The meeting was called to order at 1:30 p.m. in Room 213 Senator Thomas R. C. Wilson was in the chair.

PRESENT: Senator Thomas R.C. Wilson, Chairman
Senator Richard E. Blakemore, Vice Chairman
Senator Don Ashworth
Senator Clifford E. McCorkle
Senator Melvin D. Close
Senator C. Clifton Young
Senator William H. Hernstadt

ABSENT: None

OTHERS PRESENT: See attached guest list (Exhibit A).

SB 137 Requires substitution of less expensive drugs under certain circumstances when drugs designated by trade or brand name are prescribed.

Senator Wilbur Faiss presented a letter from E. Floyd Butler, Chief Pharmacist, Sahara Rancho Pharmacy, Las Vegas, Nevada (see Exhibit B). Senator Faiss stated that Mr. Butler supports generic substitution but is against Senate Bill 137. Senator Faiss does not necessarily concur with Mr. Butler.

John McSweeney, representing the Department of Human Resources, Division of Aging Services, stated that SB 137 is based on a Model Bill that the Federal Trade Commission has; and that Dr. Goldberg, the foremost expert on generic substitution, was involved in its inception.

Senator Ashworth questioned Mr. McSweeney about the drugs that would be involved. Mr. McSweeney replied that the Federal Drug Administration has provided a list of positive formularies which are generic equivalents and have been tested to be either biomedically or therapeutically equivalent. The state pharmaceutical board would adopt this list.

There was discussion as to who would be liable for the substitution. The pharmacist would not be liable. The doctor would have to write "medically necessary" if he did not want a substitution. It was agreed that generic drugs are as good as the original brand name drugs if they are based on the positive formula.

Orvis E. Reil, Chairman, National Retired Teachers' Association, American Association of Retired Persons, presented prepared testimony in support of SB 137 (see Exhibit C).

Mr. Reil also presented a copy of a report prepared by the New York State Assembly's Office of Legislative Oversight and Analysis for the First National Conference on Generic Drugs (see Exhibit D).

Mr. Reil explained to Senator Hernstadt that manufacturers distribute drugs under different names, which are the same, and charge a vast range of prices.

Senator McCorkle asked Mr. Reil if he wanted to mandate that the price should be kept lower, or if the option should be left to the druggist. Mr. Reil agreed that it should be left up to the druggist, but that there should be some kind of "yardstick" to insure that the consumer would get the benefit of the lower price.

James D. Pitts, M.D., representing the Nevada State Medical Association, stated that the Medical Association is in full agreement with the intent of Senate Bill 137. He stated that many physicians' background in pharmacology was in medical school, primarily using chemical or generic names, and they continue to write prescriptions in this manner. He stated that everyone is leaving it up to the federal government to determine the list of formularies.

Dr. Pitts explained that chemical and bioequivalents are different. He said it is possible to have the chemical equivalent but, for instance, if the coating is too thick, the drug could pass through the body without being absorbed. He stressed that many formularies are not developed with bioequivalents, and that bioequivalent means that "the drug taken in a similar situation with similar patients will be absorbed and come out in the serum levels as equivalent."

Dr. Pitts continued that the State Board of Pharmacy would have to determine the list of 45 equivalents by bioequivalent testing. He stated that the "medically necessary" phrase poses a problem in the way that it would be written. It could be written out, there could be a check list or the doctor could have a choice of 2 lines to indicate if the medication were medically necessary. Dr. Pitts added that the lower profit margin for the manufacturers of the drugs could have some impact on the amount of research they could do.

Ms. Pat Gothberg, representing the Nevada Nurses' Association stated that the Nurses' Association supports this kind of legislation; but that there are 3 things that the Committee should be aware of that concern the nurses regarding drug product selection that are as follows. First, the entire premise for the adoption of this legislation is based on the assumption that the product that is replacing the trade name is the same, in fact, as the drug it replaces; hence the need for formularies. Second, the consumer should play a part in the decision-making process. Lastly, the savings should be passed along to the consumer.

I. J. Sandorf, Chairman of the Reno American Association for Retired Persons, and member of the committee that advises the Division of Aging Services, stated that the Association thinks the

physician ought to have to do some thinking when making substitutions, such as actually writing "medically necessary". Mr. Sandorf presented excerpts from a pharmacy products list published by the National Retired Teachers' Association and the American Association of Retired Persons (see Exhibit E).

Mr. Sandorf stated that if doctors are allowed to make substitutions, people who belong to these organizations could then obtain drugs from the manufacturers at lower prices with satisfaction guaranteed.

George Bennett, Secretary, Nevada State Board of Pharmacy, presented suggested amendments to SB 137 (see Exhibit F). Mr. Bennett stated that the Federal Drug Administration has a list of therapeutically equivalent drugs which is being updated and will be finalized in a few months. He added that the list would include those drugs that the Administration would feel have bioequivalent problems or would be bioinequivalent.

Senator Ashworth asked Mr. Bennett to explain the product identification code mentioned in the proposed amendment. Mr. Bennett explained that this identification code is protection against possible overdose situations.

Senator McCorkle asked Mr. Bennett for examples of how the prices would vary. Mr. Bennett explained that rarely the generic drug would be priced less than the brand name drug, and that an example of the price range would be as follows. If the name drug costs $6, an average price might be $11 or $11.50; whereas a generic drug price might be $9.50. He added that the reason for the difference in the pricing, is that the manufacturer of the brand name did all of the research, and had the expense of the patent. Often when the patent expires, the brand name drug will drop its prices.

There was discussion on the question of ethics in the area of price variance. The pharmacist could quote a higher price and then offer the drug for less with the consumer not knowing that the prescription could be filled for even less.

Ms. Dayle Berke, Attorney, Bureau of Consumer Protection, Federal Trade Commission, presented a prepared statement explaining the FTC's involvement in the subject of drug substitution (see Exhibit G). Ms. Berke stressed that the statement represents her views and is not intended to be and should not be construed as representative of official Commission policy. Ms. Berke referred to Page 6 of her statement in which she states that providing pharmacists an economic incentive to select low-cost products makes a mandatory law unnecessary.

Ms. Berke stated that it has been found that those states which had mandatory laws reported a significantly lower substitution rate than those that had permissive laws. Ms. Berke added that four times as many pharmacists preferred a positive formulary,

listing substitutable drugs, as preferred a negative formulary, listing non-substitutable drugs.

Chairman Wilson asked Ms. Berke to clarify therapeutically and bioequivalent. Ms. Berke explained that therapeutic deals with the bioequivalence issue.

Ms. Berke stated that hand writing "medically necessary" for a brand name, is the best approach so that to substitute or not would be a conscious decision for the physician to make.

Ms. Berke continued that it would not be in the best interests of the pharmacist nor the consumer to require that the parmacist pass all wholesale cost savings on; because the pharmacist would not be able to profit due to costs that may be incurred in using his or her professional skills to search for, stock, and dispense lower-cost generics.

With regard to liability, Ms. Berke stated that studies have shown that in no instance has a pharmacist been held liable for legally substituting a lower cost generic or for selecting the source used to fill a generically written prescription.

Ms. Berke discussed the education of consumers and health professionals on the benefits of generic drug products. She stated that the studies have shown that pharmacists engaging in drug product selection are spending more time with their patients, that retail advertising is providing information for the consumer, and that the Model Act directs the appropriate state agency to provide for additional public information as necessary.

Ms. Katherine Laughlin, Chairman, Legislative Advisory Committee to the Aging, stated that their Committee supports SB 137.

Ed Speegle, Manager, Government Affairs, Sandoz Pharmaceuticals, stated that the reason that there have been no liability suits is because the level of substitution is very low and, by the way, the level of savings is very low. He added that claims of savings of 50 to 60 percent are very erroneous; in fact, the savings are closer to 5 to 9 percent. Mr. Speegle testified that therapeutical and bioequivalent are not interchangeable, and that the Food and Drug Administration has found that generic copies of some brand name products pose a serious danger to health and welfare. Further, that the manufacturers should be required to show bioequivalency, but are not required to do so yet. Mr. Speegle explained that a patient could be given a certain dosage for response, and a generic substitute may be made that could have a bioinequivalency of 70 to 80 percent.

In reply to Senator Hernstadt's question, Mr. Speegle stated that the practice of substitution would definitely have adverse effects on research. He added that the 2 line provision would

be the most workable and that in some states physicians do not even know that products can be substituted; also, pharmacists would be more willing to substitute with a 2-line provision because the question of liability is clarified. Mr. Speegle stated that if pharmacists were mandated to charge the lowest amount for prescriptions, they would go out of business.

Chairman Wilson called for a recess at this time.

The meeting reconvened at 3:45 p.m. with all members present.

SB 137 Requires substitution of less expensive drugs under certain circumstances when drugs designated by trade or brand name are prescribed.

Ms. Dayle Berke testified that instead of the word "substitution", the Federal Drug Commission prefers "drug product selection", and that the price range would not have to be passed on to the consumer, but just a lower price. Ms. Berke concluded that most of the provisions in SB 137 are the same as the Model Act except that the Nevada bill mandates substitution.

Chairman Wilson closed the public hearing on Senate Bill 137.

SB 138 Changes amount in vocational rehabilitation revolving fund.

Senator Hernstadt moved that SB 138 be re-referred to Finance.

Senator Ashworth seconded the motion.

Motion carried unanimously.

SB 145 Permits registered nurses to perform additional functions under certain circumstances.

Robert Brown, M.D., past president of the Nevada State Medical Association, testified that the Association is opposed to SB 145 because it is not in the best interests of the state, and that nurses are not qualified for this authorization.

At this point Senator Glaser stated that he had introduced SB 145 but now no one seemed to want to support it. Senator Glaser explained that in rural areas there are nurse practitioners who handle clinics alone.

There was discussion on the need for legislation. Chairman Wilson concluded that SB 145 is not acceptable; but that both sides favor some kind of legislation.

Ms. Pat Gothberg, representing the Nevada Nurses' Association, testified that the Association is opposed to SB 145 because the

language of the bill does not protect the consumer. Ms. Gothberg stated that when the three independent disciplines of pharmacy, medicine and nursing meet there are inevitably frictions. She stated that in 1973, the Nurse Practice Act was amended to provide for nurses functioning in an expanded role; however, the Pharmacy Law and the Medical Practice Act have not been changed, so that as it stands now the nurse practitioners are functioning against the law.

Senator Wilson directed all of the representatives of the three different groups to meet in another room to try to come to some kind of agreement, and then to report back to the Committee later in the meeting.

SB 152 Removes time limit for suspension of certain schedules by Public Service Commission of Nevada.

Heber Hardy, Chairman, Public Service Commission, testified that the Commission is against Senate Bill 152 because the present rule is satisfactory, and there is no need for legislation.

H. Joe McKibben, Vice President, Finance, Sierra Pacific Power Company, presented a prepared statement in opposition to SB 152, and added that he concurred with Mr. Hardy's testimony (see Exhibit H).

Stan Warren, representing Nevada Bell, concurred with the previous testimony.

John Holmes, representing Nevada Bell, concurred with the previous testimony. Mr. Holmes added that J.C. Penney Company and Circus Circus had arrived in the area with requests for very sophisticated equipment. Nevada Bell Company was able to supply the need within the time limit.

Charles King, representing the Central Telephone Company, and the Nevada Telephone Association, concurred with the previous testimony.

Charles Lindsey, Vice President, Finance, Nevada Power Company, concurred; and added that regulation is necessary in the eyes of most investors.

Clark Guild, Jr., representing Southwest Gas Corporation, concurred with the previous testimony.

Chairman Wilson stated that George Vargas would submit testimoney on SB 152 at a later date.

