HB
584

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

COMMITTEE REPORT

2/6/76

HOUSE

Mr. Speaker: Date _____

The Committee on JUDICIARY has had [redacted] HB 584

under consideration. A Majority of the members of the Committee

( ) recommends it DO PASS

( ) recommends it DO NOT PASS

( ) recommends it DO PASS WITH ATTACHED AMENDMENT(S)

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

( ) "a d" 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

Original Sponsors: Bradley, Bradner
and Gardiner

IN THE HOUSE BY THE FREE CONFERENCE COMMITTEE

FREE CONFERENCE CS FOR SENATE CS FOR CS FOR HOUSE BILL NO. 584

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to the Pharmacy Act."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.030(3) is amended to read:

(3) investigate [,] individually, [OR] collectively, or through its agent, for [ALL ALLEGED] violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

* Sec. 2. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (c) of this section, with the consent of the purchaser, the pharmac may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (e) of this section. Upon substitution the pharmacist shall notify the purchaser and the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs shall specify in writing or by oral communication whether or not the pharmacist may substitute a drug under (a) of this section. Written specification may be accomplished by checking a box on the prescription order labeled "DISPENSE AS WRITTEN" or "SUBSTITUTION ALLOWED" if the physician personally initials the box or check mark; in the event the physician fails or neglects to initial the box or check mark, the prescription is invalid and may not be dispensed. Written specification may also be by handwriting. If the person communicating the specification does so orally,

the pharmacist shall indicate that fact in handwriting on the written copy of the prescription order.

(c) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(d) If a person authorized to prescribe drugs is temporarily unavailable, the pharmacist may, if he cannot supply the drug requested, substitute a drug or preparation of approximately equal therapeutic value so long as he notifies the author of the prescription at an early opportunity. The pharmacist in all cases of substitution, except when specifically indicated to the contrary by the prescriber, shall relate the nature of the change to the purchaser.

(e) The manufacturer of products substituted under the provisions of this section shall comply with the following minimum good manufacturing standards and practices:

(1) maintain quality control standards equal to those of the Food and Drug Administration;

(2) comply with regulations promulgated by the Food and Drug Administration;

(3) mark products with identification code or monogram;

(4) label products with expiration date;

(5) provide services to accept return goods;

(6) maintain twenty-four hour resources for product information;

(7) maintain drug recall capabilities;

(8) provide documentation of compliance with Department of Defense (DOD) standard of purchases.

(9) shall not refuse to sell to any properly licensed pharmacy.

(f) As used in this section, unless the context requires other-

wise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "reference or trade standard product" means the original or patented product of the original manufacturer;

(4) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(5) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 3. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. PRESCRIPTION PRICES AVAILABLE TO CONSUMER. A pharmacist shall disclose the price of filling any prescription before filling it, when requested by the consumer.

* Sec. 4. AS 08.80.460 is amended by adding a new subsection to read:

(b) A person who violates the provisions of 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 Procedure Act (AS 44.62).

STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

LEGISLATIVE AFFAIRS AGENCY

M E M O R A N D U M May 17, 1976

SUBJECT: Preliminary Analysis of Constitutionality of Senate amendment to SCS for CS for HB 584

TO: David T. Walker

FROM: John Siemers, Legislative Intern

This office has been requested to examine the constitutionality of a Senate amendment to Section 2 of SCS for CS for HB 584. The amendment, which adds a subsection (e) to AS 08.80.295, provides "minimum good manufacturing standards and practices" for drug manufacturers. Because of the presence of extensive federal regulations in this area under the Food, Drug and Cosmetic Act (21 U.S.C., Section 301 et. seq.), a question has been raised as to the state's power to act on this subject matter.

It should be noted at the outset that federal legislation governing the manufacture and sale of food, drugs and cosmetics does not act to prevent the states from exercising their police powers to protect local consumers. To hold otherwise is to accept a form of federalism which would make even Hamilton blush. Thus, the Supreme Court has held that the original Food and Drug Act of 1906 did not exempt from more stringent state regulation articles of commerce which complied with federal standards (Weigle v. Curtice Bros. Co., 248 U.S. 285 (1919); Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919)).

This should not be taken to mean that the states may enjoy a jurisdictional carte blanche in regulating the manufacture and sale of food, drugs and cosmetics. For example, in McDermott v. Wisconsin, 228 U.S. 115 (1913) the court struck down a Wisconsin labeling statute for corn syrup. The statute required a label distinct from the type mandated by federal law and further required that the state imposed label be exclusively used on corn syrup sold within the state. The court took note of the fact that the exclusive labeling provisions necessitated removal of the federally required label prior to intrastate sale - thereby interfering with attempts by federal authorities to inspect corn syrup after it had been shipped into the state (id. 133-34).

More recently the court has dealt with preemption in a related area--regulation of the quality of food (Florida Lime and Avocado Growers v. Paul, 373 U.S. 132 (1963)). In Paul, California had adopted a standard for establishing the ripeness of avocados which relied upon the percentage of oil contained in the avocado. The act was contested by Florida avocado growers who were subject to the Agricultural Adjustment Act which regulated ripeness of avocados through the use of harvesting orders. Even though the effect of the California law was to exclude a substantial portion of Florida avocados from California markets because of the strictness of the California law, the court found that the California law did not stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (id. at 141). According to the court a state could adopt more stringent standards for food products which had complied with federal standards where the basis for the stricter standard was "a higher standard demanded by a state for its consumers" (id. at 145). As long as there is no conflict with the purposes of parallel federal regulations, and the state requirement is reasonable, stricter state standards existing for a purpose comparable to that of federal law is "permissable under all the authorities" (id.).

Turning to the specfic provisions of the Senate amendment, the first two paragraphs are clearly free from constitutional objection since they merely require manufacturers to adhere to federal regulations. Paragraph (3), requiring that products be marked with an identification code or monogram, may be permissable, at least if McDermott is read narrowly. In McDermott the court emphasized that the Wisconsin labeling requirement must fall, because it demanded use of the state sanctioned label only and excluded the federally sanctioned label. This constituted a clear interference with federal labeling requirements. If (3) merely requires an additional mark or code on the package, and this serves to aid in enforcement of state regulations, it would appear to be safe to conclude that such a requirement is not precluded by the federal act. The same argument would apply to paragraph (4). Currently an expiration date is required under federal law only where the Secretary of Agriculture considers it "necessary for protection of public health" (21 U.S.C. 352 (h)). Consequently, paragraph (4) would probably call for expiration labels on a number of products which are free from such a requirement under federal law. Absent an intent upon the part of Congress that the Secretary's failure to require expiration date labels on certain products acts to free manufacturers from state imposed labeling of expiration dates, this provision is probably constitutionally permissable.

Paragraph (5) (requiring manufacturers "to provide services to accept return goods") is extremely vague and should, if possible, be amended in order to clarify its meaning. If the purpose of (5) is to require manufacturers to make the return of defective products easier and more convenient for consumers, such a requirement would be a reasonable exercise of police powers. However, this provision should be redrafted to establish in clearer terms just what is expected of the manufacturers in order to achieve this purpose.

Paragraph (6) (twenty-four hour resources for product information) poses some serious problems, largely because its exact meaning is so elusive. It could be read to require manufacturers to maintain an office within the state where phone calls could be accepted at any hour of the day; or a hot line could be required to connect the manufacturers headquarters down south with Alaska consumers; or any number of other possibilities could be read into this language. If a manufacturer has gross sales in Alaska of moderate size, e.g., $20,000, (6), if construed stringently, could demand too much of the manufacturer such that a burden on commerce may be said to exist. Whatever the public policy objectives of the provision may be, this would undoubtedly be outweighed by the prohibitive costs of compliance. This provision needs to be clarified and narrowed.

Paragraph (7) (drug recall capabilities) is also somewhat vague, but if it can be read to require that manufacturers must be capable of removing unsafe products from the market as rapidly as possible, this is certainly a legitimate state objective consistent with a reasonable exercise of police power.

Paragraph (8) (provide documentation of compliance with Department of Defense standard of purchases) is extremely difficult to analyze without some understanding of what the D.O.D. standards are. Assuming that the D.O.D. standards were promulgated to assure the safety and efficacy of drugs purchased by the D.O.D., a state law tied to these same standards, even where they are stricter than those imposed by the Food, Drug and Cosmetic Act, would probably be upheld.

JS:smh

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 3/2/76
Referred: Rules

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 584 (Judiciary) am

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs may specify in writing or by oral communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the person's handwriting or, if the prohibition was communicated orally, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

Retail

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Alaska law provides that with your consent, unless prohibited by your doctor, this pharmacy may substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor." The printing on the sign shall be in block letters not less than one inch in

included on the list shall be final.

(b) The current list of the 100 most commonly prescribed drugs shall be conspicuously posted in each pharmacy registered with the board. After each prescription drug listed, the name of the manufacturer and the current selling price shall be clearly indicated for that prescription by the pharmacy. A pharmacy may change the current selling price and the posting of the price at any time.

(c) The price of all other drugs not included on the list of 100 commonly prescribed drugs shall be available and shall be quoted by the pharmacy upon request.

* Sec. 3. AS 08.80.460 is amended by adding a new subsection to read:

(b) A person who violates the provisions of 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 Procedure Act (AS 44.62).

STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

LEGISLATIVE AFFAIRS AGENCY

M E M O R A N D U M May 17, 1976

SUBJECT: Preliminary Analysis of Constitutionality of Senate amendment to SCS for CS for HB 584

TO: David T. Walker

FROM: John Siemers, Legislative Intern JS

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It should be noted at the outset that federal legislation governing the manufacture and sale of food, drugs and cosmetics does not act to prevent the states from exercising their police powers to protect local consumers. To hold otherwise is to accept a form of federalism which would make even Hamilton blush. Thus, the Supreme Court has held that the original Food and Drug Act of 1906 did not exempt from more stringent state regulation articles of commerce which complied with federal standards (Weigle v. Curtice Bros. Co., 248 U.S. 285 (1919); Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919)).

This should not be taken to mean that the states may enjoy a jurisdictional carte blanche in regulating the manufacture and sale of food, drugs and cosmetics. For example, in McDermott v. Wisconsin, 228 U.S. 115 (1913) the court struck down a Wisconsin labeling statute for corn syrup. The statute required a label distinct from the type mandated by federal law and further required that the state imposed label be exclusively used on corn syrup sold within the state. The court took note of the fact that the exclusive labeling provisions necessitated removal of the federally required label prior to intrastate sale - thereby interfering with attempts by federal authorities to inspect corn syrup after it had been shipped into the state (id. 133-34).

More recently the court has dealt with preemption in a related area--regulation of the quality of food (Florida Lime and Avocado Growers v. Paul, 373 U.S. 132 (1963)). In Paul, California had adopted a standard for establishing the ripeness of avocados which relied upon the percentage of oil contained in the avocado. The act was contested by Florida avocado growers who were subject to the Agricultural Adjustment Act which regulated ripeness of avocados through the use of harvesting orders. Even though the effect of the California law was to exclude a substantial portion of Florida avocados from California markets because of the strictness of the California law, the court found that the California law did not stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (id. at 141). According to the court a state could adopt more stringent standards for food products which had complied with federal standards where the basis for the stricter standard was "a higher standard demanded by a state for its consumers" (id. at 145). As long as there is no conflict with the purposes of parallel federal regulations, and the state requirement is reasonable, stricter state standards existing for a purpose comparable to that of federal law is "permissable under all the authorities" (id.).

Turning to the specfic provisions of the Senate amendment, the first two paragraphs are clearly free from constitutional objection since they merely require manufacturers to adhere to federal regulations. Paragraph (3), requiring that products be marked with an identification code or monogram, may be permissable, at least if McDermott is read narrowly. In McDermott the court emphasized that the Wisconsin labeling requirement must fall, because it demanded use of the state sanctioned label only and excluded the federally sanctioned label. This constituted a clear interference with federal labeling requirements. If (3) merely requires an additional mark or code on the package, and this serves to aid in enforcement of state regulations, it would appear to be safe to conclude that such a requirement is not precluded by the federal act. The same argument would apply to paragraph (4). Currently an expiration date is required under federal law only where the Secretary of Agriculture considers it "necessary for protection of public health" (21 U.S.C. 352 (h)). Consequently, paragraph (4) would probably call for expiration labels on a number of products which are free from such a requirement under federal law. Absent an intent upon the part of Congress that the Secretary's failure to require expiration date labels on certain products acts to free manufacturers from state imposed labeling of expiration dates, this provision is probably constitutionally permissable.

Paragraph (5) (requiring manufacturers "to provide services to accept return goods") is extremely vague and should, if possible, be amended in order to clarify its meaning. If the purpose of (5) is to require manufacturers to make the return of defective products easier and more convenient for consumers, such a requirement would be a reasonable exercise of police powers. However, this provision should be redrafted to establish in clearer terms just what is expected of the manufacturers in order to achieve this purpose.

Paragraph (6) (twenty-four hour resources for product information) poses some serious problems, largely because its exact meaning is so elusive. It could be read to require manufacturers to maintain an office within the state where phone calls could be accepted at any hour of the day; or a hot line could be required to connect the manufacturers headquarters down south with Alaska consumers; or any number of other possibilities could be read into this language. If a manufacturer has gross sales in Alaska of moderate size, e.g., $20,000, (6), if construed stringently, could demand too much of the manufacturer such that a burden on commerce may be said to exist. Whatever the public policy objectives of the provision may be, this would undoubtedly be outweighed by the prohibitive costs of compliance. This provision needs to be clarified and narrowed.

