HB 584

"An Act relating to substitution of prescription drugs by pharmacists."

1/15/76

COMMITTEE REPORT

JUDICIARY

HOUSE

Mr. Speaker: Date _____

The Committee on COMMERCE has had HB 524 under consideration. A Majority of the members of the Committee

( ) recommends it DO PASS

( ) recommends it DO NOT PASS

( ) recommends it DO PASS WITH ATTACH. AMENDMENT(S)

( ) recommends it BE REPLACED WITH CS FOR _____ AND THAT CS FOR _____ DO PASS

( ) "and" recommends it BE REFERRED TO THE _____ COMMITTEE

( ) reports it back WITHOUT RECOMMENDATION

( ) "other"

Members signing the Majority report:

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

Members NOT concurring in the Majority report:

_____ recommends:

_____ recommends:

_____ recommends:

_____ recommends:

_____ recommends:

_____ Chairman

February 10, 1976

Raymond T. Bonner
Consumers Union
433 Turk Street
San Francisco, Ca. 94102

Dear Ray:

I am writing to let you know that our bill permitting generic substitution has passed its first test and gotten through the House Commerce Committee. At the same time, I have forwarded your suggestions on the bill to the House Judiciary Committee and I am sure they will be incorporated in the bill.

You will be pleased to hear that we were able to tack on a price-posting requirement as well, because one of our members thought to mention the price list she had seen in a California pharmacy.

I am enclosing a copy of the committee substitute that we passed.

Thank you for the editorial. I have sent a copy to Carol Larsen so that she may forward it personally to one of the Anchorage newspapers. I also appreciate the other articles. You will be interested to know that Representative Bradley, for whom I work, introduced a bill last year on the subject of item price labeling.

Sincerely,

Terry Berman
Administrative Assistant
House Commerce Committee

Enclosure

THE LEGISLATURE OF THE STATE OF ALASKA
FISCAL NOTE
Second Session - Ninth Legislature

I. REQUEST
Bill No. CS House Bill 584
Title: An Act relating to substitution of prescription drugs by pharmacis
Requested by: _____ Date: February 4, 1976
Return Date Requested: _____
Agency: Commerce Program: Licensing of Professions

II. FISCAL DETAIL
Budget Request Unit(s) Affected: Regulating and Licensing of Professions

A. EXPENDITURES: (Thousands of dollars)

	OBJECT	FY 76	FY 77	FY 78	FY 79	FY 80	FY 81
100	PERSONAL SERVICES						
200	TRAVEL						
300	CONTRACTUAL	.3	.3	.4	.4	.5	.5
400	COMMODITIES						
500	EQUIPMENT						
600	LAND & STRUCTURES						
700	GRANTS, CLAIMS, ETC.						
	TOTAL	.3	.3	.4	.4	.5	.5

B. FUNDING: (Thousands of dollars)

GENERAL FUND	.3	.3	.4	.4	.5	.5
FEDERAL FUNDS						
OTHER						

C. POSITIONS:

PERMANENT/TEMPORARY	0/0	/	/	/	/	/
MAN MONTHS (P./T.)	/	/	/	/	/	/

III. ANALYSIS (See Fiscal Note Preparation Instructions, Section III)

Assumes printing 200 12" x 18" signs on poster board and mailing same per year. Assumes 10% inflation and an effective date before July 1, 1976.

IV. ATTACHMENTS

V. DATE: February 4, 1976 PREPARED BY: Sharon Andrew, Director

Original: Legislative Finance
cc: Budget and Management
Prime Sponsor (First Legislator Named)

H/S 50

Rodman Wilson, M.D.
Hilton Hotel, Room 710
Alaska State Medical Association

Suggested Substitute Language
for
HB 584

For Act Entitled: An Act relating to substitution and labeling of prescription drugs by pharmacists.