Chairman Wilson closed the public hearing on Senate Bill 152.

SB 170 Enables board of hearing aid specialists to establish continuing educational requirements for licenses, prohibits others from practicing.

Chairman Wilson continued Senate Bill 170 to a later date.

SB 172 Revises laws regulating dispensing opticians.

Victor Isaacson, President, Nevada Board of Dispensing Opticians, stated that the Board initiated the proposal for Senate Bill 172. Mr. Isaacson explained that the purpose of the bill is to clarify the language and update definitions of the present statute which was enacted in 1951.

In reply to Senator Ashworth's question, Mr. Isaacson explained that originally the regulation on contact lens fitting only applied to the supervision of the physician or surgeon, but now would apply to certified opticians. Mr. Isaacson added that the bill would broaden the interpretation of what a dispensing optician does; and that it complies with a National Association of Opticians Model Act. He explained that a dispensing optician receives the prescription, reads it, and analyzes it as to how it will be converted into a pair of glasses.

Senator McCorkle asked why opticians over 60 years of age should be exempt from continuing education. Mr. Isaacson explained it would help those who had retired, but wanted to retain their licenses for vacation relief or temporary services. However, if there were an objection to it, he did not think the Board would mind its being deleted.

There was discussion as to when current certificates should be renewed under the new act. It was agreed to move the date back to July 1, 1978, so there wouldn't be a lapse.

Mr. Isaacson summarized that the new statute would upgrade and give special certification for all dispensing opticians for the consumer's protection.

Don Hill, representing the State Opticians, testified that the opticians from all over Nevada concur with Mr. Isaacson's testimony.

Harold Myers, Secretary, Nevada Board of Dispensing Opticians, concurred with the previous testimony.

Ed Bostic, Vice President, State Association of Opticians, concurred with the previous testimony.

Walter Immers, representing the State Association of Dispensing Opticians, concurred with the previous testimony.

Frank Higdon, representing the State Association of Opticians, concurred with the previous testimony.

Chairman Wilson closed the public hearing on Senate Bill 172.

Hearing resumed on Senate Bill 145.

SB 145 Permits registered nurses to perform additional functions under certain circumstances.

Richard D. Grundy, M.D., President, Nevada State Board of Medical Examiners, reported that the representatives from the Nursing Association, the State Board of Pharmacy and the Medical Board agree that SB 145 is not satisfactory. Dr. Grundy explained that in 1975 the idea of the position of physician's assistants was supported by the Governor and the State Board of Examiners; at the same time the Nursing Board supported legislation for nurse practitioners, and both bills passed.

Dr. Grundy stated that after implementing this legislation, it was realized that physician's assistants could not dispense any kind of drugs other than over the counter drugs. Dr. Grundy added that two years ago legislation allowed the Pharmacy Board to, under carefully controlled conditions, allow a physician's assistant to dispense drugs--this in reality is practicing medicine.

Dr. Grundy continued that the nurse practitioner act has been stymied because the nurse practitioner wants to work as an independent agent and the State Board of Examiners thinks that there should be direct supervision of a physician. Dr. Grundy stated that the best solution would be legislation to amend the Pharmacy Act with suitable language which would state that "nurse practitioners may dispense drugs the same way a physician's assistant dispenses drugs, under the supervision of the State Board of Pharmacy, the State Board of Medical Examiners and the State Board of Nursing."

Ms. Pat Gothberg testified that the nurse practitioner functions in an expanded role beyond a Registered Nurse's duties, and this intrudes into the physician's area.

George Bennett, Secretary, Nevada State Board of Pharmacy, stated that four years ago when the physician's assistant bill was passed, the physicians pointed out that the assistants didn't have the authority to possess, administer or dispense drugs.

Mr. Bennett continued that in the last session legislation passed amending the Pharmacy Board's statutes. He explained that if "nurse practitioner" could be added after "physician's assistant" in NRS 639.1373, the problem would be solved in the eyes of the Pharmacy Board and the State Board of Medical Examiners.

Chairman Wilson continued the hearing on Senate Bill 145 to a later date.

BDR 54-844* Regulates practices of audiology and speech pathology.

Senator Blakemore moved for Committee introduction.

Senator Close seconded the motion.

Motion carried unanimously.

BDR 43-982** Relates to the financial responsibility concerning motor vehicles, increases the minimum amount of liability insurance.

Senator Blakemore moved for Committee introduction.

Senator Close seconded the motion.

Motion carried unanimously.

BDR 54-206† Provides requisites for practice of professional engineering by certain organizations.

Senator Blakemore moved Committee introduction.

Senator Ashworth seconded the motion.

Motion carried unanimously.

There being no further business, the meeting was adjourned at 5:30 p.m.

Respectfully submitted,

Betty Kalicki, Secretary

APPROVED:

Thomas R. C. Wilson, Chairman

*SB 231
**SB 230
† SB 234

SENATE Commerce and Labor COMMITTEE

GUEST LIST

ENERGY HEARING Room 131 DATE: February 12, 1979

NAME	AGENCY OR ORGANIZATION
[illegible]	DESERT OPTICAL
HAROLD MYERS	NEV BOARD. DISP OPTICIANS
DON WEATHERHEAD	Sec Nevada Assoc Disp Opticians
FRANK HIGDON	Nev Board of Disp Opticians
Walter Simmers	" " " "
CLARK GUILD, JR	SOUTHWEST GAS CORP.
Charles Lenzie	Nevada Power Company
Gene Mattenus	" "
[illegible]	Nevada State Med Assoc SB 145
James A. Gale	Nevada State Med. Assoc SB 137
David Rubsamen	
Nancy Myers	
Kelly Monaghan	Nev Welfare Division
Judith Isaacson	Nevada Board of Dispensing Opticians
Ernest Trindissi	AARP + Common Cause
Neil Laird	NRTA/AARP Nev Joint Legislative Committee
Saul K Marcher	AARP = Legion = NRTA =
ORVIS E. Reil	Chairman NRTA/AARP Nevada Joint State Legislative Committee
I. J. SANDORF	Chmn - Reno AARP Leg. Com. Mem. Advis Com. Div. of Aging
GILL BLONSLEY	Clark County Health District SB 145
John McSweeney	Aging Services
Richard D. Grundy, MD	President Nev State Board of Med Examiners
DARYL E. CAPURRO	NEVADA MOTOR TRANSPORT ASSOCIATION NEVADA FRANCHISED AUTO DEALERS ASSN.
Pat Gothberg	Nevada Nurses' Association, SB 137 SB 145
Ann M Gibbs	Nev Nurses' Assn

SENATE Commerce and Labor COMMITTEE

GUEST LIST

DATE: 2/12/79

NAME	AGENCY OR ORGANIZATION
Vincent P. Savage	SIERRA PACIFIC POWER CO.
Joe McKibben	" " "
FRANK L. TITUS	NEVADA STATE BOARD OF PHARMACY
GEORGE BENNETT	NEVADA STATE BOARD OF PHARMACY
STAN WARREN	NEVADA BELL
JOHN HOLMES	NEV. BELL
CHUCK KING	CENTRAL TELEPHONE CO.
Jim Flynn	The Upjohn Co.
Dan Hill	STATE OPTICIANS
Barry E. Gregson	Nev. Bankers Ass'n.

GUEST LIST - EXHIBIT A

PRESENT AND SPEAKING:
Senator Wilbur Faiss
Mr. John McSweeney, Department of Human Resources, Division of Aging Services
Mr. Orvis E. Reil, Chairman, National Retired Teachers' Association
James D. Pitts, M.D., Nevada State Medical Association
Ms. Pat Gothberg, Nevada Nurses' Association
Mr. I. J. Sandorf, Chairman, Reno American Association for Retired People
Mr. George Bennett, Secretary, Nevada State Board of Pharmacy
Ms. Dayle Berke, Attorney, Bureau of Consumer Protection, Federal Trade Commission
Ms. Katherine Laughlin, Chairman, Legislative Advisory Committee to the Aging
Mr. Ed Speegle, Manager, Government Affairs, Sandoz Pharmaceuticals
Robert Brown, M.D., Past President, Nevada State Medical Association
Mr. Heber Hardy, Chairman, Public Service Commission
Mr. H. Joe McKibben, Vice President, Finance, Sierra Pacific Power Company
Mr. Stan Warren, Nevada Bell
Mr. John Holmes, Nevada Bell
Mr. Charles King, Central Telephone Company
Mr. Charles Lindsey, Vice President, Finance, Nevada Power Company
Mr. Clark Guild, Jr., Southwest Gas Corporation
Mr. Victor Isaacson, President, Nevada Board of Dispensing Opticians
Mr. Don Hill, Nevada State Opticians' Association
Mr. Harold Myers, Secretary, Nevada Board of Dispensing Opticians
Mr. Ed Bostic, Vice President, State Association of Opticians
Mr. Walter Immers, State Association of Opticians
Mr. Frank Higdon, State Association of Opticians
Richard Grundy, M.D. President, Nevada Board of Medical Examiners
Mr. George Bennett, Secretary, Nevada State Board of Pharmacy

OTHERS PRESENT:
Mr. Don Weatherhead, Secretary, Nev. Association of Dispensing Opticians
Mr. Gene Matthews, Nevada Power Company
Mr. Jeff Monaghan, Nevada State Welfare Division
Mr. Gerald Prindiville, American Association of Retired Persons, and Common Cause
Ms. Nell Laird, Nevada Joint Legislative Committee on Aging, National Retired Teachers Association
Mr. Paul K. Gardner, American Association of Retired Persons, American Legion
Mr. Gill Blonsley, Clark County Health District
Mr. Daryl E. Capurro, Nevada Motor Transport Association
Ms. Ann M. Gibbs, Nevada Nurses' Association
Mr. Vincent P. Laveaga, Sierra Pacific Power Company
Mr. Frank L. Titus, Nevada State Board of Pharmacy
Mr. James Flynn, The Upjohn Company
Mr. George Vargas, Nevada Bankers' Association
Richard G. Pugh, M.D., Nevada State Medical Association
Mr. Fred Millerby, Nevada Hospital Association
Mr. Fred Mele, Ines Laboratories
Mr. David Rilsamen
Ms. Nancy Myers

EXHIBIT B

Subject: For the Record

S.B.# Relating to Drug Product Selection.

10 Feb.'79

Las Vegas, Nev.

To: Senator Spike Wilson, Chairman of the Senate Commerce Committee and Members of this Committee.

From: E. Floyd Butler, Chief Pharmacist, Sahara Rancho Pharmacy, Las Vegas, Nevada.

Representing: The Nevada Pharmacy State Association and the Nevada Pharmacy Guild, both chartered in the State of Nevada.

Gentlemen, A similar type Bill has already been introduced in the Assembly under AB 98, which is now in Committee and under extensive study and investigation. A Sub-Committee has also been appointed to insure that a fair and reasonable Bill on Drug Product Selection will ultimately be developed. The Nevada State Pharmacy Association and the Nevada Pharmacy Guild both favor the concept of Drug Product Selection. We have already pursued this objective at the first Hearing on AB 98, 1 Feb., 79. I personally have requested to meet with the Sub-Committee to offer new information and new evidence for discussion on Drug Product Selection. It was further agreed to by Assemblyman Tanner that he at least would be happy to receive more up-dated material on the subject before making any decision, and that he would convey my request to meet with the Sub-Committee at an early date. The combined efforts and further consideration of all of us in regard to Drug Product Selection will produce a Bill which, I feel, the Senate will approve the first time around. Let us continue our work on AB 98 without duplicity of effort and time on the Senate Bill dealing with the same subject. Your time can well be spent on other issues which indicates my recommendation to leave the Senate Bill in Committee at least until you see the results of AB 98. I would like to add that the Senate Bill on Drug Product Selection is a poor example in its present form of the entire subject. Not only is it contradictory, but it fails to meet very important guide lines suggested by the experts of a Model Drug Product Selection Bill. The Senate Bill would also be burdensome and too costly for the State Board of Pharmacy to enforce, and its context would require too many changes or amendments to be effective as a self supporting Bill. We want a Bill that will provide an economic incentive for all concerned, and not one that will prove as a disincentive for Pharmacists to resist.