Paragraph (7) (drug recall capabilities) is also somewhat vague, but if it can be read to require that manufacturers must be capable of removing unsafe products from the market as rapidly as possible, this is certainly a legitimate state objective consistent with a reasonable exercise of police power.

Paragraph (8) (provide documentation of compliance with Department of Defense standard of purchases) is extremely difficult to analyze without some understanding of what the D.O.D. standards are. Assuming that the D.O.D. standards were promulgated to assure the safety and efficacy of drugs purchased by the D.O.D., a state law tied to these same standards, even where they are stricter than those imposed by the Food, Drug and Cosmetic Act, would probably be upheld.

JS:smh

60% patent
10% generic
30% Multi-Manuf.

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 4/28/76
Referred: Rules

IN THE HOUSE BY THE JUDICIARY COMMITTEE

SENATE CS FOR CS FOR HOUSE BILL NO. 584 am S

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to the Pharmacy Act."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.030(3) is amended to read:

(3) investigate [,] individually, [OR] collectively, or through its agent, for [ALL ALLEGED] violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

* Sec. 2. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (c) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (e) of this section. Upon substitution the pharmacist shall notify the purchaser and the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs shall specify in writing or by oral communication whether or not the pharmacist may substitute a drug under (a) of this section. Written specification shall be accomplished by checking a box on the prescription order labeled "DISPENSE AS WRITTEN" or "SUBSTITUTION ALLOWED" if the physician personally initials the box or check mark; in the event the physician fails or neglects to initial the box or check mark, the prescription shall be dispensed as written. Written specification may also be by handwriting. If the person communicating the specification does so orally, the

Sign section

2 years

pharmacist shall indicate that fact in handwriting on the written copy of the prescription order.

(c) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(d) If a person authorized to prescribe drugs is temporarily unavailable, the pharmacist may, if he cannot supply the drug requested, substitute a drug or preparation of approximately equal therapeutic value so long as he notifies the author of the prescription at an early opportunity. The pharmacist in all cases of substitution, except when specifically indicated to the contrary by the prescriber, shall relate the nature of the change to the purchaser.

(e) The manufacturer of products ~~substituted~~ under the provisions of this ~~section~~ shall comply with the following minimum good manufacturing standards and practices:

(1) maintain quality control standards equal to those of the Food and Drug Administration;

(2) comply with regulations promulgated by the Food and Drug Administration;

(3) mark products with identification code or monogram;

(4) label products with expiration date;

(5) provide services to accept return goods;

(6) maintain twenty-four hour resources for product information;

(7) maintain drug recall capabilities;

(8) provide documentation of compliance with Department of Defense (DOD) standard of purchases.

(9) shall not refuse to sell to any properly licensed pharmacy.

(f) As used in this section, unless the context requires other-

wise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "reference or trade standard product" means the original or patented product of the original manufacturer;

(4) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(5) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 3. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. PRESCRIPTION PRICES AVAILABLE TO CONSUMER. A pharmacist shall disclose the price of filling any prescription when requested by the consumer.

* Sec. 4. AS 08.80.460 is amended by adding a new subsection to read:

(b) A person who violates the provisions of 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 Procedure Act (AS 44.62).

3/24/76
Milton

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 2/5/76
Referred: Judiciary

IN THE HOUSE BY THE COMMERCE COMMITTEE

CS FOR HOUSE BILL NO. 584

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs may specify in writing or by oral communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the person's handwriting or, if the prohibition was communicated orally, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Alaska law provides that with your consent, unless prohibited by your doctor, this pharmacy may substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor." The printing on the sign shall be in block letters not less than one inch in

height.

(d) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(e) If the physician prescribes a drug by its generic name, the pharmacist shall dispense the lowest retail cost drug product ~~brand~~ which is in stock. * complies with prescription

(f) As used in this section, unless the context requires otherwise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(4) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 2. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. POSTING OF PRICES. (a) Annually ~~in the month of August,~~ the Department of Commerce and Economic Development shall prepare a list of the generic names of 100 most commonly prescribed prescription drugs, their usual strength and amount prescribed, and distribute the list along with regulations for posting to each pharmacy registered with the board of registration in pharmacy. The determination of the department as to which drugs are to be included on the list shall be final.

(b) The current list of the 100 most commonly prescribed drugs

shall be conspicuously posted in each pharmacy registered with the board. After each prescription drug listed, the name of the manufacturer and the current selling price shall be clearly indicated for that prescription by the pharmacy. A pharmacy may change the current selling price and the posting of the price at any time.

(c) The price of all other drugs not included on the list of 100 commonly prescribed drugs shall be available and shall be quoted by the pharmacy upon request.

sec. 3 Language from sec. 2 of original bill.

May 11, 1976

to: Representative Joe McKinnon
House Chairman, Free Conference Committee,
Senate CS for CS for HB 584 am S

from: Carol Larsen, Alaska Public Interest Research Group

re: Senate CS for CS for House Bill No. 584 am S

We recommend these changes in CS for CS for HB 584 am S:

A. Section 2.(a)

The last line should be deleted. It states that:

> Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

We believe this provision will dilute the benefit of a substitution bill to the consumer. We fear that the pharmacist will choose not to substitute if by doing so he imposes upon himself the penalty of an extra chore...having to contact the prescriber by telephone.

It would seem logical to require the pharmacist to keep on file the original prescription, on which should be noted the drug product which was substituted.

B. Section 2.(d)

This section should be changed to apply to cases in which the brand name product a physician prescribes (with no substitution allowed) is unavailable. A similar section is found in our current statute.

We agree that the physician should retain the nature of the change to purchaser unless contraindicated by the physician.

C. Section 2.(e)

This section, which deals with manufacturing standards with which manufacturersof products substituted must comply, should be removed from the bill.

We do not quarrel with the establishment of good manufacturing standards and practices with which manufacturers of drugs sold in Alaska must comply. Let us set standards which all prescription drugs must meet, and not just those substituted.

Under this section, prescription drugs manufactured under inadequate standards may still be dispensed in Alaska.

The substitution bill is not the place for this issue. This issue must be dealt with after careful study in order to establish a set of standards by which to judge all prescription drug products sold in Alaska.

D. The provision requiring posting of prescription drug prices, (as found in CS for HB 584, Sec. 08.80.297) should be included.

It is rational and reasonable that pharmacists should be required to list 100 prices on an erasable board. Consider that grocers label each of hundreds of thousands of individual items in a market with the price of products whose values change much more frequently than those of prescription drugs. Some call this harassment; we call it allowing consumers to learn the price of a product.

A bill without price posting would be a disservice to consumers.

E. The provision requiring posting a sign at the pharmacy counter which informs customers that the pharmacy may substitute, as found in CS for HB 584, should be included. Substitution is a fact about which consumers should be informed.

To summarize:

By making the above changes, we have re-invented CS for HB 584, with one change: leaving out the last sentence of Section 1.(a), which requires notification of the prescriber upon substitution. We discussed this provision in A. of this memo.

CS for HB 584, with that one change, is the legislation which we feel would best serve the consumer, while at the same time providing necessary safeguards for the pharmacist and prescriber.

FCC 584 - Generic Drug

Adopt Section 1 of Senate bill Adopt

(a) of Sen CS Adopt

(b) left open

(c) left open possibly 2 year limit

(e) (8) house objects line 12 prescribed or dispensed

(6) " "

(c) Meaning?

change line 12 "prescribed or dispensed" for substituted

intrastate Commerce Clause on section (e)

(3) not needed may not be

Page 3, line 19 delete "before following it"

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 3/2/76
Referred: Rules

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 584 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

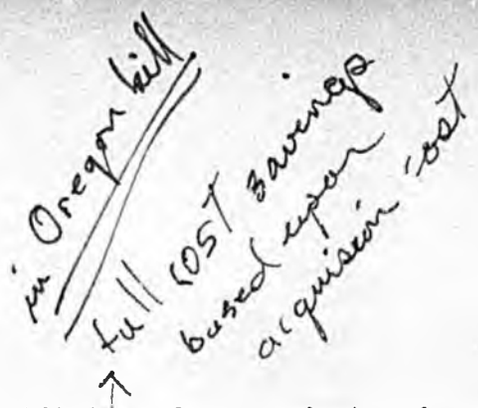
BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs may specify in writing or by oral communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the person's handwriting or, if the prohibition was communicated orally, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Alaska law provides that with your consent, unless prohibited by your doctor, this pharmacy may substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor." The printing on the sign shall be in block letters not less than one inch in



height.

(d) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(e) If the physician prescribes a drug by its generic name, the pharmacist shall dispense the lowest retail cost drug product which is in stock and [which complies with the physician's prescription.] putin

(f) As used in this section, unless the context requires otherwise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(4) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 2. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. POSTING OF PRICES. (a) Annually the Department of Commerce and Economic Development shall prepare a list of the generic names of the 100 most commonly prescribed prescription drugs, their usual strength and amount prescribed, and examples of each by brand name, if any, and distribute the list along with regulations for posting to each pharmacy registered with the board of registration in pharmacy. The determination of the department as to which drugs are to be included on the list shall be final.

(b) The current list of the 100 most commonly prescribed drugs shall be conspicuously posted in each pharmacy registered with the board. After each prescription drug listed, the name of the manufacturer and the current selling price shall be clearly indicated for that prescription by the pharmacy. A pharmacy may change the current selling price and the posting of the price at any time.

(c) The price of all other drugs not included on the list of 100 commonly prescribed drugs shall be available and shall be quoted by the pharmacy upon request.

* Sec. 3. AS 08.80.460 is amended by adding a new subsection to read:

(b) A person who violates the provisions of 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 Procedure Act (AS 44.62).

Mary Ellen Burnison – WHO Bioavailability

1.) New Drug Application 17 year patent

2.) Drug

What is name of your Phd expert?

upto 5 years to obtain patent

Abreviated New Drug Application after patent expires —

Requires a ~~lot~~ less documentation – only have to document therapeutically

NF – National Formulary – Means Chemically equivalent this is what checked in New Drug Application

12 steps or factors

Drug Manufacturer makes Products to different specification for Distributors – Do this comply with FDA standards for instance under New Drug App? With a patent are their requirements with FDA or the actual process?

In future Bioavailability lists will be developed By FDA for use by everybody

Require firms to submit Bioavailability info to FDA or state firm to form these lists

24 drugs have toxicity problems

file

Terry Gardiner

Box 1092, Ketchikan, Alaska 99901 Pouch V, Juneau, Alaska 99811

March 18, 1976

Bob Race
2300 Tongass Ave.
Ketchikan, Alaska 99901

Dear Bob,

Thank you for the copy of the letter concerning HB 757 and HB 584. Copies of the latest versions of both of those bills have been enclosed. HB 757 is presently in the House Rules Committee where it will probably be scheduled for floor action. HB 584 is presently in the Senate Judiciary Committee which is chaired by Senator Ziegler. The amended version of HB 584 was the result of a lot of hearings and input in both the House Commerce and Judiciary Committees. We heard extensively from pharmacists and representatives of the large drug companies.

It was felt that there were a lot of protections in the amended version of HB 584 to take care of some of the problems that you have brought up. The pharmacist is not required to substitute just the cheapest drug. On page 1, line 14, the language reads "..., in the pharmacists professional opinion, therapeutically equivalent." The pharmacists that testified for our committee felt that that gave them the necessary latitude and judgment to prevent the substitution of a poor quality drug. Sec. B also provides that the physician may specify a specific brand name drug and prescribe that there shall be no substitution in a case where he knows that a specific brand name drug must be used for the desired reaction in the patient. As you will see on page 2, substitution takes place when the physician prescribes a drug by its generic name.

I'm sure Senator Ziegler will take into consideration your comments if and when HB 584 is considered by his committee.

Sincerely,

_____
Terry Gardiner

GIFT SHOP POST OFFICE FOUNTAIN — LUNCH TOY SHOP — SOUND CENTER

HB 584

Race Avenue Drug
A Division of Race Ketchikan Pharmacies, Inc.
ROBERT S. RACE, Pres.
2300 Tongass Avenue
KETCHIKAN, ALASKA 99901

Senator Robert Zeigler
Alaska State Senate
Juneau, Alaska 99801

Robert Zeigler

Terry: Guess I am late but you know how I feel, and would like hearings xxx on any future bills. Understand Brad Bradley in Senate has a good or better bill pending or such
Thanks,

Bob Race

Hi Bob:

I wasn't aware before of the two house bills up or through the house no. 757 By Sullivan which has to do with posting prices on prescription drugs. The textof the bill from over the phone reading opens a "can of worms" and in several eastern states where they have passed legislation of this kind they have had many problems with it and it hasn't helped the public only given them substitution of inferior "cheap" unknow absorption rates etc. AND SHOULD NOT BECOME A LAW AS THAT BILL WAS WRITTEN.

The other House Bill 584 by Bradley and others(am confused on that point , about Bradley, Brad as he has another study bill SK with hearing before public etc. coming up which is fine if we get hearings but as I understand it 584 is also a poor bill and it allows the pharmacist to substitute any other "Generic" drug for any the physician orders and must be or can be the cheppest one. This puts responsibility on pharmacist and if the Physician or Dentist believes and has found that a Squibb or Lilly product is the one he gets best results with due to its compounding in their plant with a Bio Availability of the active drug reaching the blood stream, then that one should be the one dispensed unless the physician has authorized the substitution. Even the patient shouldn't have the right to ask for a "cheap" drug unless the physician o.k.'s it as he as well as the pharmacist is one that ends up with a law suit or manslaughter rap.