Section 1. AS 08.80.290 and AS 08.80.295 are repealed and re-enacted to read:

Sec. 08.80.290 SUBSTITUTION. In billing a prescription a pharmacist shall supply a patient with the least expensive product he has in stock so long as it has the same dosage form and therapeutic effect as the drug prescribed by the physician, osteopathic physician, dentist, or veterinarian; except that:

(1) A prescriber may specify orally or in writing but not by stamping or preprinting on prescription forms, that no substitution is permitted, and

(2) A patient or his surrogate may instruct the pharmacist orally or in writing that he does not want substitution.

Sec. 08.80.295 AFFIXING OF LABEL. At the time of dispensing a prescription there shall be affixed to the container of a prescription a label bearing the name, address, and telephone number of the pharmacy filling the prescription, the date, the serial number of the prescription, the name of the patient, the name and instructions of the prescriber, the initials of the registered pharmacist who prepared the prescription, and the name and strength of the drug contained in it unless a physician, osteopathic physician, dentist, or veterinarian specifies orally or in

writing, but not by stamping or preprinting on prescription forms, that the name and strength not appear on the container. When a drug name is affixed, the name shall be as follows:

(1) As prescribed if no substitution has been made under Sec.290 of this chapter.

(2) Generic name and either brand or manufacturer's name if a single drug agent is prescribed by brand name and a substitution has been made under Sec. 290 of this chapter.

(3) Brand name or generic names or common abbreviations if substitution is made under Sec. 290 of this chapter for a product containing a mixture of pharmacologically active substances.

(4) "Dr (name)'s mixture" if a mixture of drugs does not have a name.

Sec. 08.80.310 is repealed and re-enacted to read:

The Commissioner of Health and Social Services shall publish a formulary of generic drug types and drug products which the Commissioner of Health and Social Services determines demonstrates clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication. No pharmacist shall dispense a generically equivalent drug product if the drug product and its generic drug type is included in the formulary.

Sec. 2. AS 08.80.460 is amended by adding a new subsection to read:

(b) a person who violates the provisions of Sec. 290 or Sec. 295 of this chapter is punishable by a civil fine in an amount established by the Board in a schedule or schedules establishing

the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the Board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in the Administrative Procedures Act (AS 44.62).

Sec. 08.80.480 is amended by adding:

(20) "brand name" means the proprietary or trade name of a drug product.

(21) "generic name" means the official name of a drug as listed in nationally recognized pharmacopoeias.

HB 584

January 27, 1976

Mr. Raymond Bonner
Consumer's Union
433 Turk Street
San Francisco, California 94102

Dear Mr. Bonner:

I am enclosing a copy of the bill presently before the House Commerce Committee. Please feel free to offer criticism. A bill, identical in form except for the inclusion of a formulary, was introduced in the Senate.

If you can send some sort of signed letter to us, I will attach that to a revised copy of the testimony presented in California and present it to the Committee.

Thanks for your help.

Sincerely,

Terry Berman, Administrative Assistant
House Commerce Committee

January 21, 1976

MEMORANDUM

TO: Bob Bradley

FROM: Terry Berman

SUBJECT: HB 584, Major points on substitution of generic drugs for brand-name prescription

1) The generic drug is always cheaper than the brand-name drug even though they may be identical. Also there is no justification that a brand name drug is necessarily a better product. A good example is ampicillin manufactured by Bristol Laboratories, which is distributed by four firms. The disparities in price among the four is astonishing. Bristol, which distributes ampicillin under the name Polycillin, wholesales for $18.24. Smith, Kline, and French distributes the ampicillin manufactured by Bristol at the price of $12.00. ICN Pharmaceuticals distributes Bristol's ampicillin through its brand-name division for$14.80 and through its generic division for $7.50. Note the differential between $7.50 and $18.24.

2) In answer to the argument that chemically equivalent drugs are not necessarily bioequivalent (meaning that when administered in same amount they do not provide the same therapeutic effect), the Department of Health, Education, and Welfare's report from the Task Force on Prescription Drugs stated that only in rare instances would equivalent drug products not produce the same therapeutic effects. A U.S. Senate committee concluded the same. HB 584 (Committee Substitute) has two provisions that respond to this problem of inequivalency. First, the physician can always specify that there be no substitution. Second, the Commissioner of Health, Education and Social Services will draw up a formulary specifying which drugs are and are not bioequivalents.