Allow me to state, if you will, that there is a fundamental hazard in legislation of this type that could emerge from the efforts to develop a Model Drug Product Selection Bill. The profession of Pharmacy and Medicine embraces a delicate balance of science and art. Years of study followed by internship and practice uniquely equip these practitioners to serve the patient in a manner best suited to that patient's needs. Efforts to design Laws and Regulations governing the behavior of these professionals can easily result in denying the patient's benefits of the best skills and judgements of their Pharmacist and Physician. Some Drug Product Selection Bills allow little or no opportunity for professional judgement and artfull practice. We desire, at all costs, to avoid these errors of judgement in the Nevada Drug Product Selection Bill which has already resulted in other States.

I am indeed sorry that I could not be physically present to talk to this Committee today, and since that is the case I have imposed on Senator Wilbur Faiss to convey my respects and this presentation. My personal thanks to Senator Faiss for doing so, and to the Committee for listening. If at any time I can be of service, or if any of you feel it necessary to contact me for any reason concerning this Bill, call Sahara Rancho Pharmacy 384-4242,Las Vegas, Nevada.

Respectfully,

E. Floyd Butler Jr., B.S., Ph.G.

E. Floyd Butler Jr

PS. To the Secretary of this Committee Hearing:
Please send a copy to
E.Floyd Butler, Chief Pharmacist
Sahara Rancho Pharmacy
2300 Rancho Dr.
Las Vegas, Nevada 89102

EXHIBIT C

NATIONAL RETIRED TEACHERS ASSOCIATION

AMERICAN ASSOCIATION OF RETIRED PERSONS

NEVADA JOINT STATE LEGISLATIVE COMMITTEE

CHAIRMAN
Mr. Orvis E. Reil
424 E. Long Street
Carson City, NV 89701
(702) 882-1675

VICE CHAIRMAN
Mr. William D. McCullough
540 Avenue M
Boulder City, NV 89005
(702) 293-1774

SECRETARY
Mrs. Vivien Suiter
1905 Sunland Avenue
Las Vegas, NV 89106
(702) 382-2834

TESTIMONY PRESENTED TO THE SENATE COMMITTE ON COMMERCE AND LABOR ROOM 213

February 12, 1979 - 1:30 p.m.

by

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

EXHIBIT C

NRTA/AARP STATEMENT IN SUPPORT OF
STATE GENERIC DRUG SUBSTITUTION 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 members in Nevada.

This is the third session of the Nevada Legislature at which we have supported and requested a generic drug substitution law. Prior to Nevada's 1975 Session of the Legislature there were only 5 states with the commonly called the generic drug substitution laws. Four of those states have since amended and strengthened their laws and have been joined by 35 additional states, the District of Columbia and Puerto Rico. Now there are 40 states, the District of Columbia and Puerto Rico with generic drug substitution laws.

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 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 reason 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, skilled nursing facility or 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

EXHIBIT 8

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 environment. 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 greater 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 recovered 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 inportance 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's drug product but the one written by its brand name on the physician'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 these amendments became 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 manufaturers, even to this day.

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

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 markating.

Another common excuse of the big drug companies for excessive brand name drug prices and profits is their better quality. No duch 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 sustitution 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 particular manufacturer's product.

Not one of the 40 state 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 substitution 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 request substitution.
8. Permitting prescription forms with one printed 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 yo have attended that Conference. Although they were invited no one to may knowledge 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". 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 analyzing the questions related to the Generic Drug Substitution Laws. I have made two copies of the 17 pages and will give them to your committee but will not include them in my oral testimony.

We believe four minor changes in the text of Senate bill 137 would make it more workable.

Page 4a - Generic Drugs

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 examiners" from lines 30 and31 on page 2; the words " and the board of medical examiners" from line 36 on page 2; and on line 50 of page 2 change the word "PHYSICIAN" to PHARMACIST.

The following is results found in several of the states that now have subsitution laws.

(From a statement of Fred Wegner, Legislative Representative of NRTA/AARP before the 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.

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 Chiel 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

NATIONAL RETIRED TEACHERS ASSOCIATION

AMERICAN ASSOCIATION OF RETIRED PERSONS

NEVADA JOINT STATE LEGISLATIVE COMMITTEE

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Mr. Orvis E. Reil
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Boulder City, NV 89005
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SECRETARY
Mrs. Vivien Suiter
1905 Sunland Avenue
Las Vegas, NV 89106
(702) 382-2834

February 9, 1979

Senator Thomas R. C. Wilson, Chairman
Senate Committee on Commerce and Labor
Nevada State Legislature
Carson City, Nevada

Dear Senator Wilson:

Attached are 17 pages of material copied from a report, "Are Generics Safe?" The report was prepared by the New York State Assembly's Office of Legislative Oversight and Analysis for the First National Conference on Generic Drugs. The conference was held at the Mayflower Hotel, June 23-24, 1978.

I would like to submit the material in support of S.B. 137 and have referred to it in my oral testimony.

Respectfully,

Orvis E. Reil

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

OER/jb
Attach.

cc: John E. Jeffrey, Chairman
Assembly Committee on Commerce

EXHIBIT D

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.

NEW YORK STATE ASSEMBLY

COMMITTEE ON CONSUMER AFFAIRS AND PROTECTION

PUBLIC HEARING ON GENERIC DRUGS

May 31, 1977
10:00 A.M.

Two World Trade Center
New York, New York

BEFORE:

ASSEMBLYMAN HARVEY STRELZIN
Chairman

P r e s e n t:

WILLIAM HADDAD

* * *

THE CHAIRMAN: Good morning ladies and gentlemen.

My name is Harvey Strelzin and I am chairman of Consumer Affairs and Protection.

For 20 years the major drug manufacturers have successfully maintained that drugs prescribed under their generic names are ineffective and unsafe.

In that time they have spent billions of dollars to promulgate that untruth. They have co-opted and corrupted large segments of the medical profession and the medical media with these arguments.

Theirs was not a scientific concern. Theirs was a search and a reach for unwarranted profit based on the promulgation of these falsehoods.

What they have done, we are about to undo. It will not be an easy unwinding. It will take time and effort, and it will take the full cooperation of the public media.

What we must unwind is no less than a 20-year brainwashing of the medical profession.

Doctors who first learn of drugs by their generic names are slowly seduced by the drug industry's detail men -- the main channel for the flow of medical information -- and the drug industry's promotion campaign into believing that prescribing generically is unwise, unsafe, ineffective and

dangerous.

The busy doctor -- who cannot be completely obsolved of his role in this sordid matter -- has allowed himself to be seduced into writing prescriptions which cost their patients three to seven times as much for a drug as need be paid.

There were times when these differences ran as high as 400 percent. And there were times that vital medicines could not be used by the poor and the elderly because they could not afford them.

Today we will introduce into evidence a list of safe, effective and interchangeable drugs which should become the bible of all state agencies, all doctors and all pharmacists. Each manufacturer on that list has been approved by the Food and Drug Administration to produce, under inspection, a drug which is completely and safely interchangeable with the reference drug in its category.

This is the list the drug industry said did not exist. This is the list that the drug industry said could not be produced. This is the list which we have cold from the Food and Drug Administration and it has been certified by Dr. Donald Kennedy, the Commissioner of the Food and Drug Administration, as the certified list of safe, effective and interchangeable drugs.

We have our first witness today, Dr. Seife, who will testify to some of the monumental questions which will be posed to him and which will indicate for the first time that these drugs are safe, effective, interchangeable and they are generic

and may be used in the place of brand-name drugs.

To that end, we have through our director here, Bill Haddad, we were able to cull this list which has now been made available to the people of the State of New York, to the consumer and in accordance with the bill that was passed in the Assembly, which we hope will be passed in the New York State Senate, we will have a list -- a formulary -- set up by the Commissioner of Health of the State of New York which will be a compilation of these generic drugs which has been taken from the Food and Drug Administration and certified as safe and interchangeable.

Dr. Seife, will you please take the witness stand.

M A R V I N S E I F E, having been duly sworn by the Chairman, testified as follows:

EXAMINATION BY MR. HADDAD:

Q. Would you state your full name and your affiliation.

A. My name is Marvin Seife. I am a physician with the Food and Drug Administration in the capacity of Director of Generic Drug Monographs, Bureau of Drugs.

Q. Dr. Seife, have you reviewed this list of compilation?

A. Yes, very actively so.

Q. As you know, we plan to submit this to the industry and to all the companies mentioned and then back to the FDA for final purification to take out any typographical errors.

Within that context would it be fair to say that this list represents, in the first instance, two categories of prescription drugs, those which can be purchased from only one source and those which can be purchased from more than one source?

A. Yes.

Q. Let us focus for a moment on the multi-source drugs.

Is it true that each of these drugs is matched against a reference drug?

A. Yes.

Q. Is it true that each of the drugs listed is interchangeable with a reference drug?

A. Yes.

Q. Is it true that each of these drugs is safe?

A. Yes.

Q. Is it true that each of these drugs is effective?

A. Yes.

Q. Although we both recognize that the bioequivalent and bioavailability arguments have been misused by the drug industry to postpone the use of generics, is it not true that all of the drugs listed in group one on this list -- what the FDA calls the vast majority of the drugs -- are both bioequivalent and bioavailable, or in short, completely therapeutically identical?

A. Yes.

Q. Can a doctor be assured when he prescribes a certain drug and it is here, that it is interchangeable with its reference drug?

A. Yes.

Q. Can a pharmacist, if he were allowed to by law, safely substitute a generic product from this list for a trade name prescribed by the doctor?

A. Yes.

Q. This list includes both drugs and manufacturers.

Can you tell us if there is any difference in the way

generic manufacturer is monitored as compared to the way in which a trade-name manufacturer is monitored?

A. There is no difference whatsoever.

Q. Is it not a fact that some of the major drug companies are quietly using generic houses to produce their drugs?

A. I don't know how quietly, but they are doing it quite actively and and openly, at least, with our agency.

Q. Could you tell us some examples that you know of?

A. Well, Lederle Laboratories has a general line of up to 100 drugs. Most of these drugs are manufactured by smaller pharmaceutical firms. Another large company is Parke Davis, division of Warner Lambert which also has a generic line using brand names by obtaining these drugs from assorted smaller generic firms.

THE CHAIRMAN: Is it not a fact, doctor, that some of these large pharmaceutical houses retain the services of the small generic firms -- the small generic pharmaceutical houses -- put one of thier representatives in and pretend they are the manufacturer of these pharmaceuticals?

THE WITNESS: This is the worst abuse that I think occurs. The so-called man in the plant.

The man in the plant referring to a firm renting a plant for a week, two weeks or three weeks and having that man from that particular large firm be present while that particular drug is manufactured.

THE CHAIRMAN: In the smaller plant.

THE WITNESS: In the smaller plant.

THE CHAIRMAN: And putting their own brand name on it.

THE WITNESS: And putting their own brand name on it and marketing it under their brand name and stating that they manufactured said drug.

THE CHAIRMAN: In fact, the drug represents a generic drug manufactured by a small pharmaceutical house.

THE WITNESS: Absolutely.