Sincerely,
Bob Race

Copies to
T.Gardner
O. Freeman

Meprobamate	200mg	100's	3.85
	400mg	100's	4.50
Meprospan	200mg	30's	3.30
	400mg	30's	5.10
Mesantoin	100mg	100's	3.55
Meticortelone	5mg	100's	14.30
Generic Equivalent:			
Prednisolone	5mg	100's	4.50
Metahydrin	4mg	100's	3.35
Generic Equivalent:			
Trichlormethiazide	4mg	100's	4.50
Metamine Sustained	10mg	50's	5.60
Metandren Linguets	5mg	100's	6.30
	10mg	100's	10.50
Generic Equivalent:			
Methyl-Testosterone Sublingual	5mg	Not Available	
	10mg	100's	5.25
Metatensin	2mg	100's	5.35
	4mg	100's	7.80
Methenamine Mandelate	0.5gm	100's	3.25
	1gm	100's	5.25
Methocarbamol	500mg	100's	7.65
	750mg	100's	10.50
Methyl-Testosterone Sublingual	10mg	100's	5.25
Meticorten	5mg	100's	4.50
Generic Equivalent:			
Prednisone	5mg	100's	3.50
Milpath	400mg	50's	6.85
Milprem	200mg	60's	6.00
	400mg	60's	7.15
Miltown	200mg	50's	3.25
	400mg	50's	4.00
Generic Equivalent:			
Meprobamate	200mg	100's	3.85
	400mg	100's	4.50
Motrin	300mg	100's	11.70
	400mg	100's	13.95
Mycolog (Cream or Oint.)	5gm		2.65
	15gm		4.85
Mysoline	0.25gm	100's	7.50
	50mg	100's	2.35
Mysteclin-F	250mg	16's	5.15
		100's	27.10
Naldecon		50's	6.60
Naqua	4mg	100's	8.00
Generic Equivalent:			
Trichlormethiazide	4mg	100's	4.75
Naquival		100's	10.45
Nardil	15mg	100's	7.90
Naturetin	5mg	100's	11.15
Nebralin		50's	4.70
Neg-Gram	250mg	56's	7.15
	500mg	56's	12.50
Neostigmine Bromide	15mg	100's	3.50
Neo Synalar Cream	5gm		1.80
	15gm		3.30
Nicalex		100's	8.15
Nicobid	125mg	100's	6.75
	250mg	100's	8.45
Nitrobid	2.5mg	100's	9.80
	6.5mg	100's	13.00
Generic Equivalent:			
Nitroglycerin L.A.	2.5mg	100's	4.50
	6.5mg	100's	7.95
Nitrofurantoin Tabs	50mg	100's	6.50
	100mg	100's	12.00
Capsules	50mg	100's	11.35
	100mg	100's	21.50
Nitroglycerin, Sublingual			
All strengths		100's	1.55
		2x100's	2.60
Nitroglycerin L.A.	2.5mg	100's	4.65
	6.5mg	100's	8.20
Nitroglyn 1/50		100's	10.60
Nitrospan	2.5mg	100's	9.80
Generic Equivalent:			
Nitroglycerin L.A.	2.5mg	100's	4.65
Nitrostat, All Strengths		100's	2.20
Nodular Tablets	200mg	100's	7.80
Capsules	300mg	100's	9.15
Norgesic		100's	11.55
Norinyl 1mg			
1/50 (21) or (28)		1 packet	2.65
		3 packet	7.40
		6 packet	13.45
1/80 (21) or (28)		1 packet	2.65
		3 packet	7.40
		6 packet	13.45
Norisodrine	25%	4 vials	10.50
Norlestrin 1mg			
(21) or (28)		1 packet	2.80
		3 packet	8.05
		6 packet	15.10
2.5mg (21)		1 packet	2.80
		3 packet	8.05
		6 packet	15.10
Norpramin	25mg	50's	6.60
Novahistine LP		50's	6.35
Nylidren HCl	6mg	100's	5.75
	12mg	100's	9.25
Ogen	1.25mg	100's	7.20
Oracon (21)		packet 21's	2.65
		packet 63's	7.15
		packet 126's	13.65
Orinase	0.5gm	50's	5.30
		100's	10.15
		200's	19.75
Ornade		100's	14.90
Generic Equivalent:			
Chlorade TD		100's	7.25
Ortho-Novum 2mg		packet 21's	3.15
		packet 63's	8.45
		packet 126's	15.60

*Generic Manufacturers Trade Name Stocked by Getz.
(For information about Generic Drugs, see page 58.)

Ortho-Novum 1/50 (21)			
or 1/80 (21)		packet 21's	2.90
		packet 63's	7.80
		packet 126's	14.90
Os-Cal-Mone		100's	7.50
Ovral (21)		packet 21's	2.90
		packet 63's	8.15
		packet 126's	15.30
Ovulen (21)		packet 21's	2.90
		packet 63's	8.15
		packet 126's	15.30
Ovulen (28)		packet 28's	2.90
		packet 84's	8.15
		packet 168's	15.30
Oxytetracycline	250mg	50's	7.50
Pabacyl N.S.*		100's	2.95
Pabalate S.F.		100's	4.30
Generic Equivalent:			
Pabacyl N.S.*		100's	2.95
Pamine		100's	6.55
Papaverine	1gr	100's	3.70
	1½gr	100's	3.95
Papaverine HCl TR	150mg	100's	6.75
Parest-400		100's	10.50
Pavabid		100's	13.65
Generic Equivalent:			
Papaverine HCl TR	150mg	100's	6.75
Pathibamate-400		100's	12.80
Penicillin G			
Buffered	200,000 U	100's	3.45
	250,000 U	100's	3.55
	400,000 U	100's	4.10
Penicillin VK	250mg	100's	8.50
	500mg	100's	10.95
Pen Vee K	500mg	100's	22.75
Generic Equivalent:			
Penicillin VK	500mg	100's	10.95
Pentids	200,000 U	100's	7.65
	400,000 U	100's	11.95
Generic Equivalent:			
Penicillin G. Buffered	200,000 U	100's	3.45
	400,000 U	100's	4.10
Pentritol	30mg	100's	11.05
	60mg	60's	9.80
Generic Equivalent:			
P.E.T.N. L.A.	30mg	100's	4.95
	60mg	Not Available	
Pentritol	60mg	60's	9.15
Perinetin	4mg	100's	7.80
Peritrate	10mg	100's	4.80
	20mg	100's	5.45
Generic Equivalent:			
P.E.T.N.	10mg	100's	1.95
	20mg	100's	2.95
Peritrate w/Pb	10mg	100's	4.80
	20mg	100's	6.15
Generic Equivalent:			
P.E.T.N. w/Pb	10mg	100's	2.25
	20mg	100's	3.25
Peritrate SA Tabs	80mg	100's	11.60
Generic Equivalent:			
P.E.T.N. TD Caps	80mg	100's	7.25
Peritrate SA w/Pb	80mg	100's	13.00
Permitil Chronotabs	1mg	100's	9.15
Persantine	25mg	100's	10.45
Pertofrane	25mg	100's	12.80
P.E.T.N.	10mg	100's	1.95
	20mg	100's	2.95
P.E.T.N. w/Pb	10mg	100's	2.25
	20mg	100's	3.25
P.E.T.N. LA	30mg	100's	4.95
P.E.T.N. TD Caps	80mg	100's	7.25
Phenaphen Capsules		100's	3.05
Phenergan	12.5mg	100's	5.60
	25mg	100's	9.50
Generic Equivalent:			
Promethazine	12.5mg	100's	4.00
	25mg	100's	6.20
Phenergan	50mg	100's	14.90
Phenoxene Tablets	50mg	100's	7.80
Phentermine TD Caps	15mg	100's	7.50
	30mg	100's	7.95
Placidyl	200mg	100's	5.75
	500mg	100's	10.15
Plaquenil	200mg	100's	13.00
Polaramine Repetabs	4mg	100's	6.35
	6mg	100's	9.50
Polycillin	250mg	100's	22.55
	500mg	50's	21.65
Generic Equivalent:			
Ampicillin	250mg	100's	12.95
	500mg	50's	12.95
Poly-Flor Chewables*		100's	2.50
Poly-Vi-Flor Chewables		100's	4.30
Generic Equivalent:			
Poly-Flor Chewables*		100's	2.50
Poly-Vi-Flor Drops		50cc	3.70
Ponstel		100's	12.65
Potassium Chloride E.C.	5gr	200's	2.30
	15gr	200's	3.60
Prednisolone	5mg	100's	4.50
		200's	8.00
Prednisone	5mg	100's	3.50
		200's	6.20
Preludin	25mg	100's	9.15
Endurets	75mg	50's	11.20
		100's	21.65
Premarin w/Methyl Testosterone	0.625mg	50's	6.10
	1.25mg	50's	10.30
Generic Equivalent:			
Conjugated Estrogens w/Methyl Testosterone	0.625mg	100's	6.50
	1.25mg	100's	10.50

*Generic Manufacturers Trade Name Stocked by Getz.
(For information about Generic Drugs, see page 59.)

Elavil	10mg	100's	5.60
	25mg	100's	10.60
	50mg	100's	17.90
Eldec		100's	8.70
Enarax "5"		60's	11.95
Enarax "10"		60's	13.95
Enduron	2.5mg	100's	6.85
	5mg	100's	9.15
Enduronyl		100's	12.80
Forte		100's	15.20
Envoid E 2.5 mg	packet	21's	3.05
	packet	63's	8.45
	packet	126's	15.90

Entozyme		100's	5.60
Generic Equivalent:			
Hydrozyme*		100's	3.90
Equagesic		50's	6.15
Equanil	200mg	50's	3.50
	400mg	50's	4.25
Generic Equivalent:			
Meprobamate	200mg	100's	3.85
	400mg	100's	4.50
Equanil L.A.	400mg	50's	7.50
Equanitrate "10"		50's	5.20
Equanitrate "20"		50's	6.00
Erythrityl Tetranitrate	10mg	100's	2.65
	15mg	100's	3.25

Erythrocin	250mg	100's	20.55
Generic Equivalent:			
Erythromycin	250mg	100's	11.95
Erythromycin	250mg	100's	11.95

Esidrix	25mg	100's	4.95
	50mg	100's	7.10
Generic Equivalent:			
Hydrochlorothiazide	25mg	100's	3.00
	50mg	100's	4.25
Esimil		100's	15.30
Eskatrol		50's	7.80

Estinyl	0.02mg	100's	3.85
	0.05mg	100's	6.35
Generic Equivalent:			
Ethinyl Estradiol	0.02mg	100's	2.15
	0.05mg	Not Available	
Ethinyl Estradiol	.02mg	100's	2.15

Etrafon Plain	2/25	60's	10.15
Forte	4/25	60's	10.95
"A"	4/10	60's	8.80
Euthroid-2		100's	4.70
Euthroid-3		100's	5.60
Eutonyl	25mg	100's	13.75
Eutron		100's	20.85
Fiorinal Capsules		100's	6.15

Fiorinal Tablets		100's	5.20
Generic Equivalent:			
Fiorphen*		100's	3.40
Fiorphen*		100's	3.40
Flagyl Tablets		100's	21.65
Inserts		10's	4.95
Folic Acid	1mg	100's	3.25

Folvite	1mg	100's	5.60
Generic Equivalent:			
Folic Acid	1mg	100's	3.25
Formatrix		60's	13.95

Fulvicin UF Tablets	125mg	100's	9.80
	250mg	100's	17.90
	500mg	60's	20.40
Generic Equivalent:			
Griseofulvin Microfine Capsules	250mg	100's	13.95
One Strength Only			

Furadantin Tabs	50mg	100's	13.65
	100mg	100's	26.50
Generic Equivalent:			
Nitrofurantoin Tabs	50mg	100's	6.50
	100mg	100's	12.00
Gantanol	0.5gm	50's	4.95

Gantrisin	0.5gm	100's	4.80
Generic Equivalent:			
Sulfisoxasole	0.5gm	100's	3.50
Gevrine		100's	9.50
Gitaligin	0.5mg	100's	3.85

Grifulvin V Tablets	125mg	100's	8.45
	250mg	100's	15.60
	500mg	100's	20.60
Generic Equivalent:			
Griseofulvin Microfine Capsules	250mg	100's	13.95
One Strength Only			

Grisactin Capsules	125mg	100's	9.15
	250mg	100's	16.20
	500mg	60's	18.80
Generic Equivalent:			
Griseofulvin Microfine Capsules	250mg	100's	13.95
One Strength Only			

Griseofulvin Microfine Capsules	250mg	100's	13.95
Haldol	1mg	100's	13.00
Hydrone	1mg	100's	10.95
	2mg	100's	20.40
Hexadrol	0.75mg	100's	11.65
Hiprex		100's	13.65
Hydergine		100's	11.65
Hydralazine HCl	25mg	100's	2.35
	50mg	100's	3.95
Hydrochlorothiazide	25mg	100's	3.00
	50mg	100's	4.25
Hydrocortisone Cream	½%	1oz	2.25
Ointment	1%	20gm	2.25
Tablets	20mg	100's	5.95

Hydrocortone	20mg	100's	8.15
Generic Equivalent:			
Hydrocortisone	20mg	100's	5.95

*Generic Manufacturers Trade Name Stocked by Getz.
(For information about Generic Drugs, see page 58.)