3) Giving the pharmacist some discretion takes into account his extensive training and his knowledge of drug products, which in some instances may be greater than other health professionals. Physicians lack drug price comparison data which would allow them to chose the best drug at the lowest available price.

4) People over 65 account for 25 per cent of the retail drug expenditures. On prescriptions to the elderly, the average cost per prescription is $3.91. For brand names alone the average cost per prescription is $4.11 while generic name prescriptions average $2.02.

5) There are 11 states with legislation permitting substitution: Arizona, Kentucky, Arkansas, Oregon, Minnesota, Connecticut, Michigan Maine, Massachusetts, Florida, and Maryland.

6) Groups that have endorsed such legislation: American Pharmaceutical Association, American Journal of Pharmacy, National Academy of Sciences, Consumers Union and HEW Special Task Force.

7) Hospitals use generic name products.

HOUSE COMMERCE COMMITTEE
January 21, 1976

House Bill 584

The meeting was called to order by Chairman Bob Bradley noting that a quorum was present.

Ronald Sedgewick, owner of Ron's Apothecary and a member of the Alaska Pharmacy Association began the testimony on House Bill 584. He stated that he basically had no problems with the bill itself. He did, however, feel uncomfortable with some sections and wished to express them at this time. Section C concerning the posting of a sign was a good idea and was intended for the consumer's benefit. It does, however, offend the professional standards. If a sign was posted it indicates dishonesty in the past. Section E pertaining to the physician using the generic name and the pharmacist must then issue the drug which is the lowest priced. He felt that often the lowest priced drug is not the best and would not select such a drug for his own family. He felt it should be left up to the pharmacist to select the best drug and still give the customer the best deal.

Chairman Bradley stated that Section 1 08.80.205 might answer the objection to Section E. That section gives the pharmacist the option of using his professional judgement.

Mr. Sedgwick felt that the section should be eliminated due to the option the physician has in writing the prescription. He continued stating that in Section G pertaining to labeling was also not necessary due to how the law presently is. He did suggest that an addition be made under that section. The addition being the name and quantity of the drug for the purpose of emergency care. Hospitals often refer to him for the quantity of the drug he issued and this would make it easier on hospital personnel. The Section which states that the Department of Health and Social Services was to provide a formulary seemed unrealistic. The department does not have the resources to provide such a formulary. The Federal department has been working on a list for the last three years and the department would probably have to issue the Federal list.

Rep. Urion questioned whether or not it was typical of pharmacists to stock all brand names of one drug.

Mr. Sedgwick stated there are a number of multiple drugs. They are now able to select from major companies with price in mind. He again stated that price should not be the only criteria, the best drug at a lower price.

Mr. Jim McCorcle, owner of Harry Race Drug Store, stated he was representing the Alaska Board of Pharmacists. The Board had reviewed the bill and generally agreed with it. They did feel that it was not possible for the Board to administer the formulary. Much of the Board's feeling were the same as Mr. Sedgewick had expressed.

Dr. Rodman Wilson, member of the Alaska State Medical Association Committee on Legislation and past President, testified that the committee had alot to do with the present statutes and feel they are fairly workable. The main purpose of the bill was to save the consumer money. He stated that physicians by and large do not know much about the price of individual drugs and how they are sold. The Committee felt that some changes were needed in the bill. He referred to the section pertaining to who prescribes drugs describing them as "medical practioners". It could be defined more by using the common language as presently in the statutes; "physicians, osteopathic physicians, dentists or veternarians". Also all through the bill it describes the communication between the physician and the pharmacist as "telephonic" and he felt it should be changed to "orally" which gives a little more lead way. The Committee also objected to the sign to a point of ascetics. It implies in a subtle way that doctors were trying to give people expensive drugs on purpose. It is unnecessary because the pharmacist has to or should explain to them the substitution when it is done. He stated he could see the others objection to Section E. There are multiple drug agents selling a single substance but one or two have some different active ingredients. The bottles are not big enough to list all the ingredients. He continued stating that the Committee also had their doubts whether or not Health and Social Services could produce a formulary. They would probably just rely on the FDA's list. He surmised that it was included for the purpose of taking the pharmacists off the hook as far as liability was concerned. The pharmacists would be taking alot of responsibility. He then submitted in writing to the members some of the language changes he had discussed.