MR. HADDAD: We brought it to the attention of the United States Senate investigators.

BY MR. HADDAD:

Q. Doctor, is it not a fact that the basic materials from which most drugs are made come in bulk form and are purchased by trade-name houses basically in the same manner as purchased by generic houses?

A. Yes, in fact many times the generic house buys their particular drug from the brand-name house, so that you have the same drug being made from the same raw materials.

For example, sulfisoxazole, which is called gantrisin is practically sold to every generic house in the country by Roche, the manufacturer of the brand name.

THE CHAIRMAN: And they are sold to the consumer at different prices.

THE WITNESS: Absolutely.

THE CHAIRMAN: The brand name at a much higher price.

THE WITNESS: The prices vary greatly.

BY MR. HADDAD:

Q. Doctor, how do you check to make sure that a manufacturer is producing safe and effective drugs?

EXHIBIT

Q. So you are saying that every antibiotic --

A. Every biologic and insulin is tested batch by batch by FDA and each firm pays a fee for this service.

Q. That is for the trade name and the generic?

A. Yes.

Q. Isn't it a fact that among the most widely prescribed drugs, particularly for young people, are the antibiotics?

A. Yes.

Q. And this is where the largest price differential has characteristically existed?

A. Frequently.

Let me make it clear: All antibiotics, all biological or insulin products are therapeutically equivalent, regardless of who makes them. Regardless of the fancy trade name or generic name. This has always been true. This has been true since the discovery of penicillin.

Q. How long is that, doctor?

A. That goes back to 1943 or 1944.

They didn't formulate the antibiotic preclearance regulations until about 1950. This has been going on for over 25 years.

Q. And we are basically in the two widely prescribed antibiotics today, tetracycline and ampicillin,and both of those are batch-tested?

A. Yes.

Q. And they have been for some time?

A. Yes.

If a firm does not have a batch of their antibiotics, and I don't care whether it's neomycin or any topical material, mixture, within a 24-month period, they are decertified. They are removed

If you would, would you start with the antibiotics which is group one of the vast majority of drugs and then on to group two which is only 84 dosages.

Could you tell us how you go about making sure that both the trade and generic names are safe, effective and interchangeable?
A. Let's dispense initially with the absolutely original new entity. That is a long, ongoing process which requires what we recall an IND, an investigative new drug application. When this is well along its way, a manufacturer submits a new drug application; the IND contains phase one which consists of detailed pharmacology studies in a small number of persons; phase two, studies are conducted on a limited number of patients with a specific disease, or for prevention; phase three studies involve extensive clinical trials in order to demonstrate reasonable assurance of safety and effectiveness.

Q. You headed that division at one time, didn't you?
A. Yes. That is a long process and it usually takes six years before you get an original brand new entity.

Getting down to the basic day to day, minute to minute used drugs, starting with antibiotics: The antibiotics are batch-certified. Every antibiotic firm or every firm that makes biologics or insulin must submit their material on a batch-to-batch basis for certification by FDA.

Q. Let me stop you for a moment.

Is there any more intricate way to test drugs in America than batch by batch?

A. No.

from the certification list and therefore, can no longer be sold.

Q. What is hard to get across is that this has been going on for some time and the price differentials that we have had in our surveys through the years represent several hundred percent differences between the trade name and the generic and has never been any difference, to your knowledge, if the company has batch-tested with FDA and there has never been any difference between those two products?

A. No

Q. Always interchangeable?

A. Always therapeutically equivalent.

THE CHAIRMAN: Let me ask you, doctor: You are talking about batches.

How many dosages of a particular drug is contained within a single batch as a rule on an average?

THE WITNESS: A tremendous number

THE CHAIRMAN: Several thousands of dosages?

THE WITNESS: Thousands of dosages.

BY MR. HADDAD:

Q. Would you continue on with the other --

A. Let's get on to the large number of nonantibiotic, nonbiological and noninsulin drugs.

These drugs, in order to be approved, precleared by FDA, must have labeling, immediate container labeling as prescribed by law that they are safe. They must have a package insert that is --

THE CHAIRMAN: Descriptive?

A. -- concluded by the FDA as showing both safety and efficacy and giving full information as to the use of the drug, the safe use of the

drug, et cetera. That is the initial step.

In the approval process we have the chemistry and manufacturing reviewed very carefully by the chemists.

Frequently on many of the drugs we request samples of the final finished dosage form and also of the raw material for validation by FDA laboratories.

If the material comes from overseas, we have international inspectors that travel throughout the world to check foreign plants. The only countries to my knowledge where pharmaceuticals are manufactured where our inspectors have not been are Red China and the Soviet Union.

The Soviet Union is anxious to trade with the United States in pharmaceuticals, but apparently suffer from some sort of paranoia refusing to allow our inspectors into their plants.

Our international inspectors have been to such countries as Poland; Hungary has a huge pharmaceutical industry -- Czechoslovakia, Yugoslavia, Bulgaria, Isreal, Western Europe and teams go to the Far East.

Q. You have the same methodology here as in the United States?
A. Absolutely. These firms must conform to our same current good manufacturing procedures that we require in this country of raw pharmaceutical manufacturers -- of both pharmaceutical manufacturers.

So we have a two-way check. We do not only check the final finished dosages for final pre-clearance, but we also check the plant where the final finished dosage form is made as to current good manufacturing procedures, as well as any satellite of that manufacturer.

There may be testing laboratories, laboratories that do analyses that are affiliated with the manufacturers and these places are checked by our inspectors.

EXHIBIT D

This goes into the approval process.

Q. In short, you are saying that this intricate process is identical for trade and generics.

A. In order to receive approval by the FDA, each firm must follow our regulations to the nth degree as spelled out. If they do not, they will not receive an approval.

Q. According to a recent court decision, the person who signs the application, if he lies in the application, he is criminally liable; is that correct?

A. Yes. This is the Park decision as determined by the Supreme Court. This happened to be a food case where Mr. Park, head of Acme foods, was repeatedly told of a filthy warehouse in Baltimore.

He was given a small fine and he was determined and he stated that he would fight the case to the Supreme Court, which he did. He was found guilty of being president of a firm that had a filthy warehouse and he suffered the consequences.

Q. Doctor, after you were a witness at our last hearing, a doctor of pharmacology presented us with what we felt was the basis for another investigation and startled us. He told us that trade-name drugs which are advertised widely by the drug companies under their trade names, that over a period of years there is an identity made with the trade-name product and the name of that product, and that there has been repeated instances which were brought to our attention where the ingredients of the trade-name product have been changed, and yet, the trade name has been allowed to stand on the bottle.

As far as the doctor was concerned, it was the same drug; is this true?

A. Yes.

Q. How does that occur?

A. Well, oftentimes the manufacturer might not notify the FDA, although they should. They usually notify us and because of work load or perhaps apathy on the part of our agency, the firm goes ahead and makes a change as an improvement. Oftentimes, the change really doesn't represent an improvement.

THE CHAIRMAN: They call it a new formulary, don't they?

THE WITNESS: A new formulation which may result in a variance of delivery of the drug to the body.

In other words, they change the excipients or infrequently omit or add an active ingredient. Incidentially USP-grade excipients must be used in all pharmaceuticals in this country.

By the way, in mentioning the approval procedures these firms must follow the United States Pharmacopeia monograph in manufacturing their product or the USP's newly acquired National Formulary monographs. If no public standard, monograph exists, we draft one, which is probably a lot more stringent than either of these bodies.

Q. But doctors are basically conditioned, it is almost like a conditioned reflex to prescribe a trade name based on medical advertising and detail men.

From what we can determine they frequently do not know that as many as three products have been changed, in one instance presented to us, and in several instances two out of three ingredients have been changed and the name stays the same. And, in his mind, it is what the original marketing suggested.

A. Well, apparently the firms in these instances have met with FDA and they have talked to certain division people who handle the drug and have convinced the firm to market the product under the same name, even though they have changed some of their ingredients.

Q. Would you let your superiors know that we will be looking to that.

One final question: Another part of the impending investigation which really distrubs us is in looking into the list that is here and reading medical journals, and these are all respected medical journals, and take the names of the drugs out of those journals and put it up against this list and many of the drugs in the medical journals are not on your list.

How do you account for that?

A. These are drugs that were put on the market without preclearance by the FDA. They are not contained in the validated material we gave to New York State nor have I seen any of these drugs in your publication.

For example, I will give you an awful example. I was asked the same question by Senator Kennedy and I will bring up this horror. This is one of the most widely prescribed drugs.

There is a drug call Pavabid.

Q. Spell it, please.

A. P-a-v-a-b-i-d.

I imagine by this time Mr. Ewing Kaufmann of Kansas City is very angry with me, but I was asked by Senator Kennedy how Pavabid was allowed to reamin -- or how did it get on the market and why was it still on the market.

Pavabid came into being after Mr. Kaufmann -- and that is two N's -- came to a company which is now defunct, known as NYSCO.

He requested several formulations; one called for a long acting nitroglycerin called Nitrobid and the other called for a long acting Papaverine called Pavabid.

He obtained these formulations and through his firm called Marion Laboratories of Kansas City proceeded to market those two products plus several others without preclearance by the FDA.

Within a matter of years these products developed a vast market. Many, many elderly patients receive Pavabid twice a day, supposedly to dilate the vessels of their brain.

It is very hard for me to understand how you can dilate a calcified pipe, a hardened artery of the brain of any human being, because to get dilatation you must have flexible smooth muscle tissue. Pavabid cannot act against hardened --

Q. The thing that bothers me about that is that these were ads of responsible trade-name companies at the time, advertising in medical journals, medical journals accepting those ads -- I checked it against your approved list and these drugs are not on the approved list.

Now, Pavabid -- Marion is a major company. Pavabid is a major drug. It is supposed to reduce senility, I would suspect.

I that the purpose of it?

A. Supposedly.

Q. It is on the market; is that widespread?

A. The very same drug called Cerespan, also a timed release Papavarine

EXHIBIT D

produced and marketed by USV which is owned by Revlon. There is no end to this. They put it on the market and they defy FDA to take action. FDA will gradually take action.

The Agency has published a Federal Register announcement concerning these timed release Papaverine preparations and requesting efficacy data for them.

Supposedly the firms are submitting such data. Meanwhile they get a free ride on the market for many years.

I would like to say, this whole thing, if it goes on television, Mr. Kaufmann, who owns the Kansas City Royals will probably buy two more ball-players. This is the big lie technique as perfected during World War II, namely, whether you say something good or bad, something good comes out of it for the firm.

Q. Doctor, one final question:

You have immediate family and you are a physician. I know you sneak away from the FDA to practice in a ward sometimes to keep up your profession.

A. Yes.

Q. Do you have any hesitation in prescribing for persons of your immediate family from that list?

A. No, none whatsoever.

THE CHAIRMAN: What is your feeling about requiring physicians in the State of New York, if it does become law, mandating them to prescribe generically?

THE WITNESS: It will be the ideal thing, the most ideal situation I can conceive of. It boggles my mind that any state would go this far and it would set a precedent for

the rest of the nation.

THE CHAIRMAN: Thank you very much.

This concludes our hearing this morning.