Hydrodiuril	25mg	100's	5.05
	50mg	100's	7.10
Generic Equivalent:			
Hydrochlorothiazide	25mg	100's	3.00
	50mg	100's	4.25
Hydromox	50mg	100's	9.50

Hydropres	25mg	100's	7.15
	50mg	100's	10.95
Generic Equivalent:			
Hydroserpine*	25mg	100's	4.50
	50mg	100's	6.50
Hydroserpine*	25mg	100's	4.50
	50mg	100's	6.50
Hydrozyme*		100's	3.90
Hygroton	50mg	100's	10.15
	100mg	100's	11.85
Iberol F		100's	10.50
Inderal	10mg	100's	5.20
	40mg	100's	8.45
Indocin	25mg	100's	10.45
		200's	19.75
	50mg	100's	15.60

Ionamin	15mg	100's	15.60
	30mg	100's	16.20
Generic Equivalent:			
Phentermine TD Caps	15mg	100's	7.50
	30mg	100's	7.95

Ismelin	10mg	100's	11.85
	25mg	100's	15.90
Isoniazid	50mg	200's	1.60
	100mg	100's	1.35
Isopto-Carpine	1%	15cc	2.65
		30cc	3.55
	2%	15cc	2.65
		30cc	3.55
Isorbide Dinatrate			
Oral	5mg	100's	3.70
	10mg	100's	4.05
Sublingual	2.5mg	100's	3.50
	5mg	100's	3.70
T. D. Capsules	40mg	100's	8.20

Isordil, Oral	5mg	100's	5.20
	10mg	100's	5.90
Generic Equivalent:			
Isosorbide Dinitrate	5mg	100's	3.70
	10mg	100's	4.05
Isordil Sublingual	5mg	100's	5.20
Generic Equivalent:			
Isosorbide Dinitrate Sublingual	5mg	100's	3.70
Isordil Tembids	40mg	100's	13.35
Generic Equivalent:			
Isosorbide Dinitrate TD Capsules	40mg	100's	8.20
Isuprel Mistometer		15cc	4.30

Kuridium	2.2mg	180's	3.45
Generic Equivalent:			
Sodium Fluoride	2.2mg	200's	2.45

K-Lor		30's	5.90
K-Lyte		30's	5.90
Kafocin		40's	16.20
Kaochlor Eff.		60's	9.15
Kaon		100's	5.20
Karidium	2.2mg	180's	3.95

Kenacort	4mg	30's	8.70
		100's	25.10
Generic Equivalent:			
Triamcinolone	4mg	100's	16.00

Kenalog (Cream or Oint.)	1%	5gm	1.90
		15gm	3.10
	.025%	80gm	4.40
Ketochol		100's	5.20
Klorvess		60's	8.80
L-Dopa Tablets	250mg	100's	5.10
	500mg	100's	8.45
L-Thyroxine Sodium	0.1mg	100's	1.50
	0.2mg	100's	1.95
Larodopa Tablets	500mg	100's	8.45
Lanoxin	0.25mg	100's	1.55
Lasix		100's	10.60
Letter	0.025mg	100's	1.95
	.05mg	100's	2.05
	.1mg	100's	2.35
	.2mg	100's	3.05
	.3mg	100's	4.40
	.5mg	100's	5.60
Lextron		84's	4.95
Ferrous		84's	4.95
Librax		50's	5.10
Librium	5mg	100's	6.00
	10mg	100's	8.00
	25mg	100's	11.70
Lomotil		100's	10.95
Luride Lozitabs		120's	3.15
Drops		40ml	2.90

Macrodantin Caps	50mg	100's	17.25
	100mg	100's	33.65
Generic Equivalent:			
Nitrofurantoin Caps	50mg	100's	11.35
	100mg	100's	21.50

Mandelamine	0.5gm	100's	5.90
	1gm	100's	9.15
Generic Equivalent:			
Methenamine Mandelate	0.5gm	100's	3.25
	1gm	100's	5.20

Marax		100's	8.00
Marplan	10mg	100's	9.15
Meclizine	12.5mg	100's	4.20
	25mg	100's	6.90
Mediatric Caps.		100's	11.15
Medihaler Iso w/Adapter		15cc	4.40
Refill		15cc	3.95
Medrol	4mg	30's	7.00
Medules	4mg	30's	7.00
Mellaril	10mg	100's	9.15
	25mg	100's	12.15
	50mg	100's	13.00

*Generic Manufacturers Trade Name Stocked by Getz.
(For information about Generic Drugs, see page 58.)

THE FOLLOWING PAGES WERE TREATED AS
A UNIT IN THE ORIGINAL FILE.

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)

Testimony given by Representative Bob Bradley
House Bill 584
Commerce Committee meeting 2/2/76

Ampicillin is the generic name of a particular drug manfactured by Bristol Laboratories and distributed by four firms. Under the brand name "polycillin", Bristol markets the ampicillin for $18.24 wholesale, while Smith, Kline and French distributes Bristol's ampicillin for only $12.00. This same Bristol manufactured ampicillin is sold by ICN Pharmaceuticals under still another brand-name for $14.80, while ICN's generic division sells an identical amounts of ampicillin for $7.50. If the doctor happens to write "polycillin", the pharmacist is prohibited from filling the prescription with the ICN ampicillin even though they are manufactured identically by Bristol. Thus, the consumer must pay more than double what he might if anti-substitution laws weren't in effect.

Generic drugs are always less costly than brand-name drugs. Thus, anti-substitution laws function to support artificially high prices for brand-name drugs. Prices for brand-name drugs are higher because the drug industry must spend around a billion dollars annually to promote these names and then make us, the consumers, pay for the advertising. Unless the doctor prescribes by generic name, we have no choice of what price we pay and the sad fact is that brand-name drugs, with their high prices, cannot be considered superior products. In fact, in 1972 of 638 drug recalls, 291 were brand-name.

Twenty-three percent of the retail drug expenditures in this country are by those over 65. For the elderly person living on a fixed income the difference in what he pays for a brand-name drug as opposed to a generic name may mean a difference in what he is able to spend on food and housing.

It is not surprising that eleven states--Arizona, Kentucky, Arkansas, Oregon, Minnesota, Connecticut, Michigan, Maine, Massachuetts, Florida and Maryland--have already repealed their anti-substitution laws. In Canada, where several provinces have also allowed pharmacists to substitute generics, the province of Ontario has found increases in the number of prescriptions written for generic and lower price brand names.

We are not only concerned with lower prices. Our main goal in drug treatment is better health. For every prescription drug, there is an average of 30 brand names, or shall we call them aliases, which obscures the identity of the particular medication even from physicians who must prescribe them. The National Academy of Sciences supported generic substitution, recognizing that "the pharmacist may in some situations have greater knowledge of drug products than other health professionals, including knowledge of both quality and cost."

At present, because they cannot substitute, pharmacists must keep large inventories to have all brands available. This means a slow turnover of stock and is apt to mean higher prices in general. This is particularly relevant in Alaska where there are many small pharmacies and a large inventory can be extremely costly to them. If allowing the pharmacist to substitute enables him to reduce his inventory, keeping on hand those drugs that are lowest in price or those which he personally may consider superior.

One of the major arguments against substitution is drug inequivalence. Bio or clinical equivalence occurs when chemically equivalent drugs in the same amount provides the same therapeutic effect. The U.S. Department of Health, Education and Welfare Task Force on prescription drugs concluded that "the lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health." Only in rare instances would equivalent drugs products not produce the same therapeutic effects. Morris Aarons, a member of the Review Committee of the Task Force, who represents the National Association of Pharmaceutical Manufactures, concurred with this.

A report on this subject was completed by the office of Technological Assistance, a Congressional investigative body. D.. Robert Berliner Dean of the Yale University Medical School chaired the study and reported that 85-90% of chemically equivalent products presents no problem of therapeutic inequivalency and can be used interchangeably. In fact, Dr. Berliner stated, "Most drugs ought to be prescribed generically."

The Food and Drug Administration puts new drugs through difficult tests. Whenever manufacturers wish to place drug products chemically equivalent to existing ones on the market, they must submit for FDA approval adequate data to demonstrate the equivalency of the product. This is given a thorough review.

Equivalency studies have been done on all antibiotics, which accounts for one out of every five prescriptions. Any antibiotic offered for sale in the United States regardless of whether it is an brand-name or generic drug has met the same high FDA standards. The FDA is presently compiling lists of equivalent drugs and has conducted its studies starting with the most frequently prescribed drugs. The FDA will eliminate variations by makers of generic drugs by requiring them to match the effectiveness of standard drugs or withdraw the drugs from the market. A complete compilation will be available by 1978. Although information is presently being made available as it is compiled.

In any case, if a doctor has reason to believe a drug manufactured by a specific firm is best for his patient, he may write no substitution. It is hoped that HB 584 will also serve to make the physician think twice before writing a prescription and by allowing their patients to have pharmacists substitute products, get for them the best drug at the lowest available price.

HB584 will allow Alaskans who are already paying substantially higher prices for drug products than the lower 48 to save several million dollars annually.

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 pharmacists.

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.

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 23 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.

The Last Stand of Brand-Name Drugs

Companies Protest as State Moves to Allow Use of Low-Cost Substitutes

BY RAYMOND T. BONNER

artial relief from the high cost of prescrip- drugs may be near—but the battle is by neans won.

n California and more than 40 other states, rmacists are currently prohibited from stituting a lower-cost but otherwise equiv- nt generic drug for the more expensive e brand indicated on a prescription. wever, the State Assembly has approved nd the Senate is now considering—an act t would have the effect of repealing this hibition.

ctually, there is no need for this legislation or the ban on substitution in California is art of regulations promulgated by Sta harmacy Board. Indeed, independen- t of legislative moves and faced with a suit, the board has amended its regulation llow substitution, a rule which does not ome final, however, until the board holds rings in the near future.

s a result of these actions, drug-company ists, not surprisingly, have mounted a paign to maintain the status quo, with its ecessarily high drug prices.

very drug, of course, has a generic name, may also have one or more brand names. neric names are usually chemical tongue- sters, while brand names are short, simple catchy—designed to be remembered easi- by physicians. For example, Darvon is a nd name for propoxyphene hydrochloride; rvon wholesales for $33.35 (500 capsules), eneric equivalent for $8.45.

onsider also the disparity in prices for the mon antibiotic known as ampicillin. Bris- Laboratories manufactures ampicillin for ribution by three firms besides itself. Bris- own ampicillin is marketed under the le name Polycillin, and wholesales for .24 (100 capsules); the same quantity of tol-manufactured ampicillin distributed Smith, Kline & French fetches $12.

eanwhile, ICN Pharmaceuticals rather ly charges $7.50 and $14.80 for identical unts of Bristol's ampicillin. The lower e is charged by ICN's generic division and higher price by its brand-name division. e drug, same company—but a price vari- n of 200%. It is all too apparent that ny consumer dollars go not for what is in bottle but for the name that is on it.

Why is the industry opposed to the greater of generic drugs? Primarily, to protect fits. Since 1961, the drug industry has ked as one of the two most profitable manufacturing industries in the country, and brand-name products account for a substantial portion of those profits.

Drug companies spend $1 billion annually promoting their brand-name products among American physicians. (This amounts to $5,000 per private practitioner.) By contrast, the industry spent $620 million on all research and development in 1971, and medical schools spent $884 million on all their educational activities in 1972-73.

While permitting substitution would obviously be good for consumers' financial health, the drug industry does not view it as beneficial to its own welfare. Recently, eight drug manufacturers spent more than $15,000 to publish large advertisements in newspapers throughout California declaring that consumers would not benefit from substitution, and urging them to write their senators to oppose the legislation. Same manufacturer

One of the sponsors of that campaign, Parke-Davis, sells a brand-name tetracycline, Cyclopar, for $5.15 (100 capsules). A competitor sells an identical number of tetracycline pills manufactured by the same West Virginia company. The only significant difference is the lack of a brand name on the bottle and, of course, the price: $1.50. Thus, consumers could save more than 200% if pharmacists were permitted to substitute this generic tetracycline for Cyclopar—a good reason for Parke-Davis to oppose substitution.

Raymond T. Bonner, an attorney, is director of the West Coast office of Consumers Union, based in San Francisco.

When the Pharmacy Board begins hearings on its proposed amended regulation, the drug industry will no doubt offer its well-worn panoply of arguments. In the past, this standard position has been based more on scare tactics than fact. It has used the term "generic" disparagingly, and attempted to equate it with "bad" or "inferior" pharmaceuticals. In fact, however, nearly one-half of the defective drugs recalled in 1972 bore brand names.

The industry tenaciously clings to its contention that all substitution should be forbidden because a few equivalent drugs may not perform identically in a particular patient. This argument ignores findings of the Health, Education and Welfare Department's Task Force on Prescription Drugs, which was under the direction of Dr. Philip Lee, a distinguished physician and former chancellor at UC's medical school at San Francisco.

After an exhaustive two-year study, this task force unequivocally concluded that only in "rare instances" would equivalent drug products not produce substantially the same therapeutic effects. And, the researchers noted, these rare instances have been "grossly exaggerated" as hazards to public health.

