant
29. Carolyn Hastings
30. Karen Hadfield