* * *

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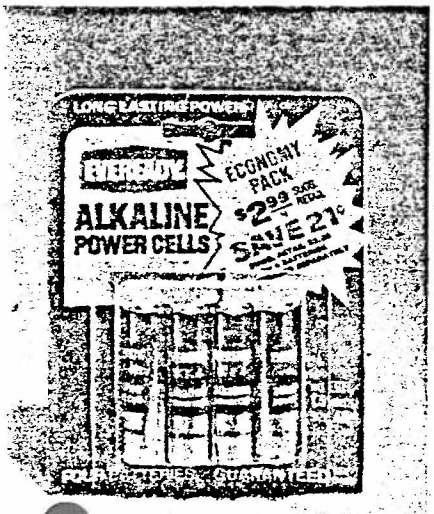

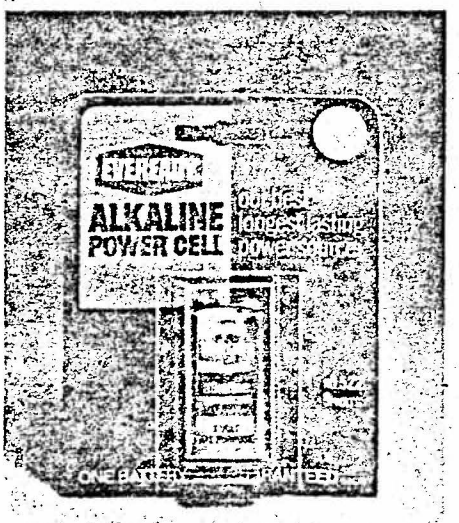

			NRTA-AARP
E91B	AA 1.5 volt	Sugg. Retail 2.99...4's	2.39
E522	9 volt	Sugg. Retail 1.89 1	1.49

ALL ABOUT OUR CUSTOMER SATISFACTION POLICY

You must be satisfied with every item we sell. If an item is not satisfactory when you receive it, return it. We'll exchange it or, if you prefer, refund the price or credit your account. Please include a copy of the invoice to facilitate proper handling.

In many cases you'll want time to evaluate your purchase . . . so use what you buy from us. If, after a reasonable period of time, you don't get the service you have a right to expect, just let us know what is wrong. Write or call and tell us what you want. We'll make every effort to correct what's wrong. If we cannot satisfy you, we'll make a proper adjustment in cash or credit.

This policy does not apply to prescription medications ordered by your physician.

These prices effective as of August 15, 1978. Prices subject to change without notice.

FUTURO THERMOLASTIC COMFORTERS

FOR THE HAND, ANKLE, KNEE AND ELBOW

Thermolastic: a totally new concept using retained body warmth plus mild compression to help soothe stiff and aching joints. Provides thermal compression for supportive comfort.

The soothing properties lie in the blending of basic fibers to achieve the specific benefit offered by each. Cashmere blended with lambs wool for extra strength and acrylic for body and softness. Hand washable.

ELBOW COMFORTER

Measure around elbow.

X3422—Small 9-10"
X3423—Medium 10¼-11"
X3425—Large 11¼-12"
X3426—X large 12¼-13"
List Price each 4.50

NRTA/AARP Price each 3.40

HAND COMFORTER

Measure around hand at knuckles.

X3432—Ladies' Up to 8"
X3435—Men's Over 8"
List Price each 8.95
NRTA/AARP Price each 6.75

KNEE COMFORTER

Measure around knee cap.

X3442—Small 10½-12½"
X3443—Medium 12¾-14½"
X3445—Large 14¾-16½"
X3446—X large 16¾-19½"
List Price each 4.50

NRTA/AARP Price each 3.40

ANKLE COMFORTER

Measure around ankle at smallest point.

X3452—Small 7-8"
X3453—Medium 8¼-9"
X3455—Large 9¼-10"
X3456—X large 10¼-11"
List Price each 3.95

NRTA/AARP Price each 3.00

COLOSTOMY PRODUCTS

Please check with your area Retired Persons Pharmacy Center for the many other Coloplast and Colostomy items not listed. Compare our low prices with what you are now paying—and save!

STOMAHESIVE—Squibb

Peristomal Covering

H995-1 4" x 4" Wafers ...5's 5.59
H996-1 8" x 8" Wafers ...3's 12.79

FUTURO HEALTH SUPPORTS

PRODUCT NO.	ITEM	PRICE
H057-0	#34 **KNEE BRACE DELUXE** 4 Way, X-Action, Natural Knee Action. Retail	5.65
	NRTA-AARP PRICE	4.23
H058-0	#44 **KNEE BRACE REGULAR** Won't slip, Firm support. Sizes: Small (10½-12½), Medium (12¾-14½), Large (14¾-16½). Retail	3.40
	NRTA-AARP PRICE	2.55
H017-0	#45 **ANKLE BRACE** Smooth, snug fit, good support. Sizes: Small (7"-8"), Medium (8¼"-9"), Large (9¼"-10"). Retail	2.50
	NRTA-AARP PRICE	1.89
H013-0	#47 **SACROILIAC BRACE** Relieves back pain caused by sacroiliac sprain. Allows freedom of movement without binding. Sizes: Small (30-35), Medium (35½-41), Large (41¼-46) Retail	10.50
	NRTA-AARP PRICE	7.39
H066-0	#48 **HERNIA AID** made for the common reducible, inguinal hernia, either left, right or double. Supports both sides. Sizes: Small (30-35"), Medium (35¼-41"), Large (41¼-46"). Retail	10.50
	NRTA-AARP PRICE	7.39
H003-0	#71 **V-GARD SUPPORTER** 3" Waist band, tubular leg straps. Retail	3.95
	NRTA-AARP PRICE	2.97
H004-0	#76 **WIDE BAND SUPPORTER** 6" Waist band, relieves fatigue. Elastic leg straps. Sizes: Small (26-32"), Medium (32¼-38"), Large 38¼-44") Retail	7.50
	NRTA-AARP PRICE	5.65
H059-0	#87 **SUSPENSORY** Elastic Waist, Small, Med., Lge. pouch sizes. No leg straps. Retail	2.95
	NRTA-AARP PRICE	2.21
H067-0	#23 **WRIST BRACE** Wrap around, adjustable one size. Retail	2.00
	NRTA-AARP PRICE	1.59

SANI-PAC

INCONTINENT PANTS

VELCRO closures create fully-sealed pants. No uncomfortable snaps. Fully washable, plastic coated rayon pants.

	WAIST	RETAIL	NRTA-AARP PRICE
S010-0	S (20-25)	8.49	6.39
S010-2	M (26-31)	8.49	6.39
S010-4	L (32-37)	8.49	6.39
S010-6	XL (38-44)	8.49	6.39

S011-0 Reusable Liner.
Contour-fit for your comfort. Preshrunk, triple-layered and super absorbent.
One size fits all.
Retail 7.39
NRTA-AARP Price 5.49

S012-0 Tape-II Super Liner, Disposable. One size fits all.
25's Retail 8.29
NRTA-AARP Price 6.19

Complete convertible system (one pants — one reusable liner—two disposable liners).
S013-0 Small (20-25)
S013-2 Medium (26-31)
S013-4 Large (32-37)
S013-6 X-Large (38-44)
Retail 12.95
NRTA-AARP Price 9.68

DISPOSABLE UNDERPADS

Super Absorbent — protects bedding from incontinence or drainage.

S024-2	(17½ x 24")	40s	6.29
S025-2	(17½ x 24")	3-40s	16.88
S026-2	(23 x 36")	20s	6.29
S028-2	(23 x 36")	3-20s	16.88

Coloplast

	ORDER SIZE	BAG SIZE	ADHESIVE AREA	OPENING	PRICE PER 100
H005-1	No. 1	5"x8"	3"x3"	15/16"	26.25
H006-1	No. 2	5½"x8"	3½"x4"	1 3/16"	26.25
H008-1	No. 3	6½"x10"	4¾"x4¾"	1 3/16"	31.25
H011-1	No. 1 Extra (odorproof)	5"x8"	3"x3"	15/16"	36.25
H012-1	No. 2 Extra (odorproof)	5½"x8"	3½"x4"	1 3/16"	37.50
H014-1	No. 3 Extra (odorproof)	6½"x10"	4¾"x4¾"	1 3/16"	38.75
H015-1	Karaya Rings			Per Tray of 12	4.49

ALL NRTA-AARP FORMULAS APPEAR IN RED

NEVADA STATE BOARD OF PHARMACY

SUGGESTED AMENDMENTS OF SB 137

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

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

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

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

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

SUGGESTED AMENDMENTS OF SB 137, Continued

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

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

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

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

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

These remarks represent the views of a member of the Federal Trade Commission staff. They are not intended to be, and should not be construed as, representative of an official Commission policy.

"The Model Drug Product Selection Act"

Presented by

Dayle Berke, Attorney
Bureau of Consumer Protection
Federal Trade Commission

Before the

Nevada State Legislature

Carson City, Nevada
February 12, 1979

I'm pleased to be here today, and would like to thank you for giving me the opportunity to discuss the findings and conclusions of the study on drug product selection (often also called generic drug substitution) conducted by the staff of the Federal Trade Commission. On January 9, the Federal Trade Commission released a Staff Report on Drug Product Selection, which included a jointly endorsed FTC-HEW Model Drug Product Selection Act. The Staff Report presents the findings of our two-year investigation of drug product selection. During the course of our investigation, we collected and analyzed numerous articles, dissertations and surveys. We solicited comments and supporting documentation from representatives of brand-name and generic manufacturers, consumers, pharmacists and physicians, and worked closely with officials in FDA and HEW. We hired consultants to estimate the economic impact of drug product selection. We also had IMS America, an independent market research firm, study seven states with different product selection laws (Arkansas, California, Delaware, Minnesota, Oregon, Pennsylvania, and Wisconsin) to help determine the provisions of state laws that most effectively encourage pharmacists to select low-cost generics.

As a result of this investigation, we developed, with the advice and support of the Food and Drug Administration, the model drug product selection law. This model law is intended to serve as a guide for state legislatures, such as Nevada, that are considering enacting drug product selection legislation.

Antisubstitution laws were first enacted in the 1950's, when a large number of "counterfeit" drugs, which resembled the popular brand-name products in appearance but often contained different active ingredients from unknown sources, were passed off to consumers through unwitting or unscrupulous pharmacists. All responsible members of the health care profession, as well as the general public, were outraged (new federal controls later virtually eliminated drug counterfeiting). Trading on this outrage, the major drug manufacturers led a highly successful effort to enact state antisubstitution laws. These laws were broader than necessary to assure their anticounterfeiting aims, specifically prohibiting pharmacists from dispensing, not only a different drug entity, but a different brand from the one prescribed.

Our investigation revealed that antisubstitution laws restrict price competition for drugs that have gone off patent and are now available from multiple sources. These laws thus impose unnecessary costs on consumers. They do so by preventing pharmacists from selecting the most cost-effective drug products for their patients. Studies show that most physicians readily admit that they have little or no knowledge of the prices of the drugs they prescribe. And they are more likely to underestimate than overestimate those prices. For example, one recent study asked physicians from a diversity of practices to rank their knowledge of drug prices on a scale from one (very informed) to five (uninformed). Over 32% of the responding physicians replied that they had "no idea" of the prices of commonly-prescribed drugs,

and over two-thirds of the remainder assessed themselves at a four of five. When the same study measured physicians' knowledge of the prices of drugs prescribed in their specialties it found that two and a half times as many physicians underestimated as overestimated the price.

The reason for this lack of price awareness is the lack of incentive for physicians to shop around for the least expensive drug products. Patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. In fact, probably only a small percentage of patients currently know enough about the availability and comparative prices of generic equivalents to ask their physicians to prescribe low-cost generics. Furthermore, it is time-consuming and therefore costly for busy 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. Economists in our Bureau of Economics noted that, in 1970, 30 of the largest drug manufacturers spent $682 million on drug promotion, an outlay of over $2400 per practicing physician. Not surprisingly, physicians write nearly 90% of their prescriptions by these heavily-promoted, easily-remembered brand names. For example, consider writing the generic name chlordiazepoxide hydrochloride rather than a brand called Librium. Also, consider whether you would be inclined to begin writing that same generic name if you

had written Librium for 12 or 15 years when, because of patent protection, there were no alternatives.