Drug-industry lobbyists, moreover, have selectively quoted from a report prepared by the congressional Office of Technology Assessment. On the one hand, they emphasize OTA's observation that, in a particular patient, some equivalent drugs may produce somewhat different effects from those carrying brand names. On the other hand, these lobbyists conveniently fail to cite a declaration on the very next page of the OTA report noting that this disparity "is not, in itself, evidence that the use of such products will produce practical problems in the treatment of patients."

The drug companies also overlook a fact central to the new law: It would only permit — not require — substitution. Thus, if a doctor believes an equivalent drug would not produce the same therapeutic response as the one prescribed, he or she simply writes "no substitution" on the prescription.

Also disregarded by the drug companies is the routine practice by nearly all major hospitals to substitute generic drug products; moreover, substitution has been required for Medi-Cal patients since 1961—all without any documented harm to recipients. Unless the industry means to suggest there is one standard of health care for the poor and another for everyone else, generic drugs should be equally available to all.

Finally, the industry has contended that substitution won't result in any cost saving to consumers. It is hard to understand why the drug companies bother to make such an argument, for it cannot be supported by facts. For example, the HEW task force discovered that the average price for brand-name drugs was $4.11, while those dispensed under a generic name cost less than half as much, or $2.02. For Californians, this means paying an extra $45 million each year for their prescription-drug needs, according to the California Department of Consumer Affairs.

It should be clear that one prescription for relieving the pain of high-priced drugs is to permit pharmacists to engage in generic substitution. We must vigilantly guard against the drug industry's desperate efforts to block the administration of this relief.

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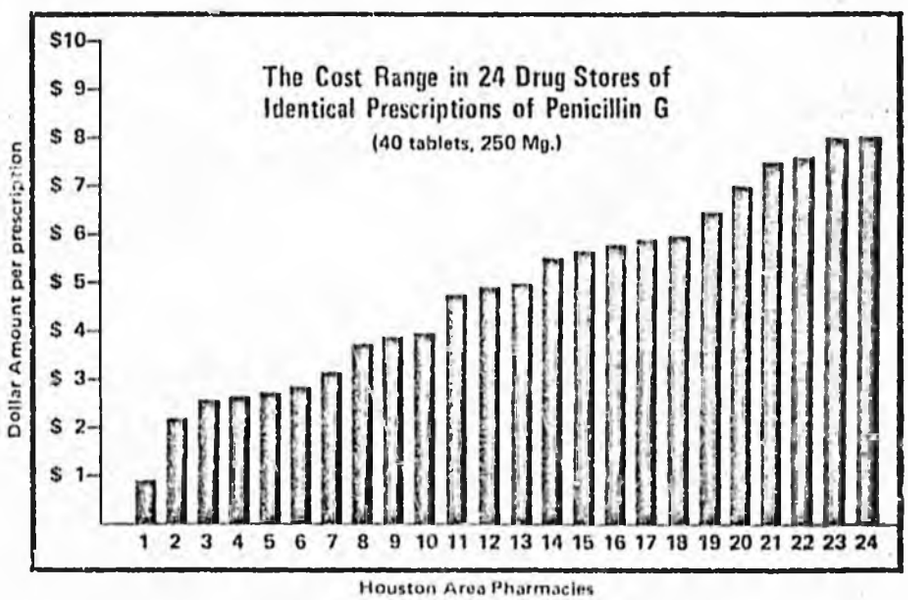
MIKE HUDSON, DIRECTOR TRACI HARTE, RESEARCH COORDINATOR

The Real Cost of Prescription Drugs

In Houston between Nov. 2 and 4, 8 prescription drugs were priced at 24 randomly-selected drug stores. In the case of Penicillin G the cost range was from 88¢ to $8.00.



Four billion dollars a year is spent on prescription drugs.[1] "This represents over one billion prescriptions . . . in other words five prescriptions for every man, woman and child in the country."[2]

In recent years, much has been said and written about prescription drugs and their cost to the consumer. Two issues have emerged as the salient aspects of the controversy. First, it is extremely difficult for the consumer to obtain information about the price of a prescription prior to the actual purchase. Advertising of prescription drugs is forbidden by statute or by regulation in thirty-four states. Current prices of common prescriptions are not posted, and price information is not freely available over the telephone. The second important issue is the question of generic versus brand-name prescriptions. Most states, including Texas, have anti-substitution laws which require that a pharmacist fill a prescription exactly as it is described by the doctor on the prescription sheet. This statute protects the welfare of the consumer by insuring that the physician's intended therapy is accurately fulfilled. However, it prevents a pharmacist from substituting a therapeutically equivalent but cheaper generic drug in the case of a brand-name prescription. This report will review some of the recent developments in these controversies and present the results of a prescription drug price survey in the city of Houston.

The Price of Secrecy and the Non-Competitive Market

There are a number of groups who are currently interested in the advertising issue. Pharmacists are officially opposed to advertising because it reduces their standing as professionals. Rivalry, especially business rivalry, has been long frowned upon by all medical professionals. However, the enforced lack of price disclosure has the side effect of protecting every pharmacist's profits, perhaps another reason for the reluctance to advertise. Doctors are generally in favor of drug price disclosure, but they are reluctant to initiate any action that would change the current policy. In fact, it was difficult to find doctors who would participate in this survey in more than an advisory capacity. Another issue which pharmacists are quick to point out is the effect of advertising on the relationship between doctor and patients. Generally, pharmacists believe that patients will urge physicians to prescribe advertised drugs and that doctors will respond accordingly.

Many pharmacy professors state that if advertising is allowed, consumers will shop around and thereby destroy the comprehensive patient profile that some pharmacists like to maintain for regular customers. While TexPIRG is in support of this clinical approach to pharmacy, each individual should have the necessary information to choose between a patient profile and a cost reduction, if both cannot be obtained. For most consumers, the difference between $.88 and $8.00 (the cost range for Penicillin G) is significant. Indeed, if this is the cost of maintaining a patient profile, it is a luxury that the large majority of consumers cannot afford. It is possible, however, to achieve price reduction as well as maintain important patient services. Prescription drugs are not a luxury, they are an immediate necessity. Consumers cannot spend large amounts of time shopping around, nor can they wait for "good buys" as they might with groceries. There are many indications that price disclosure, and the competitive pricing that would result, would eliminate excessive mark-ups and stabilize prices so that the consumer could choose a pharmacy on the basis of the services provided, not on the basis of cost differences. This issue is summarized in the case of Sav-a-lot vs. Commissioners of Pharmacy (Baltimore): "The promotion of the monitoring function (patient profiles) by a statute forbidding the advertising of prices of prescription drugs at best is a very indirect and arbitrary method to accomplish such a goal."[3]

The fight to allow advertising has been led by certain chain drug stores. Osco Drugs, Inc., with 178 stores in 17 states began posting prices of its 100 most frequently filled prescriptions in October 1971. As a consequence, Osco has become involved in litigation and other forms of harassment from state boards of pharmacy. At the present time, Osco has won favorable rulings in North Dakota and Wisconsin, and a suit challenging advertising laws is pending in Illinois. The constitutionality of advertising prohibitions has been upheld in New. Jersey (Supermarkets General Corp. vs. Sills) and denied in Florida (Stadnik vs. Shell City, Inc.). In part, the decision of the Florida Supreme Court reads as follows:

> "The effect of the rule is simply that the druggist cannot advertise the price of a prescription drug even though he is prohibited by law from selling the drug except upon the prescription of a physician. There is simply no reasonable justification

for such an administrative intrusion on private rights when the regulation is so completely lacking in public benefit."[4]

The Pennsylvania Supreme Court ruled in January 1971 that the ban on advertising was unconstitutional because the statute promoted "the dampening of price competition in the retail sale of prescription drugs." By December, the Pennsylvania Pharmacy Board enacted new regulations requiring that advertisements provide full disclosure of a drug's actions, interactions, indications, contraindications, adverse reactions, and dosage. This kind of "disclosure", most of which only a physician can understand, is obviously designed to cripple the advertising movement. Pharmacies attempting to advertise in Florida and Illinois have encountered intense harassment from state pharmacy boards. The problem ranges from threatened revocation of pharmacists' licenses to blacklisting in pharmacy schools.

Government consumer agencies have been highly vocal in support of repealing anti-advertising laws. The HEW Task Force on Prescription Drugs states "...if the patient is to maintain the right to select a pharmacy, he also has a right to know the prices it charges and to compare these with other prices."[5] The United States Department of Justice has recently issued a strong statement on the subject. Two passages from the "Research Paper and Policy Statement of the U.S. Department of Justice on the Advertising of Retail Prescription Prices" are well worth quoting here:

> "The Department of Justice believes that the major effect of legislation or regulations prohibiting price advertising of prescription drugs is to reduce retailer incentives to engage in price competition with resulting higher costs to the public."

and,

> "Accordingly, it is the Department's view that existing state legislation or regulations which prohibit or restrict price advertising of prescription drugs may well be adverse to the public interest. Since such restrictions appear to be unnecessary to protection of the public and result in unjustifiable expenditures by consumers, the Department feels they should be eliminated."

In a speech before the 1972 Pharmaceutical Conference of the National Association of Chain Drug Stores, Inc., Virginia Knauer, Special Assistant to the President for Consumer Affairs, stated her opinions on advertising:

> "It is true that there is a distinction between prescription drugs and other drug store items. The consumer does not have the choice of <u>what</u> to buy. But this does not mean that the consumer should not have the right to choose <u>where</u> to buy, taking into consideration both the price and the services he is offered by various drug stores."

and more bluntly,

> "Pharmacy laws are widely recognized as a means of protecting the independent drug store from his larger competitors. While it is true that large operations have an advantage in price competition, the economies of scale offer no superiority on such vital elements of competition as the convenience of the location or of the friendliness of the service."

Some local agencies[6] are actively pursuing solutions to this problem. The Director of the Seattle Consumer Protection Office has raised the issue of price disclosure in the state of Washington. He became interested in this aspect of consumer affairs after he encountered great reluctance on the part of Seattle pharmacists to price prescriptions over the telephone.[6]

What exactly is the cost of price secrecy and lack of competition among drug stores? Logically, one could expect that pricing would be arbitrary. Prices would vary widely from store to store, even well beyond what could be expected from variations in overhead costs. The implication is that the consumer will often have to pay more than he should.

To determine the effects of price secrecy in Houston, members of the Texas Public Interest Research Group conducted a price survey of Houston drug stores. Twenty-four pharmacies were randomly selected from those within the Houston city limits. Valid prescriptions were obtained from sympathetic physicians. The prescriptions consisted of four common brand-name prescriptions and four equivalent

generic prescriptions, as indicated below:

Pentids	250 mg.	40 tabs	antibiotic
Potassium Penicillin G	250 mg.	40 tabs	antibiotic (generic)
Equanil	400 mg.	42	tranquilizer
Meprobamate	400 mg.	42	tranquilizer (generic)
Sumycin	250 mg.	40 caps	antibiotic
Tetracycline	250 mg.	40 caps	antibiotic (generic)
Nembutal	30 mg.	14	sedative
Sodium Pentobarbital	30 mg.	14	sedative (generic)

Student volunteers were organized into twelve two-man teams, each team member having one valid prescription. A team would visit a store, present its prescriptions, and ask the prices. Each team member witnessed the price quoted to the other. With each team visiting eight stores, a total of four prescriptions, two brand name drugs and their generic equivalents, were priced in each store. Consequently, price data for each drug is drawn from a sample of twenty-four pharmacies.

The need to resort to the complicated (some would say devious) data-collecting procedure outlined above underscores the inaccessibility of information. A telephone survey was impossible. Only four of ten pharmacies contacted would price a Potassium Penicillin G prescription over the telephone. The first team to visit a given pharmacy would invariably obtain the desired information. However, the second team was not as fortunate. By this time, some druggists realized what our intentions were; this realization was occasionally accompanied by missing data. On the whole, however, data-gathering was successful using this procedure.

The results of this survey speak for themselves. Table 1 shows the average price, price range, and the number of pharmacies consenting to quote prices. Unfortunately, the Nembutal and Sodium Pentobarbital prescriptions were written for an uncommon dosage, the 50 milligram tablets being the common dosage. This explains the relatively scarce data for these prescriptions.

Table 1 Range of Prescription Drug Costs *

Pentids
Average: $6.40
Range: $4.86 - $10.49
23 pharmacies

Potassium Penicillin G
Average: $4.71
Range: $0.88 - $8.00
23 pharmacies

Equanil
Average: $4.37
Range: $3.56 - $6.20
23 pharmacies

Meprobamate
Average: $3.23
Range: $1.53 - $7.20
21 pharmacies

Sumycin
Average: $3.55
Range: $1.99 - $5.50
23 stores

Tetracycline
Average: $3.47
Range: $1.93 - $6.00
23 stores

Nembutal
Average: $1.66
Range: $0.76 - $3.00
12 stores

Sodium Pentobarbital
Average: $1.31
Range: $0.88 - $2.25
11 stores

It is fair to assume that the average Houston consumer would not pay $8.00 for 40 penicillin tablets if he were aware that the same prescription cost $0.88 elsewhere. This particular case represents a variation in price of over 900%. If the drugstores in the sample were openly competing with each other for business, this variance, as well as the large variances for the other seven prescriptions, could not possibly exist.