Rep. Freeman questioned whether or not there was a monetary benefit to physicians on the drugs they prescribe.

Dr. Wilson stated that it was basically unethical by all standards and he wasn't sure if physicians were allowed to own pharmacies.

Chairman Bradley questioned if physicians received free samples from drug companies.

Dr. Wilson replied not as frequently as in the past. He added one other remark concluding his testimony. If not for the drug industry we wouldn't have all the advances we now have and they should be aware of this.

David Freer, Special Assistant to Commissioner of Health and Social Services testified to the section which would apply to the department. He agreed with other witnesses that the department would not be able to carry out that section of the bill without the resources to do it. The department has one pharmacist who is at the Alaska Psychiatric Institute.

Chairman Bradley questioned the witnesses if they felt that if the section on a formulary would help lessen the liability of pnarmacists.

Mr. Sedgwick answer that yes it would help the legal liability question.

Chairman Bradley asked that someone clarify what type of training a pharmacist has and whether or not they know what kind of reaction a drug

would have on patients.

Mr. Sedgwick stated that all pharmacists receive training in bio-equivalents.

Senator Meland then asked to speak to the bill. He stated that the bill was based on the California law and he felt it would help. He then asked if it was true that major hospitals use generic drugs.

Mr. Sedgwick answered that major hospitals establish a formulary and then stock only one brand.

HOUSE COMMERCE COMMITTEE
February 2, 1976

House Bill 584

The meeting was called to order by Chairman Bob Bradley noting that a quorum was present.

Co-sponsor, Speaker of the House Mike Bradner was asked to begin the testimony by explaining the bill. Speaker Bradner stated that this had been recommended to him by many people. It was something which would clarify the process to the consumer. He further stated that he had discussed the bill with a number of pharmacists and some had definite concerns with this. Some pharmacists do do this now, however, their right to do it was a bit cloudy. The present bill is designed after the California statutes.

Representative Bradner further stated that he felt there were areas in the bill which needed to be amended. One area was that of the penalties as stated under the bill. He felt that no penalties should be placed on a pharmacist if he cannot comply. The bill should indicate that they do it but leave a margin for if they can't. Another area was that of the Commissioner of Health & Social Services to establish a list of generic substitutions. He was not sure they could accomplish this with the present staff.

Rep. Freeman questioned objections heard from pharmacists concerning a sign in each pharmacy. How important was the sign?

Rep. Bradner replied that it was not important either way and that it does have implications. Bradner continued stating that the section relating to the a physician must put in his own handwriting that there, could be no substitution, that he was unsure what it was designed to accomplish.

Rep. Wallis questioned whether or this bill would have implications of malpractice for pharmacists.

Chairman Bradley stated that there could be a liability.

Rep. Fischer objected to a pharmacist having the right to alter what a physician prescribes. Many people have a great deal of faith in their doctors and would not want this.

Rep. Rudd explained that the bill allowed a patient to also refuse substitution. Chairman explained further that a doctor could refuse substitution and described the section which states this.

Representative Bradley then asked to leave the Chair to testify on behalf of the bill. (see attached)

February 24, 1976

Mr. Paul May
SRA A Box 1447 B
Anchorage, Alaska 99502

Dear Mr. May:

Enclosed is a copy of the Committee Substitute for House Bill No. 584 as you requested.

The bill is presently in the House Judiciary Committee pending their review.

Sincerely,

Bob Bradley