Brand prescribing has a special significance under antisubstitution laws. If the physician writes a prescription for a drug obtainable from different sources by a brand name, neither the pharmacist nor the patient can choose from among diversely priced equivalents. Thus, firms that succeed in familiarizing physicians with their brand-name products are insulated from the competition of lower-priced equivalents.

Prescription drugs now cost American consumers over nine billion dollars a year. A considerable portion of this expenditure could be saved if pharmacists were not unnecessarily restricted in their ability to substitute lower-cost generic equivalents for expensive brand-name drug products. Studies show that opening the prescription drug market to the forces of competition could save consumers hundreds of millions of dollars a year. Our Bureau of Economics staff estimates that drug product selection for 60 popular multisource drugs could save consumers as much as $340 million a year, and that the potential benefits from selection of lower-cost generic equivalents for all multisource drugs could be as much as $400 million a year. Other studies show comparable potential savings. For example, at our request the Pharmaceutical Manufacturers Association submitted a number of documents from its files. Several of these documents reported on a study prepared by IMS America for PMA on the estimated retail-priced savings from generic-prescribing for 37 multisource drugs. Although this

figure is more conservative than the savings from generic-dispensing since the more expensive brand may still be used to fill a generic prescription, the study nevertheless estimated a potential savings of $323 million a year.

Studies similiarly document the savings that actually result when drug product selection takes place. A Wayne State University study by Dr. Theodore Goldberg found a 17% savings in Wisconsin and a 20% savings in Michigan for substituted prescriptions. A Delaware prescription audit by Joseph Fink of the Philadelphia College of Pharmacy found savings of 30-60% on substituted prescriptions for 7 of 10 drugs studied. Just a few weeks ago, a prescription audit by researchers at the University of Florida reported a 32% savings in the retail price (nearly $2 per prescription) on substituted prescriptions in Florida -- a consumer savings of $425,000 in a 4-month period.

What effects could product selection have on consumers' medical bills in Nevada? The FTC's Bureau of Economics looked at the wholesale prices for sixty popular multisource drugs. Our economists compared the wholesale costs of the brand-name products with those of the generic equivalents. Based on their calculations, they estimated that pharmacists' selection of low-cost generic versions of these 60 drugs could save Nevada consumers as much as $622,000 a year. I'd like to give you several specific examples of the amount of cost savings that potentially could be provided to consumers if drug product selection were permitted. A recent survey conducted in Texas showed substantial differences in prices

of brand-name products and their generic equivalents. For example, Librium, the brand-name, was priced at $9.31 per 100, as opposed to its generic equivalent, chlordiazepoxide hydrochloride, which was $4.60 per 100. Hydrodiuril was priced at $7.15 per 100, while hydrochlorothiazide, the generic version, was $3.95 per hundred. Miltown was priced at $8.40 per 100, whereas the generic, meprobamate, was only $3.49 per 100.

Now that I've given you some idea of the kinds of savings that potentially could be realized from drug product selection, I'd like to explain the major elements of our model drug product selection law.

We designed the Model Act to be as simple and as self-enforcing as possible, to recognize the physician's control of patient therapy, and to minimize any regulatory intrusion into the pharmacist's management prerogatives.

1. Permissive Drug Product Selection

The Model Act permits but does not require the pharmacist to select a lower-cost equivalent drug product, whether that product is marketed under another brand name or under the generic name. We think that providing pharmacists an economic incentive to select low-cost products makes a mandatory law unnecessary. And we think that mandatory laws may be unworkable because pharmacists' resistance to such government intrusion may produce low rates of product selection unless costly enforcement efforts are undertaken.

For example, our survey found that pharmacists in Pennsylvania, which has a mandatory law, reported a significantly lower substitution rate than pharmacists in several other states (such as Delaware, Wisconsin, and California) that had permissive laws.

2. An FDA-Based Drug Formulary

The Model Act limits the pharmacist's selection to products determined by FDA to be therapeutically equivalent or to additional therapeutic equivalents listed by the appropriate state agency. The opinions of physicians and other professionals, and objective measurement indicate that pharmacists are qualified to select drug sources competently and efficiently. They have, of course, been selecting drug sources for generically-written prescriptions for years. However, since a relatively small but significant percentage of chemically equivalent drug products may not be therapeutically equivalent, the Model Act supplements pharmacists' decision-making by recommending use of a positive formulary (or drug list) based on an FDA list of therapeutic equivalents. FDA released its proposed list in January. I should note that 80% of the generic-name products designated by FDA as therapeutic equivalents are made by the same PMA companies who make most of the brand-name products. Studies also indicate that higher rates of product selection are associated with states that establish drug formularies. And the study conducted for the FTC showed that four times as many pharmacists preferred a positive formulary, listing substitutable drugs, as preferred a negative formulary, listing nonsubstitutable drugs.

3. Physician Assurance of Medical Necessity

The Model Act retains the absolute authority of the prescriber to insist upon a particular drug source he or she judges medically necessary. The Act requires simply that the physician who wants a brand-name product for a specific medical purpose take a second or two to handwrite "medically necessary" or similar words on the prescription. (This is the same language required by HEW's Maximum Allowable Cost program for Medicaid prescriptions.)

Studies show that only rarely do physicians find it necessary to handwrite the "medically necessary" legend. Pharmacists responding to our survey estimated that such indications appear on less than five percent of all prescriptions. We have chosen this approach -- requiring some affirmative action, however slight, to indicate that selection of a brand name is deliberate -- because studies show that it works better than the use of preprinted signature lines on the prescription. The use of preprinted forms is less likely to ensure that the decision to limit the prescription to an expensive brand-name represents a conscious decision that a particular drug source is medically necessary for that particular patient.

4. Cost Savings

The Model Act requires that the product selected be lower in cost than the brand prescribed, but does not require that the pharmacist pass on all the wholesale cost savings to the consumer.

Many states have tried to achieve the maximum savings possible by requiring pharmacists to pass on to consumers all wholesale cost savings. This appears on its face to be pro-consumer, but in practice is contrary to consumers' best interests. This provision means the pharmacist cannot profit by so much as a penny for costs that may be incurred in using his or her professional skills to search for, stock, and dispense lower-cost generics. Rather than encourage competition, mandatory pass-ons may provide an economic disincentive for pharmacist source selection. Our survey confirms that a substantial number of pharmacists, particularly pharmacy owners and managers, state that such provisions often deter them from selecting lower-cost generics. Mandatory pass-ons may be unworkable as well as unnecessary. It is difficult to specify the savings that must be passed on because pharmacists' pricing systems vary and because an actual event (the sale of the dispensed product) must be compared with a hypothetical event (the sale of the brand prescribed but not dispensed). To enforce and monitor pass-on provisions would require ascertaining the wholesale costs and retail prices of the prescribed and dispensed products at the time a particular selection occurred. This determination would certainly be costly and might be impossible.

The Model Act also requires that the consumer be notified when product selection occurs, thus alerting the consumer to expect to pay a lower charge. With the price information now available through advertising, the marketplace should work to ensure that

pharmacists pass on to consumers a large portion of the cost savings. Indeed, the recent University of Florida study indicates that, although Florida does not require pharmacists to pass on all wholesale cost savings, approximately 90% of that savings is passed on to the consumer.

5. Reassuring Pharmacists About Liability

Various studies show that pharmacists are concerned about the liability risks of product selection and that many are therefore deterred from selecting drug sources as often as they would otherwise. Yet our own computer-assisted search of reported cases and the responses of every brand-name manufacturer, trade association, and pharmacy insurer we contacted failed to identify any instance in which a pharmacist has been held liable for legally substituting a lower-cost generic or for selecting the source used to fill a generically-written prescription. Although pharmacists may be exercising their professional judgment more often in selecting the drug source, the nature of their activity remains the same as that involved in filling generically-written prescriptions -- an activity pharmacists have engaged in for years. Therefore we believe that statements concerning liability have been greatly exaggerated.

Our study also indicates that most pharmacists in states with provisions limiting or defining their liability for product selection apparently are unaware of the existence of those provisions. Therefore, we cannot determine whether such provisions

are effective in encouraging pharmacists to engage in product selection. We do think that pharmacists should be provided with objective information about professional liability. And the Model Act includes an optional provision assuring pharmacists that they incur no greater liability for drug product selection than they incur when filling generically-written prescriptions.

6. Education

Even the best product selection law will take time to become fully effective, as consumers and health professionals are informed of the benefits of generic drug products. Our Model Act requires that the pharmacist inform the patient when drug product selection occurs and further inform the patient of his or her right to instead insist upon the brand prescribed. Our study indicates that pharmacists engaging in drug product selection are spending more time with their patients. This increased communication affords the pharmacist the opportunity to help educate the consumer about cost-saving generic equivalents. Retail advertising is another means of providing consumer information. And the Model Act directs the appropriate state agency to provide for additional public information as necessary.

The Model Act thus provides at least as many safeguards as antisubstitution laws, and possibly more -- the use of an FDA list of therapeutic equivalents, the decision of the physician to permit product selection, the judgment of the pharmacist in selecting a lower-cost equivalent, and the acceptance by the patient

of the product selected. We believe that drug product selection laws that follow the principles of the Model Act will work to foster price competition and reduce drug costs without compromising the quality of health care.

We would like to commend your recognition of the importance of this issue. I hope that you will feel free to call on us in the future if you need further information or have any questions about our report. Thank you again for giving me the opportunity to speak here today.

Sierra Pacific Power Company

TESTIMONY OF H. JOE McKIBBEN, VICE PRESIDENT
FINANCE OF SIERRA PACIFIC POWER COMPANY,
BEFORE THE SENATE COMMITTEE ON COMMERCE AND LABOR,
IN OPPOSITION TO PROPOSED PROPOSAL SB 152

I first will review with you the time frame, under existing law, in obtaining rate relief in our general rate cases.

(A) Upon determination by Sierra that rate relief is necessary, the Company begins preparation of an application in accordance with Nevada Statues and Public Service Commission Rules and Regulations. This process takes a minimum of three months.

(B) Upon receipt of the filing, the Commission has 30 days to accept or reject the application. (NRS 704.110(2).)

(C) At the end of the 30-day period, the 150-day suspension period begins. (NRS 704.110(2).) Under normal conditions, an order is issued on or about the 150th day.

(D) Immediately following the order, the new rates are put into effect, however, 12 more months are required to collect the annual revenue increase granted by such order.

Therefore, it can readily be seen from the above that the elapsed time between the time of application preparation and full recovery of the resultant Public Service Commission order is about 21 months:

Pre-filing		3 months
Notice and Suspension Period		6 months
Revenue Recovery Period		12 months
	Total	21 months

Adding any more regulatory lag, as suggested by this proposed change in the statutes, could be harmful to the financial health of the utilities affected, and consequently more costly to the customers served.

The financial community is well aware of the Nevada Statutes affecting utilities, and it is my opinion that NRS 704.110(2) as it exists today has had a favorable effect on financial ratings and consequently financing costs for Nevada utilities--costs which are paid by the consumber. Obviously, Security Analysts and Rating Agencies are much more comfortable knowing that a Commission must render a decision within a certain time frame as opposed to having the ability to delay a decision indefinitely.

I am convinced that should this proposed statutory revision be adopted in any form, it would result in unnecessary increased costs to Nevada utilities which would have to be borne by the consumers.