Attempts were made to correlate prices with three factors thought to influence drug prices: whether or not the pharmacy was located in a disadvantaged socio-economic area, whether the pharmacy was a chain member or an independent, and whether the pharmacy provided minimal, some, or most drugstore services. The evidence for the influence of these three factors was either inconclusive or insufficient. If these conditions indeed do influence price, they fall far short of justifying the price variation described.

*See Appendix for complete data

Is the Repeal of the Advertising Prohibition the Answer?

Our primary objective is to make drug price information available to the public. Ideally, every drugstore's prescription prices should be accessible to the consumer. The choice of a drugstore would then be determined by balancing the important factors: convenience, services, and price.

Advertising per se would have two important effects: advertisements would provide consumers with a general idea of what specific prescriptions should cost, and pricing would become more competitive. This situation, although far from ideal, would certainly be preferable to what exists now. The problems with advertising are worth mentioning. First, it is already practice among a few pharmacists to sell a very common prescription drug such as birth control pills at a loss. Through this practice, the pharmacist hopes to attract the regular business of a customer. We could expect the same situation with advertising. A few drugs will be advertised at very low prices, thus attracting consumers to a store which may sell all other drugs at excessive prices.

In general, advertising will not provide consumers with all the necessary data to make sound decisions. They will only know the prices in those stores which can afford to advertise, and then only for selected drugs.

There is only one truly effective means of providing the public with the information it needs. A statute must be enacted which would require each drugstore to post on the premises the prices of the 100 drugs most commonly prescribed nationwide. This formulary, which would list drugs according to generic class, would be drawn up by the state board of pharmacy and the health department. This program has already been put into effect in Vermont, and legislation has been introduced in several other states.

In addition, we recommend that the state board of pharmacy, HEW, and representatives of consumer groups establish maximum prices for all drugs. (This would be quite similar to what already exists in the Vendor Drug Program within the Welfare Department.) The Attorney General should be empowered to levy fines whenever a drug was sold for more than the maximum established price.

The Case for Substitution

The American Pharmaceutical Association defines substitution as "the substitution of one manufacturer's therapeutically effective and chemically equivalent drug product for the product of another prescribed by trade name alone."[7]

-Trade name (brand name): The name coined and usually registered by the manufacturer to describe a specific drug product made by him alone
-Established name (generic or nonproprietary name): established names include:

1) Names used in the National Formulary and the United States Pharmacopeia to describe drug entities
2) Names promulgated by the Secretary of HEW to describe drug entities
3) In the absence of a name in category (1) or (2), the common name of the drug entity if it has one

(Definitions provided by A. Ph. A.)

Very simply, generic refers to an entire class of drugs; the brand name drugs within the class as well as the non-proprietary drugs, those which are not given names by their manufacturers. All the unnamed drugs are called by the generic name.

Currently, pharmacists are not allowed to stustitute a generic drug for a brand name drug when the two drugs are chemically identical. For instance, Pentids is the Squibb brand name for penicillin G. When a pharmacists receives a prescription for penicillin G, he may fill it with Pentids or any brand name of his choice. However, if a doctor prescribes a specific brand name, such as Pentids, the pharmacist is not allowed to substitute an equivalent but cheaper brand. Simple statistical analysis indicates that generically filled prescriptions can be expected to cost less than equivalent brand names virtually 100% of the time.

Today, pharmacists, almost without exception, are in favor of generic substitution. They would like to see the anti-substitution laws repealed. This would grant them more professional responsibility in making drug therapy decisions for their patients. The American Pharmaceutical Association's Policy Committee on Public Affairs is clear on this issue:

"The pharmacist's training and expertise qualify him as an expert on drugs and permit him to make judgments about quality drug products. Thus, in the Committee's view, antisubstitution laws serve for the most part to eliminate the pharmacist as a decision-maker in providing rational drug therapy for patients. To state the proposition in other terms, a major effect of antisubstitution laws is to make the pharmacist's function more mechanical than professional..."

The APhA further argues that allowing generic substitution would increase efficiency; lower the cost of widely-used drugs, permit reduction of inventories of generic drugs manufactured by many different companies, force drug manufacturers to compete, and require physicians to obtain drug information from sources other than medical journal advertisements.[8] The Texas Pharmaceutical Association favors modification of the Texas antisubstitution law to allow generic substitution and is currently engaged in legislative activity toward that end.[9] A director of the Texas Pharmaceutical Association states "...this would allow the pharmacist the professional perogative of selecting from a wide variety of quality drugs of identical chemical composition the one which provided the most reasonable price consistent with high standards."[10]

Doctors have mixed feelings on the issue of generic substitution. Although they recognize that there is little if any clinical difference among brands of a generic drug to justify large price differences, they are reluctant to allow pharmacists to assume what has been a doctor's responsibility. There have been some instances however, where doctors have voluntarily co-operated in plans which would allow substitution. In Charlottesville, Virginia, a plan was worked out between the pharmaceutical association and the medical society whereby "physicians agreed to prescribe by nonproprietary (generic) name, and pharmacists agreed to dispense accordingly and pass on cost savings to the patient."[11]

The only serious opposition to repeal comes from the major drug manufacturers. They are the people who successfully pushed for the adoption of antisubstitution laws in 44 of the 50 states during the 1950's. These laws now serve to protect the large profits of the big drug manufacturers. "About 90-95% of all drugs sold by manufacturers are brand name products protected by patents or supported by highly promotional expenses."[12] The drug manufacturers use 'the necessity for quality control' as their central argument. Yet the stringent testing and regulation by the FDA in recent years removes the basis for these arguments; there are few generic drugs on the market today of inferior or detrimental quality.[13]

It is generally believed by consumer groups that if pharmacists were allowed to substitute generic equivalents in the case of brand name prescriptions that they would pass on cost savings from stock reduction and competition among manufacturers to their customers. There is no reason to believe that this would not be the case. There would be other benefits to the consumer as well. A customer would no longer be inconvenienced by a pharmacist not having the specific brand name drug that was prescribed.

If, however the consumer is to benefit in any <u>major</u> way, there are two critical questions which must be answered.

1) IF A PHARMACIST IS ALLOWED TO SUBSTITUTE, IS THERE ANY INDICATION THAT HE WILL SUBSTITUTE A LOW PRICED GENERIC EQUIVALENT?

The most disturbing fact revealed by the Houston survey relates directly to this. One of the drugs used in our survey was Tetracycline, the generic name for an inexpensive commonly prescribed antibiotic. Sumycin, brand name tetracycline, of slightly higher than average cost, was also used. In 8 of the 24 drug stores surveyed, the price quoted for generic tetracycline was higher than the price quoted for Sumycin. This means that 1/3 of the pharmacists were filling generic prescriptions with one of the most expensive brand names, even when cheaper brand name drugs were available. It is conceivable then that the repeal of the antisubstitution law by itself could actually serve to increase drug costs.

2) IF PHARMACISTS WERE SUBSTITUTING GENERALLY LOW PRICED GENERIC EQUIVALENTS, IF THERE ANY INDICATION THAT THEY WOULD NOT ENGAGE IN HUGE MARKUPS?

A pharmacy professor at the state university of New York conducted a survey similar to TexPIRGs. Professor Wertheimer concluded that "prices varied according to the customer's dress, his age, his race, the time of day or week he purchased

the prescription, and other irrelevant factors."[14]

There is evidence enough that repeal of the substitution laws might act only to increase the pharmacists' margin of profit and actually result in even greater financial burden for the consumer. We believe that the only means for assuring that both pharmacist and consumer benefit from repeal of the law is if it goes hand in hand with the requirement that every drug store post prices. This will not only avoid excessive markups, but a consumer can then ask the pharmacist to substitute according to the prices posted in the store.

TexPIRG will lobby extensively for passage of a posting requirement. We will urge that the antisubstitution law be repealed, but only after the posting requirement has become law. We will actively support any other legislation which provides for a more clinical orientation to the pharmacy profession.

The drug pricing survey was developed and carried out by TexPIRG members at the University of Houston and Rice University, with the help of Ms. Sandra Dement of the Citizen Action Group in Washington, D.C. The report was done by Paul Sanner, Rice University senior, and TexPIRG staff.

For further information or additional copies of the report, contact:

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713 667-1087

Austin: Traci Harte (TexPIRG State Office)
512 477-3118

NOTES

1 HEW, "Prescription Drug Data Summary," p. 6.

2 Vordenbaum, Statement to the Texas Senate Interim Committee on Rising Medical Costs, Dec. 5, p. 1.

3 Sav-a-lot vs. Commissioners of Pharmacy, p. 9.

4 "Prescription Drug Pricing," CFA, p. 4.

5 Sav-a-lot vs. Commissioners of Pharmacy, p. 16.

6 The Post-Times, Seattle, Sat. Nov.4.

7 "Pharmacist's Role in Product Selection," p. 6.

8 Ibid., p. 5.

9 Vordenbaum, Statement, Dec. 5, p. 5.

10 Ibid.

11 "Pharmacist's Role in Product Selection," p. 8.

12 "Controlling Health Care Costs in Illinois," p. 9.

13 Burack, The New Handbook of Prescription Drugs, p. 13.

14 "Prescription Drug Pricing," p. 5.

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Knauer, Virginia, Remarks before National Association of Chain Drug Stores, Inc., 1972 Pharmaceutical Conference.

"Pharmacist's Role in Product Selection," The Board of Trustees, American Pharmaceutical Association, March 1971.

Porterfield, Paul, Director, Seattle Consumer Protection Office, Statement to Washington State Board of Pharmacy on Drug Advertising and Drug Discounting.

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Wertheimer, Albert, "Prescription Pricing: Art, Science, or Whim", California Pharmacist, March 31, 1971, p. 6.

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.

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

I. REQUEST
Bill No. House Bill 584
Title: An Act relating to substitution of prescription drugs by pharmaci
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

THE PRECEDING PAGES WERE TREATED AS
A UNIT IN THE ORIGINAL FILE.

~~page 1 line 27 & 28~~
~~another~~

page 2 line 24 after
"of the" "generic names of the"

line 25
"and examples of each by brand
name if any" after the word
persuded.

Passed

IB584
2-25-76

page 1 line 14 other words rather than therapeutically equivalent; Bio equivalent

Bio equivalent is defined in scientific community.

Blood levels are the problem. if it is is it therapeutically equivalent.

April 28 Fed. Regulations will take effect re: bio equivalent.

page 2 line 4 drugs are to be bio equivalent.

Add quantity to label

Counsel of State governments to see if any of the 11 states have problems with the bill.

B. R Grace is holsaler in MA

Bill to Use In C S

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 2/6/76
Referred: Judiciary

IN THE HOUSE BY THE COMMERCE COMMITTEE

CS FOR HOUSE BILL NO. 584

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs may specify in writing or by oral communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the person's handwriting or, if the prohibition was communicated orally, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Alaska law provides that with your consent, unless prohibited by your doctor, this pharmacy may substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor." The printing on the sign shall be in block letters not less than one inch ir

height.

(d) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(e) If the physician prescribes a drug by its generic name, the pharmacist shall dispense the lowest retail cost ~~brand~~ drug product which is in stock. which and complies with the prescription

(f) As used in this section, unless the context requires otherwise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(4) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

* Sec. 2. AS 08.80 is amended by adding a new section to read:

Sec. 08.80.297. POSTING OF PRICES. (a) Annually ~~in the month of August~~, the Department of Commerce and Economic Development shall prepare a list of the generic or brand names of the 100 most commonly prescribed prescription drugs, their usual strength and amount prescribed, and distribute the list along with regulations for posting to each pharmacy registered with the board of registration in pharmacy. The determination of the department as to which drugs are to be included on the list shall be final.

(b) The current list of the 100 most commonly prescribed drugs

shall be conspicuously posted in each pharmacy registered with the board. After each prescription drug listed, the name of the manufacturer and the current selling price shall be clearly indicated for that prescription by the pharmacy. A pharmacy may change the current selling price and the posting of the price at any time.

(c) The price of all other drugs not included on the list of 100 commonly prescribed drugs shall be available and shall be quoted by the pharmacy upon request.

Re insert sec 2 as sec 3

Introduced: 1/15/76
Referred: Commerce and Judiciary

IN THE HOUSE BY BRADLEY, BRADNER AND GARDINER

HOUSE BILL NO. 584

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent.

(b) A licensed medical practitioner may specify in writing or by a telephonic communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the practitioner's handwriting or, if the prohibition was communicated by telephonic communication, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on the sign shall be in block letters not less than one inch in height.

(d) A pharmacist shall substitute a drug product under (a) of

this section only when there will be a savings in or no increase in cost to the purchaser.

(e) If the physician prescribes a drug by its generic name, the pharmacist shall dispense the lowest retail cost brand which is in stock.

(f) Except as provided in (g) of this section, when a pharmacist dispenses a substituted drug as authorized by (a) of this section, he must label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug manufacturer. and quantity

(g) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container except if the prescriber writes "do not label," or words of similar import, on the prescription or so designates in an oral transmission of the prescription.

(h) As used in this section, unless the context requires otherwise:

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

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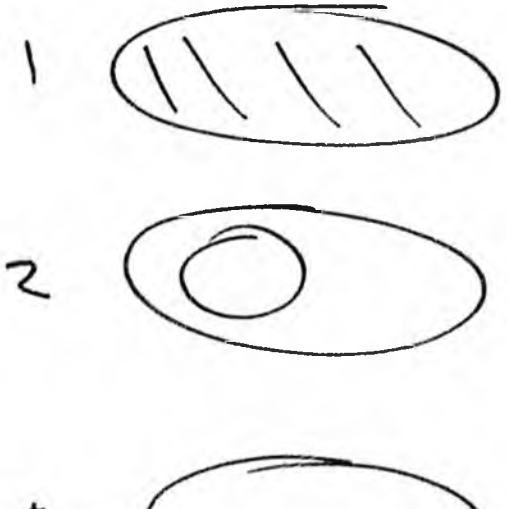
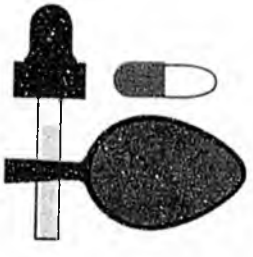
(b) A person who violates the provisions of sec. 295 of this chapter is punishable by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in the Administrative Procedure Act (AS 44.62).

The chairman of the Medical Association's special subcommittee on the question of generic substitution ~~is the a drug~~ was the only drug wholesale business in the state. This information was given to me by AkPirg.





Keflex®
cephalexin
Lilly

HB584 - Drugs Bradley

Ron Sedwick - Alaska Pharmacy Assoc.

Support concept - better prescription quality & price

Page 1, line 14 "therapeutically equivalent"

too broad language

"bio equivalents" → same blood level in system

April 28 - Fed Regs

We should tie ourselves to Fed standards developed

Pag 1 line 15, 16 change person to "physician or agent"

Tetracycline 15^{00} for 100
Most common antibiotic 2^{cc} for 100 $3^{00} - 5^{00}$ $75\frac{1}{2}$

Section (e) have refer back to (a) as (d) does

put (f) + (g) original bill back in this is existing statute

suggestion - add quantity of container requirement to this section

---

Paul Mitchell

Grace is only wholesaler in Alaska

1967 —

Original Sponsors: Bradley, Bradner and Gardiner

Offered: 2/6/76
Referred: Judiciary

IN THE HOUSE BY THE COMMERCE COMMITTEE

CS FOR HOUSE BILL NO. 584

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to substitution of prescription drugs by pharmacists."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.80.295 is repealed and re-enacted to read:

Sec. 08.80.295. SUBSTITUTION. (a) Except as limited by (b) and (d) of this section, with the consent of the purchaser, the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. Upon substitution the pharmacist shall notify the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs may specify in writing or by oral communication that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or words of like import must be in the person's handwriting or, if the prohibition was communicated orally, in the pharmacist's handwriting, and shall not be preprinted or stamped or initialed on the prescription form.

(c) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Alaska law provides that with your consent, unless prohibited by your doctor, this pharmacy may substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor." The printing on the sign shall be in block letters not less than one inch in

shall be conspicuously posted in each pharmacy registered with the board. After each prescription drug listed, the name of the manufacturer and the current selling price shall be clearly indicated for that prescription by the pharmacy. A pharmacy may change the current selling price and the posting of the price at any time.

(c) The price of all other drugs not included on the list of 100 commonly prescribed drugs shall be available and shall be quoted by the pharmacy upon request.

F Add Section #2 of HB584

REVIEW & OUTLOOK

Bureaucracy at Work

We really don't have anything personal against bureaucrats, pointy-headed or otherwise. It's not the people but the system, which is currently on display in the Food and Drug Administration's recent proposal to test the quality of generic drugs.

It's not that there ever has been a particularly serious problem with the quality of generic drugs, which are the chemical equivalents of brand-name drugs. Brand names are given to a drug by the company that develops and patents it. Naturally, the patent protection allows a company to establish its drug as standard. After the patent protection runs out, other firms are free to bring out generic versions. But doctors have tended to continue to prescribe by brand name. They knew what they were getting, and somehow the quality of generic drugs never arose as an issue.

The FDA has discovered, however, that a problem with the quality of generic drugs is now upon us. The problem is caused by the FDA's parent bureaucracy, the Department of Health, Education and Welfare, which frowns on brand-name prescriptions. The brand-name drugs typically cost more than the generic-name equivalents, and HEW is setting out to protect the consumer with something called Maximum Allowable Cost. In brief, under Medicare and Medicaid, it will reimburse for the cost of generic drugs, not for brand ones.

HEW estimated that its new rules would save $88.8 million of the $1.2 billion spent for drugs under federal programs. But it turns out that this includes savings from other proposals, such as limiting the retail markup. The substitution of generic for brand-name drugs will save, it says, $48 million. This is about 4% of the federal drug bill.

Now, lo and behold, the FDA announces that, just as brand-name manufacturers have always contended, generic drugs are not necessarily the same as brand-name ones. The active ingredients are the same, but sometimes the binders and fillers do make a difference. So the FDA will require makers of generic drugs to demonstrate that their versions are as effective as the "reference" (read "brand-name") drugs. In some cases the FDA will accept laboratory tests on dissolution rates, but for about half of the 137 drugs immediately involved it will require human tests to measure the concentration of drugs in the blood stream.

We do not recall noticing how much this new FDA program will cost, but we assume it is well under $48 million, since the entire FDA payroll is some $200 million. Of course, the generic drug manufacturers will have to pay for extra testing, thus somewhat cutting the $48 million savings. The real catch is that the FDA has yet to face the big problem, which is not fillers and binders, but quality control in the factories.

When HEW campaigns against brand-name prescriptions, it in effect takes upon itself the responsibility for quality control formerly exercised by prescribing physicians. If the source of the drug is decided not by the physician but by a pharmacist officially encouraged to use the lowest-cost source, someone has to worry about the quality of drugs made in every chemical shop in the nation capable of cooking up a recipe already spelled out in an expired patent. This implies an army of government inspectors, all devoted to solving a problem the doctors formerly handled with a stroke of a pen.

And for what? Any true saving for the consumer is highly problematical. The drug companies need to get enough return to justify their research, and if they cannot get it through market position after patents expire they will have to get it through higher prices while the patents apply. New tests for generic drugs will represent additional costs, which someone has to pay. And if the FDA gets deeply into quality control, as it almost certainly must, most of any envisioned savings would merely be shifted from the consumer's drug bill to his taxes, over which he has even less control.

The likelihood is that the drug companies will maintain their profits, and that the salaries of extra bureaucrats will represent merely an increase in the total cost to the consumer. But assume for a moment that the consumer breaks even, that the bureaucrats' salaries are offset by lower drug company profits. What have you then done? You have taken money that would go into drug research and other capital investments, and paid it instead to bureaucrats hired to solve a problem that didn't exist until the bureaucrats caused it.

Reprinted from THE WALL STREET JOURNAL—*July 10, 1975*

When Friends or Patients Ask About . . .

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The Cost of Drugs

Mickey C. Smith, PhD

PATIENT concern over drug prices frequently finds expression in questions asked of their physicians. What responses can be given?

It is good to recognize the pervasive role of drugs in the lives of most patients. The total sales of prescription drugs in 1974 was more than $5 billion. The average patient received eight prescriptions in that year; the patient over 65 years old may have received 15 or more prescriptions. In addition, some $3.5 billion worth of nonprescription drugs were sold.

The prescription drug has other characteristics that make it vulnerable to patient complaint. Remember that the patient first visits his physician, and then still must get his prescription filled. Also, as has been pointed out before by others, prescription drugs are unusual in being one commodity where the person who chooses is not the one who pays. To place these expenses in perspective, it is well to remember that the ratio of physician charges to drug charges is about 3:1.

Elements of Drug Costs

When your patient has a prescription filled he pays for several things. The first of these is, of course, the cost of the drug itself. This drug cost includes the active ingredient as well as the cost of putting that active ingredient into a dosage form that fits the needs of the patient and conforms to the quality control standards required—either by the Food and Drug Administration (FDA) or, more often, the higher standards that may be imposed by the manufacturer himself.

Added to the cost of the physical drug product are marketing costs. The most obvious of these is the cost of physical distribution, which includes, in many cases, 12% to 15% for the wholesaler.

Another marketing cost is promotion, which includes detail men, direct-mail and journal advertising, convention displays, and the like. Even though this expenditure has been criticized, it is true that promotion enables considerable information to reach the physician. Too, the drug manufacturers would *also* like to eliminate these costs if they believed this was possible.

Brief mention should also be made of expenditures on two types of research. The first, market research, is only a minor part of drug costs. While it is, admittedly, aimed at improving the firm's sales position, market research has also resulted in some products tailor-made to physicians' needs and, furthermore, aims to build efficiency into the promotion process. Costs of basic research on the drugs themselves, and the attendant costs associated with demonstrating the safety and effectiveness to the FDA, are probably familiar to most physicians. It is worth repeating that without such expenditures there will be no new drugs.

A final element of the cost of the drug is profit. Recent experiences with the oil industry have served to highlight the role of profit in the discovery of new resources. The same applies to new drugs. The problem of whether drug industry profits are excessive is far too complex to treat perfunctorily.

The second major component of the prescription charge is the pharmacist's fee, which normally is either a uniform charge added to the cost of the drug or a percentage "markup" on the cost of the drug, or some combination. The increasing role of third parties has resulted in a greater movement toward the first of these systems.

The pharmacy fee, it should be obvious, pays for more than simply "counting the tablets." A partial list of the reasons for this fee would include the pharmacy owner's salary and return on investment, salaries of employed pharmacists and nonprofessional personnel, inventory carrying costs (a major item), rent, utilities, insurance, delivery, credit, and other operating expenses. Some return on

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the investment in five or six years of college education is also expected.

Physicians may tend to ignore the cheaper nonprescription drugs, but they should not, since these medicines represent an important component in the patient's total health expenditure. Not nearly as much is known about the makeup of nonprescription drug costs, but it is certain that, for those that are promoted widely to the public, the major element is promotional costs. An example was provided in a recent review by *Advertising Age* of promotional costs of two analgesics, Tylenol (promoted primarily to professionals) and Anacin. According to the report, $2 million was expended in a one-year period to promote Tylenol sales through professional channels; $45 million worth of the drug was sold. During the same period, the makers of Anacin were reported to have spent about $29 million and to have had between $60 million and $70 million in sales.

Drug Price History

By any index, prescription prices can be shown to have remained reasonably steady in recent years, while dramatic increases have occurred in the price index of other health care goods and services. With 1967 as a base year, the Bureau of Labor Statistics (BLS) index for prescription drugs for 1973 was only 106.

At our institution, further indices have been prepared in the past. Even though a bit dated now, they provide further insight into the behavior of drug prices. With 1960 as a base year (index number, 100), the following index numbers appeared for 1968:

Geriatric drug prices	84.6
Pharmacy services (ie, the pharmacist's fee)	94.0
Wholesale prescription drug prices	105.3
Nonprescription drug prices	124.6

For purposes of comparison, the 1968 price indices (BLS) for certain other medical care expenses were as follows: dentists' fees, 128.5; physicians' fees, 137.1; hospital daily charges, 201.0.

Even though these figures indicate that in the aggregate, prescription drug charges may not be excessive, the individual patient may be unimpressed. What can he do about his own prescription charges?

What the Patient Can Do

The single most important tool that the patient can use to minimize his prescription drug expenditures is *communication*—with his physician and with his pharmacist. The patient should gain from his physician as complete an understanding as possible of his drug therapy, particularly with reference to the expected duration of such therapy. Savings can result from obtaining drugs for long-term use in larger quantities.

The patient should also have a frank discussion with his pharmacist about the pharmacist's fee system. He should find out what determines the fee and what services are provided in return, and indicate whether he wants such services as credit and delivery.

It is also worthwhile for the patient to discuss his nonprescription drugs with the pharmacist. As noted previously, a major portion of the cost of nonprescription proprietary drugs is attributable to promotion. The pharmacist, however, has many quality nonprescription drugs that have not gone through the "television game," in which he may possibly have greater confidence.

A final issue concerns "shopping" for prescription prices. Should the patient shop around? Yes! But not for each prescription. The patient should shop for a family pharmacist the same way he does for a physician. He should acquire a total picture of the total service/fee mix. (Does the pharmacist maintain family drug profiles?) He should choose a pharmacist in whom he can have confidence over the long haul. This trust should rest on the professional competence of the pharmacist, his personal interest in the patient and his family, and an equitable fee system. In the long run, such a procedure is certain to be more economical (and to result in better services) than "pharmacy hopping" with every prescription.

What the Physician Can Do

The physician must be an expert on the use of drugs, and that expertise should include economic factors. Some patients never get their prescriptions filled (partially or even completely) because of the money involved. Others will fail to procure needed refills. Furthermore, patient misunderstanding of, or antagonism toward, drug costs reflects on the entire health care system, including the prescribing physicians.

The physician can start by gaining some idea of the cost ranges of drugs he prescribes most often—particularly on a cost per day basis. That is particularly important for patients who will be taking medication for extended periods of time. A $5 prescription charge may seem less formidable if it is understood that the needed medication may cost less than does one's daily intake of coffee.

Where possible, the physician should attempt to know personally the pharmacists who serve most of his patients. He can discuss the pharmacists' charges frankly, and thus he will be in a better position to answer patient questions. Frequently, physicians and pharmacists working together have been able to resolve economic difficulties for patients faced with particular problems. Certainly, there is no ethical conflict when both work for the benefit of the patient.