Background Paper 79-11

GENERIC v. BRAND-NAME DRUGS

February 2, 1979

GENERIC v. BRAND-NAME DRUGS*

BACKGROUND

Prescription drug use in the United States has increased approximately 400 percent since 1950. Americans now purchase more than two billion prescriptions each year at an estimated cost of $10 billion. Per capita expenditures for drugs rose from $19 in 1960 to $45 in 1974. Persons over 65 years of age pay 25 percent ($103 per capita in 1974) of the nation's drug bill but comprise only 11 percent of the population. Many of them are on fixed incomes and Medicare covers only in-hospital prescriptions. In fact, according to a survey conducted by the National Center for Health Statistics, 75 percent of the 1.7 billion outpatient prescriptions in 1974 were paid for by the consumer.

There are several factors that influence the use and cost of prescription drugs: Promotion by the pharmaceutical industry, prescribing habits of physicians, anti-substitution laws, the public demand for drugs and inflation. In 1971, for example, drug manufacturing firms spent over $1 billion on promotional activities, including $700 million for retailing, $167 million for journal and direct mail advertising, and $150 million for convention displays, education seminars and so forth. In 1971, however, there were only 300,000 practicing physicians, meaning the industry spent $3,333 per physician.**

Prior to World War II the pharmaceutical industry supplied bulk medicinal chemicals to the pharmacist. He filled his own capsules, rolled his own pills and made his own liquid tinctures. Sulfa drugs were introduced in 1936 and their widespread use and the needs of the war effort revolutionized the industry following World War II. Research efforts to make drugs safer and more effective were increased and drugs, such as penicillin,

* Most drug products have three names: A chemical name which describes the drug product's chemical structure (an example is dextro 3-methoxy-N-methylmorphinan hydrobromide); a generic name, which is a simpler version of the chemical name, and is the name most commonly used in scientific literature (the generic name of the above example is dextromethorphan hydrobromide); and the brand-name which is assigned to the drug compound by the manufacturer to distinguish it from identical compounds made by other firms (the active agent in the product "Romilar", produced by Hoffman-LaRoche, Inc., is the above generic name).

** Mark C. Hornbrook, "Prescription Drugs: Problems for Public Policy," Current History. (May/June 1977), p. 220.

streptomycin and tranquilizers, were introduced. Another effect of the war was the military's need for drugs in finished, dosage form. The pharmacist no longer compounded the drugs. The trend was toward factory-made drugs, making the brand-name all important. By 1960, brand-name drugs constituted 94 percent of the prescription market.* Large-scale promotional campaigns became an integral part of the industry's activities. But many of the so-called "new" drugs were only new salts or minor molecular variations of existing drugs. The price of these drugs was very high and long-term drug therapy, which most elderly people needed, was nearly prohibitive.

Significant public criticism of the industry lead to hearings in December 1959 by the U.S. Senate Antitrust and Monopoly Subcommittee, under the chairmanship of Senator Estes Kefauver (D-Tennessee). The majority views, expressed in the subcommittee's final report, charged the industry with "unreasonably high prices, monopolistic restriction of the market, abuses of the patient privilege and excessive wastes of resources in their selling efforts." A bill was introduced to correct some of these alleged abuses; however, it did not pass. The subject was addressed again in 1962 following a set of unfortunate circumstances which occurred in several West European countries in 1959-60. Many babies were born with seal-like deformities of their arms and legs (phocomelia) as the result of a drug, thalidomide, taken by their mothers during pregnancy. In response to this, the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (1938) were passed by Congress in 1962. These amendments only addressed the safety and therapeutic value of prescription drugs.

By 1972 every state had enacted a drug anti-substitution law, which prohibited pharmacists from substituting a generic drug for a brand-name drug. These were passed in response to "counterfeit" drugs manufactured during the 1950's. Counterfeit drugs were duplicate products produced by a manufacturer who also made brand-name drugs. Manufacturers would encourage pharmacists to dispense the brand-name product and would also clandestinely produce a counterfeit drug which looked similar to the brand-name but was of unknown quality, content and origin. Unwitting or unscrupulous pharmacists would pass these on to the consumer. As a result, anti-substitution laws were passed (the Nevada state board of pharmacy promulgated an anti-substitution ruling in 1963).

* "Drug Product Selection," Staff Report to the Federal Trade Commission (hereinafter referred to as FTC Staff Report). January 1979, p. 145.

By the early 1970's the anti-substitution laws were questioned during the development of state Medicaid programs. Several states adopted welfare formulas imposing cost limits on the drug products listed in them and they encouraged prescribing and dispensing by generic, rather than brand-name. For example, the California Health and Welfare Agency in 1965 issued preprinted prescription forms that allowed pharmacists to dispense chemical equivalents when the prescription cost more than the stated maximum. The California Attorney General issued an opinion in 1965 stating that pharmacists who followed the preprinted statement did not violate the state's anti-substitution law. In addition, the American Pharmaceutical Association in 1970 called for the repeal of anti-substitution laws.*

GENERIC DRUGS ARE CHEAPER, BUT ARE THEY SAFE & EFFECTIVE?

Presently 40 states have drug product selection laws.** There are two overriding issues regarding the adoption of drug product selection laws: Does the consumer save by purchasing a generic drug instead of a brand name? Are generic drugs equivalent to brand-name drugs?

A study by the Federal Trade Commission's Bureau of Economics shows that the annual wholesale price savings could be between $400 and $500 million.*** In Michigan, a Wayne State University study matched the retail prices of actual substituted prescriptions with the retail prices of comparable nonsubstituted prescriptions for the same drug and estimated that the potential savings in Michigan could range from $11 to $15 million a year. If this were extrapolated nationwide, consumers could save from $260 to $450 million.**** There have been nine major studies which have tried to estimate consumer savings derived from drug product selection.***** While these studies differ in methodology, scope

* FTC Staff Report, p. 153.

** Alabama, Hawaii, Indiana, Louisiana, Mississippi, New York, Nevada, North Carolina (except for Medicaid), North Dakota, Texas and Wyoming do not have drug product selection laws.

*** FTC Staff Report, p. 196.

**** Ibid.

***** Ibid.

and findings, they do reach one conclusion: Drug product selection laws will result in substantial savings for the consumer. Finally, an independent study, conducted for the Pharmaceutical Manufacturers Association in 1974, found that brand-name prescriptions cost consumers 19 percent more than generic ones.*

However, the Wayne State Study, mentioned earlier, points out that Michigan's drug product selection law is reducing drug prices by only $200,000 a year instead of the potential $13.5 million. Pharmacists in Michigan attribute this to people with health insurance who have all but $2 of their prescriptions paid for, therefore, they request the doctor's prescription.**

The FTC, et. al., have found that the cause is related to the effectiveness of drug product selection laws. The Wayne State University study found an 18-20 percent rate of drug product selection in Wisconsin but only 1.5 percent in Michigan. One reason for this is that the law in Michigan was interpreted to require that the purchaser request a generic equivalent before the pharmacist could dispense it (Attorney General's opinion, February 5, 1975. This requirement was removed in 1977). The FTC conducted a similar study in 1978. They questioned 723 pharmacists in seven states (Arkansas, California, Delaware, Minnesota, Oregon, Pennsylvania, and Wisconsin) that had drug product selection laws. All the pharmacists said they were aware of the selection laws in their states, however, less than 30 percent said their stores' policy was to substitute when possible. (Two exceptions are Delaware and Wisconsin where 60 percent said they would substitute when possible.) In Pennsylvania, the only state surveyed that requires substitution, less than one-quarter of the pharmacists said they complied. (However, nearly 75 percent of the pharmacists thought that a selection law resulted in lower retail prices with the consumer saving an average of about 20 percent!***) Finally, in November 1978, the New York City Consumer Affairs Department visited 25 randomly selected pharmacies and found 13 were violating the substitution law and 27 of 74 pharmacies in the state failed to stock leading generic drugs. The New York Public Interest Research Group also reported that

* Ibid., p. 8.

** Wall Street Journal, December 7, 1978, p. 27.

*** FTC Staff Report, p. 190.

only 28 of the 60 pharmacies they checked supplied a generic drug when required.*

Are generic drugs equivalent to brand-name drugs? With the passage of the Pure Food and Drug Act, the United States Pharmacopeia (U.S.P.) and the National Formulary were recognized by the federal government as the official compendium for the U.S. The U.S.P. sets forth the standards of strength, quality and purity for drugs and admits a drug on the basis of its therapeutic value. There are three types of equivalence: Chemical equivalents, which are drug products with identical amounts of the same active drug ingredient; bioavailability (biological availability) which measures how fast and how much of the drug gets into the body or appears in the blood; and therapeutic equivalents which are two or more drugs that are equally effective in treating a particular disease state. Drug product selection laws can be implemented with or without a drug formulary (30 states do have a formulary). These formularies may be either positive, listing which drugs have a substitute, or negative, stating which drugs cannot be substituted because their therapeutic equivalence is questionable. New York, for example, has adopted a positive formulary (1978) of approximately 800 drugs which have been certified by the Food and Drug Administration as safe, effective and therapeutically equivalent.

In 1969, a report issued by the HEW Task Force on Prescription Drugs said that some instances of bioinequivalence among chemical equivalents did exist, but it had been "grossly exaggerated as a major hazard to the public health." In 1974, the Office of Technology Assessment (OTA) issued a major study on drug bioequivalence that has been cited by both opponents and proponents of drug product selection. One of the major conclusions of the study is: "Current standards and regulatory practices do not insure bioequivalence for drug products." This supports the industry's argument that not all drugs are alike and that generic drugs should not be substituted for higher quality brand-name drugs. In his testimony before a Senate Subcommittee on Health in 1974, C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association, said that the FDA does not have the capability and/or the resources to assure the equivalence of marketed drugs. Based on OTA's conclusion, he says the problem of drug inequivalence is real; it is serious, and equivalency cannot be assured until new stringent criteria are met.

* New York Times, December 26, 1978, p. B-1.

However, OTA also concluded: "It is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products." The chairman of the OTA panel, Dr. Robert W. Berliner, said that "It is very important to point out * * * that two drugs may differ in bioavailability, that is be bio-inequivalent, but may still be therapeutically equivalent."*

Finally, Eli Lilly and Company released a study in 1978 that found prescription drug recalls were as much as seven times higher for products from companies that do little research (implying the generic drug manufacturers), than for the larger, research intensive brand-name companies. However, FDA's Commissioner Donald Kennedy said before a Senate subcommittee that the FDA's analysis of drug samples has shown "no evidence of widespread difference between the products of large and small firms, or between brand-name and generic name products."** Kennedy also pointed out that a major firm, that has had numerous recalls, was omitted from the Lilly study and that it emphasized products not listed by the FDA as therapeutically equivalent.

THE MODEL DRUG PRODUCT SELECTION ACT

In an effort to encourage and assist states in amending their laws to promote drug product selection, the Federal Trade Commission and HEW have designed a model drug product selection act. Its major provisions are: Pharmacists are allowed to select a lower cost generic drug from a positive formulary, listing drugs that are therapeutically equivalent according to the FDA. Physicians can prohibit drug product selection, pharmacists will share the savings with the consumer (an incentive for pharmacists to use generic drugs), customers can choose whether or not they want less expensive generic drugs, and an optional provision to assure pharmacists that there is no greater liability for using generic drugs instead of brand-name. Presently HEW has a program designed to ensure against the government paying more in reimbursement for drugs under Medicaid than is necessary. The Maximum Allowable Cost (MAC) Program began in 1973 and encourages the use of generic drugs. It has thus far established price maximums for only five drugs of various strengths and dosage forms.

* Statement before Senate Subcommittee on Monopoly, as found in FTC Staff Report, p. 238.

** Annabel Hecht, "Generic Drugs: How Good Are They?" FDA Consumer, (Febrary 1978), p. 19.

GENERIC DRUG LEGISLATION IN NEVADA

Identical drug product selection bills, A.B. 436 and A.B. 204, were introduced in the Nevada Assembly in 1975 and 1977, respectively (both of these bills died in committee). Those two bills would have allowed a pharmacist to substitute a generic drug for a brand-name drug except when the physician specified otherwise. The cost of the drug was to be reduced by at least the difference between the wholesale price for the brand-name drug and the generic drug. The hearings held in 1975 on A.B. 436 generally followed the argument outlined above: Generic drugs are cheaper but they may not be therapeutically or biologically equivalent. For example, the Consumer League of Nevada conducted a survey in 1972 and found that identical doses of the same drug varied in price by as much as 567 percent. Representatives of the league thought a drug substitution law would certainly reduce prescription prices. A representative of Northern Nevada Pharmacists said that the quality of generic drugs cannot be ensured; therefore, substitution should not be allowed.

SUMMARY

The price of health care has risen sharply. Between 1960 and 1970 the Consumer Price Index (CPI) for medical care increased 50 percent. Prescription drug prices rose sharply during the late sixties and early seventies. They accounted for 10 percent of the nation's health care dollars during this period. The prescription price component steadily increased to 14 percent of health care dollars between 1970 and 1976. Prescription drugs have become much more expensive.

Efforts to reduce the price of prescription drugs through substitution laws have been partially successful. They have not reached the ultimate goal, as seen in Michigan, but they have had an impact. The FTC estimates that the potential consumer savings from drug product selection in Nevada (using 60 drugs*) would be $622,000.** Whether or not generic and brand-name drugs are equivalent is still a highly controversial issue. Should Congress pass a new drug regulatory act in 1979, which seems likely, the FDA will issue a drug formulary which is the result of lengthy and intensive research.

* 60 randomly chosen multisource brand-name drugs from a dollar volume ranking of the leading 200 prescription drugs.

** FTC Staff Report, p. 206.

Two recommendations for a drug product selection law to be effective and successful are: (1) Posting of generic and brand-name prices which will make the consumer aware of price differences and more likely to ask for the generic drug, and (2) Part of the savings which result from the use of substitutions should be passed on to the pharmacist as an incentive to dispense generic drugs.

SUGGESTED READING

(Available In The Research Library Except As Noted.)

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Goldsmith, Lee. "More States Adopt Generic Substitution Laws," The Journal of Legal Medicine. Vol. 5 (October 1977), pp. 31-2.

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"Pricing of Drugs, 1977," Report of the Committee on Human Resources, Subcommittee on Health and Scientific Research and the Committee on the Judiciary, Subcommittee on Antitrust and Monopolies, U. S. Senate, 95th Congress, 1st Session, July 14, 1977. (Available through University of Nevada-Reno Library.)

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Statement by Joseph A. Califano, Jr., Secretary of Health, Education and Welfare, January 9, 1979.

S. B. 137

SENATE BILL NO. 137—SENATORS FAISS AND ECHOLS

JANUARY 29, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Requires substitution of less expensive drugs under certain circumstances when drugs designated by trade or brand name are prescribed. (BDR 54-145)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: Yes.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to pharmacists and pharmacy; requiring the substitution of less expensive drugs under certain circumstances when drugs designated by a trade or brand name are prescribed; requiring certain formularies of drugs; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 639 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 12, inclusive, of this act.

SEC. 2. *"Generically equivalent drug" means a drug having the same active chemical ingredients, finished dosage form and strength as a particular drug designated by a trade or brand name.*

SEC. 3. *1. Except as provided in subsection 2, a registered pharmacist who is requested to fill a prescription for a drug designated by a trade or brand name shall fill the prescription with a less expensive generically equivalent drug that is:*

(a) Listed in the formulary required by section 6 of this act; and

(b) Distributed by a person doing business in the United States and subject to service of process.

2. A registered pharmacist shall not fill a prescription for a drug designated by a trade or brand name with a generically equivalent drug if:

(a) The purchaser requests him not to substitute the generically equivalent drug;

(b) The person prescribing the drug:

(1) Writes the words "medically necessary" in his own handwriting on the prescription; or

(2) If the prescription is oral, expressly states to the pharmacist that the drug designated by a trade or brand name is medically necessary.

SEC. 4. *If a prescription is for a generic drug, the pharmacist shall fill*

SENATE BILL NO. 138—COMMITTEE ON HUMAN RESOURCES AND FACILITIES

JANUARY 29, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Changes amount in vocational rehabilitation revolving fund. (BDR 53-421)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: Contains Appropriation.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to vocational rehabilitation; increasing the amount in the vocational rehabilitation revolving fund; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. NRS 615.255 is hereby amended to read as follows:

615.255 1. There is hereby created the vocational rehabilitation revolving fund in the amount of [$10,000] *$50,000* to be used for the payment of claims of [clients] *applicants for or recipients of services from the bureau* and vendors providing services to [clients] *those applicants or recipients* under procedures established by the bureau.

2. Upon written request from the chief, the state controller [is authorized and directed to] *shall* draw his warrant from [funds] *money* already appropriated in favor of the chief in the sum of [$5,000, and upon presentation of the same to the state treasurer, the state treasurer is authorized and directed to pay the same from the general fund in the state treasury.] *$40,000*. When the warrant is paid, the chief shall deposit the [$5,000] *$40,000* in a bank [of reputable standing.] *qualified to receive deposits of public money as provided by law*. The bank [shall] *must* secure the deposit with a depository bond satisfactory to the state board of examiners, unless it is otherwise secured by the Federal Deposit Insurance Corporation.

3. After expenditure of money from the revolving fund, the chief shall present a claim to the state board of examiners. [to be passed upon as other claims against the state.] When approved by the state board of examiners, the state controller shall draw his warrant in the amount of [such] *the* claim in favor of the vocational rehabilitation revolving fund,

SENATE BILL NO. 145—COMMITTEE ON HUMAN RESOURCES AND FACILITIES

JANUARY 30, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Permits registered nurses to perform additional functions under certain circumstances. (BDR 54-530)
FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to nursing; expanding the scope of services which may be performed by registered nurses; authorizing the state board of pharmacy to issue registration certificates to registered nurses for the prescription, possession, administration and dispensing of controlled substances, poisons, dangerous drugs and devices; providing for registration fees; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 632 of NRS is hereby amended by adding thereto a new section which shall read as follows:

A registered nurse may provide under special circumstances defined by regulation of the board those nursing services which generally require additional education and training.

SEC. 2. Chapter 639 of NRS is hereby amended by adding thereto the provisions set forth as sections 3 and 4 of this act.

SEC. 3. *The board may adopt such regulations as may be necessary to ensure that proper and adequate safeguards, including dispensing procedures, are followed to protect registered nurses who provide the nursing services described in section 4 of this act.*

SEC. 4. *1. A registered nurse may, if authorized by the board, prescribe, possess, administer or dispense controlled substances, poisons, dangerous drugs or devices in or out of the presence of a physician but only to the extent and subject to the limitations specified by the state board of nursing.*

2. Each registered nurse who is authorized by the state board of nursing to prescribe, possess, administer or dispense controlled substances, poisons, dangerous drugs or devices must apply for and obtain

SENATE BILL NO. 152—SENATOR NEAL

JANUARY 30, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Removes time limit for suspension of certain schedules by public service commission of Nevada. (BDR 58-287)
FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to regulation of public utilities; removing time limit for suspension of certain schedules by the public service commission of Nevada; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. NRS 704.110 is hereby amended to read as follows:

704.110 1. Whenever there is filed with the commission any schedule stating a new or revised individual or joint rate, fare or charge, or any new or revised individual or joint regulation or practice affecting any rate, fare or charge, or any schedule resulting in a discontinuance, modification or restriction of service, the commission may, either upon complaint or upon its own motion without compliant, at once, and if it so orders, without answer or formal pleading by the interested utility or utilities, enter upon an investigation or, upon reasonable notice, enter upon a hearing concerning the propriety of such rate, fare, charge, classification, regulation, discontinuance, modification, restriction or practice.

2. Pending the investigation or hearing and the decision thereon, the commission, upon delivering to the utility or utilities affected thereby a statement in writing of its reasons for the suspension, may suspend the operation of such schedule and defer the use of the rate, fare, charge, classification, regulation, discontinuance, modification, restriction or practice. [, but not for a longer period than 150 days beyond the time when the rate, fare, charge, classification, regulation, discontinuance, modification, restriction or practice would otherwise go into effect.]

3. Whenever there is filed with the commission any schedule stating an increased individual or joint rate, fare or charge for service or equipment, the public utility shall submit with its application a statement showing the recorded results of revenues, expenses, investments and costs of

SENATE BILL NO. 170—COMMITTEE ON COMMERCE AND LABOR

FEBRUARY 1, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Enables board of hearing aid specialists to establish continuing educational requirements for its licensees and prohibits unlicensed persons from engaging in business of hearing aid specialist. (BDR 54-273)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to hearing aid specialists; enabling the board of hearing aid specialists to establish requirements for the continuing education of its licensees; prohibiting any person who is not licensed from engaging in the business of a hearing aid specialist; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. NRS 637A.110 is hereby amended to read as follows:

637A.110 The board may:

1. Appoint a technical, clerical and operational staff as may be required, from the classified personnel of the State of Nevada, under the provisions of chapter 284 of NRS. The number of the staff appointed [shall] *must* be limited by the [funds] *money* available for [such] *that* purpose in the hearing aid licensing fund.

2. Grant or refuse licenses after examination and revoke or suspend [the same] *them* for any of the causes specified in this chapter. [pursuant to the Nevada Administrative Procedure Act.]

3. Administer oaths, take depositions, issue subpenas and take testimony for the purpose of any hearing authorized by this chapter.

4. Establish reasonable educational requirements for applicants [.] *and apprentices and reasonable requirements for the continuing education of licensees.*

SEC. 2. NRS 637A.200 is hereby amended to read as follows:

637A.200 1. Licenses [shall] expire on June 30 next following the date of issuance.

2. [Licenses may be renewed for 1 year from each succeeding July 1, upon payment of the annual license fee prescribed in NRS 637A.210.]

SENATE BILL NO. 172—COMMITTEE ON COMMERCE AND LABOR

FEBRUARY 1, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Revises laws regulating dispensing opticians. (BDR 54-270)
FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to dispensing opticians; providing for special certification of persons who fit contact lenses; providing for an application fee for registering apprentices and for increases in certain other fees; providing for injunctions; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. NRS 637.020 is hereby amended to read as follows:

637.020 In this chapter, unless the context otherwise requires:

1. [“Apprentice dispensing optician” means a person receiving practical training and experience in ophthalmic dispensing in accordance with regulations established by the board.

2.] “Board” means the board of [dispensing opticians.

3. “Dispensing optician”] *ophthalmic dispensers.*

2. “Ophthalmic dispenser” means a person engaged in the practice of ophthalmic dispensing.

[4. “Licensed physician, surgeon or optometrist” means a person licensed by the respective state board having jurisdiction thereof.

5.] *3.* “Ophthalmic dispensing” means the [practice of filling prescriptions of licensed physicians, surgeons or optometrists, and includes the taking of facial measurements, fitting and adjustment of lenses or frames, duplication of lenses, and the measurement, fitting or adaptation of contact lenses to the human eye under the direction and supervision of a physician or surgeon.

6.] *Design, verification and delivery to the intended wearer of lenses, frames and other specially fabricated optical devices upon prescription. The term includes:*

(a) Prescription analysis and interpretation;