Finally, there is prescribing itself. The physician can do a great deal in his prescribing habits to lower drug costs for his patients. Again, an understanding of pharmacists' fees can help determine whether, for example, prescribing larger quantities of medications to be taken for prolonged periods would work to the patient's advantage.

There is also the issue of whether to prescribe by generic name. Again, the physician-pharmacist relationship can come into play. There is no question that *some* savings to the patient can result from *some* generic prescribing if it is known *what* preparations the pharmacist stocks and will dispense. The physician should know the quality and bioequivalence of competing drugs. Perhaps the patient might have some input into this decision as well.

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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. 29. 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.

The Last Stand of Brand-Name Drugs

Companies Protest as State Mc[illegible] to Allow Use of Low-Cost Substitutes

BY RAYMOND T. BONNER

tial relief from the high cost of prescrip- drugs may be near—but the battle is by eans won.

California and more than 40 other states, macists are currently prohibited from ituting a lower-cost but otherwise equiv- generic drug for the more expensive brand indicated on a prescription. ever, the State Assembly has approved d the Senate is now considering—an act would have the effect of repealing this ibition.

tually, there is no need for this legislation the ban on substitution in California is ly a part of regulations promulgated by State Pharmacy Board. Indeed, indepen- of legislative moves and faced with a it, the board has amended its regulation low substitution, a rule which does not ne final, however, until the board holds ngs in the near future.

a result of these actions, drug-company ists, not surprisingly, have mounted a paign to maintain the status quo, with its cessarily high drug prices.

ery drug, of course, has a generic name, may also have one or more brand names. nic names are usually chemical tongue- ers, while brand names are short, simple catchy—designed to be remembered easi- y physicians. For example, Darvon is a d name for propoxyphene hydrochloride; on wholesales for $33.35 (500 capsules), generic equivalent for $8.45.

nsider also the disparity in prices for the non antibiotic known as ampicillin. Bris- Laboratories manufactures ampicillin for bution by three firms besides itself. Bris- own ampicillin is marketed under the name Polycillin, and wholesales for 4 (100 capsules); the same quantity of ol-manufactured ampicillin distributed mith, Kline & French fetches $12.

anwhile, ICN Pharmaceuticals rather y charges $7.50 and $14.80 for identical nts of Bristol's ampicillin. The lower is charged by ICN's generic division and higher price by its brand-name division. e drug, same company—but a price vari- n of 200%. It is all too apparent that y consumer dollars go not for what is in ottle but for the name that is on it.

hy is the industry opposed to the greater of generic drugs? Primarily, to protect ts. Since 1961, the drug industry has ed as one of the two most profitable manufacturing industries in the country, and brand-name products account for a substantial portion of those profits.

Drug companies spend $1 billion annually promoting their brand-name products among American physicians. (This amounts to $5,000 per private practitioner.) By contrast, the industry spent $629 million on all research and development in 1971, and medical schools spent $884 million on all their educational activities in 1972-73.

While permitting substitution would obviously be good for consumers' financial health, the drug industry does not view it as beneficial to its own welfare. Recently, eight drug manufacturers spent more than $15,000 to publish large advertisements in newspapers throughout California declaring that consumers would not benefit from substitution, and urging them to write their senators to oppose the legislation. Same manufacturer

One of the sponsors of that campaign, Parke-Davis, sells a brand-name tetracycline, Cyclopar, for $5.15 (100 capsules). A competitor sells an identical number of tetracycline pills manufactured by the same West Virginia company. The only significant difference is the lack of a brand name on the bottle and, of course, the price: $1.50. Thus, consumers could save more than 200% if pharmacists were permitted to substitute this generic tetracycline for Cyclopar—a good reason for Parke-Davis to oppose substitution.

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When the Pharmacy Board begins hearings on its proposed amended regulation, the drug industry will no doubt offer its well-worn panoply of arguments. In the past, this standard position has been based more on scare tactics than fact. It has used the term "generic" disparagingly, and attempted to equate it with "bad" or "inferior" pharmaceuticals. In fact, however, nearly one-half of the defective drugs recalled in 1972 bore brand names.

The industry tenaciously clings to its contention that all substitution should be forbidden because a few equivalent drugs may not perform identically in a particular patient. This argument ignores findings of the Health, Education and Welfare Department's Task Force on Prescription Drugs, which was under the direction of Dr. Philip Lee, a distinguished physician and former chancellor at UC's medical school at San Francisco.

After an exhaustive two-year study, this task force unequivocally concluded that only in "rare instances" would equivalent drug products not produce substantially the same therapeutic effects. And, the researchers noted, these rare instances have been "grossly exaggerated" as hazards to public health.

Drug-industry lobbyists, moreover, have selectively quoted from a report prepared by the congressional Office of Technology Assessment. On the one hand, they emphasize OTA's observation that, in a particular patient, some equivalent drugs may produce somewhat different effects from those carrying brand names. On the other hand, these lobbyists conveniently fail to cite a declaration on the very next page of the OTA report noting that this disparity "is not, in itself, evidence that the use of such products will produce practical problems in the treatment of patients."

The drug companies also overlook a fact central to the new law: It would only permit—not require—substitution. Thus, if a doctor believes an equivalent drug would not produce the same therapeutic response as the one prescribed, he or she simply writes "no substitution" on the prescription.

Also disregarded by the drug companies is the routine practice by nearly all major hospitals to substitute generic drug products; moreover, substitution has been required for Medi-Cal patients since 1961—all without any documented harm to recipients. Unless the industry means to suggest there is one standard of health care for the poor and another for everyone else, generic drugs should be equally available to all.

Finally, the industry has contended that substitution won't result in any cost saving to consumers. It is hard to understand why the drug companies bother to make such an argument, for it cannot be supported by facts. For example, the HEW task force discovered that the average price for brand-name drugs was $1.11, while those dispensed under a generic name cost less than half as much, or $2.02. For Californians, this means paying an extra $45 million each year for their prescription-drug needs, according to the California Department of Consumer Affairs.

It should be clear that one prescription for relieving the pain of high-priced drugs is to permit pharmacists to engage in generic substitution. We must vigilantly guard against the drug industry's desperate efforts to block the administration of this relief.

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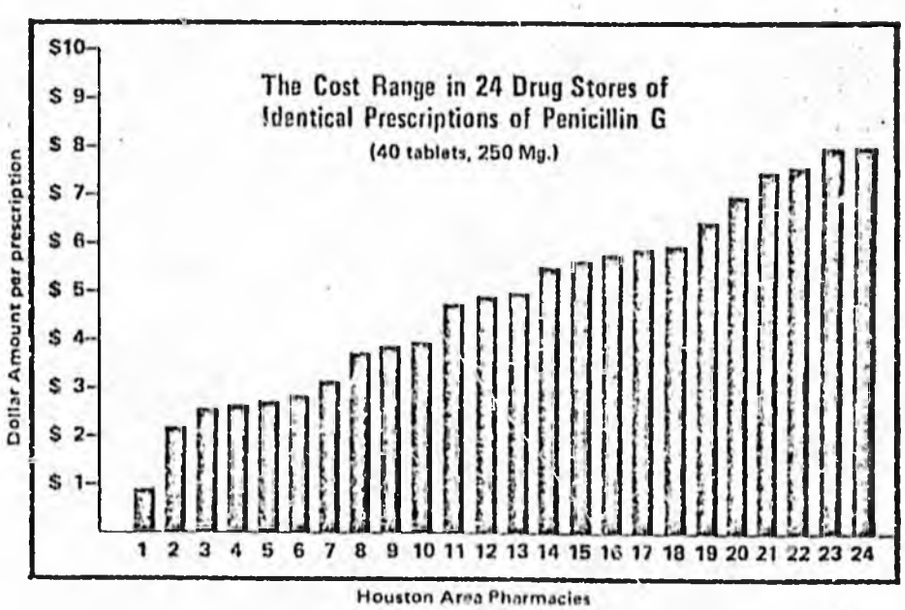
The Real Cost of Prescription Drugs

In Houston between Nov. 2 and 4, 8 prescription drugs were priced at 24 randomly-selected drug stores. In the case of Panicillin G the cost range was from 88¢ to $8.00.



Four billion dollars a year is spent on prescription drugs.[1] "This represents over one billion prescriptions . . . in other words five prescriptions for every man, woman and child in the country."[2]

In recent years, much has been said and written about prescription drugs and their cost to the consumer. Two issues have emerged as the salient aspects of the controversy. First, it is extremely difficult for the consumer to obtain information about the price of a prescription prior to the actual purchase. Advertising of prescription drugs is forbidden by statute or by regulation in thirty-four states. Current prices of common prescriptions are not posted, and price information is not freely available over the telephone. The second important issue is the question of generic versus brand-name prescriptions. Most states, including Texas, have anti-substitution laws which require that a pharmacist fill a prescription exactly as it is described by the doctor on the prescription sheet. This statute protects the welfare of the consumer by insuring that the physician's intended therapy is accurately fulfilled. However, it prevents a pharmacist from substituting a therapeutically equivalent but cheaper generic drug in the case of a brand-name prescription. This report will review some of the recent developments in these controversies and present the results of a prescription drug price survey in the city of Houston.

The Price of Secrecy and the Non-Competitive Market

There are a number of groups who are currently interested in the advertising issue. Pharmacists are officially opposed to advertising because it reduces their standing as professionals. Rivalry, especially business rivalry, has been long frowned upon by all medical professionals. However, the enforced lack of price disclosure has the side effect of protecting every pharmacist's profits, perhaps another reason for the reluctance to advertise. Doctors are generally in favor of drug price disclosure, but they are reluctant to initiate any action that would change the current policy. In fact, it was difficult to find doctors who would participate in this survey in more than an advisory capacity. Another issue which pharmacists are quick to point out is the effect of advertising on the relationship between doctor and patients. Generally, pharmacists believe that patients will urge physicians to prescribe advertised drugs and that doctors will respond accordingly.

Many pharmacy professors state that if advertising is allowed, consumers will shop around and thereby destroy the comprehensive patient profile that some pharmacists like to maintain for regular customers. While TexPIRG is in support of this clinical approach to pharmacy, each individual should have the necessary information to choose between a patient profile and a cost reduction, if both cannot be obtained. For most consumers, the difference between $.88 and $8.00 (the cost range for Penicillin G) is significant. Indeed, if this is the cost of maintaining a patient profile, it is a luxury that the large majority of consumers cannot afford. It is possible, however, to achieve price reduction as well as maintain important patient services. Prescription drugs are not a luxury, they are an immediate necessity. Consumers cannot spend large amounts of time shopping around, nor can they wait for "good buys" as they might with groceries. There are many indications that price disclosure, and the competitive pricing that would result, would eliminate excessive mark-ups and stabilize prices so that the consumer could choose a pharmacy on the basis of the services provided, not on the basis of cost differences. This issue is summarized in the case of Sav-a-lot vs. Commissioners of Pharmacy (Baltimore): "The promotion of the monitoring function (patient profiles) by a statute forbidding the advertising of prices of prescription drugs at best is a very indirect and arbitrary method to accomplish such a goal."[3]

The fight to allow advertising has been led by certain chain drug stores. Osco Drugs, Inc., with 178 stores in 17 states began posting prices of its 100 most frequently filled prescriptions in October 1971. As a consequence, Osco has become involved in litigation and other forms of harassment from state boards of pharmacy. At the present time, Osco has won favorable rulings in North Dakota and Wisconsin, and a suit challenging advertising laws is pending in Illinois. The constitutionality of advertising prohibitions has been upheld in New. Jersey (Supermarkets General Corp. vs. Sills) and denied in Florida (Stadnik vs. Shell City, Inc.). In part, the decision of the Florida Supreme Court reads as follows:

> "The effect of the rule is simply that the druggist cannot advertise the price of a prescription drug even though he is prohibited by law from selling the drug except upon the prescription of a physician. There is simply no reasonable justification

for such an administrative intrusion on private rights when the regulation is so completely lacking in public benefit."[4]

The Pennsylvania Supreme Court ruled in January 1971 that the ban on advertising was unconstitutional because the statute promoted "the dampening of price competition in the retail sale of prescription drugs." By December, the Pennsylvania Pharmacy Board enacted new regulations requiring that advertisements provide full disclosure of a drug's actions, interactions, indications, contraindications, adverse reactions, and dosage. This kind of "disclosure", most of which only a physician can understand, is obviously designed to cripple the advertising movement. Pharmacies attempting to advertise in Florida and Illinois have encourtered intense harassment from state pharmacy boards. The problem ranges from threatened revocation of pharmacists' licenses to blacklisting in pharmacy schools.

Government consumer agencies have been highly vocal in support of repealing anti-advertising laws. The HEW Task Force on Prescription Drugs states "...if the patient is to maintain the right to select a pharmacy, he also has a right to know the prices it charges and to compare these with other prices."[5] The United States Department of Justice has recently issued a strong statement on the subject. Two passages from the "Research Paper and Policy Statement of the U.S. Department of Justice on the Advertising of Retail Prescription Prices" are well worth quoting here:

> "The Department of Justice believes that the major effect of legislation or regulations prohibiting price advertising of prescription drugs is to reduce retailer incentives to engage in price competition with resulting higher costs to the public."

and,

> "Accordingly, it is the Department's view that existing state legislation or regulations which prohibit or restrict price advertising of prescription drugs may well be adverse to the public interest. Since such restrictions appear to be unnecessary to protection of the public and result in unjustifiable expenditures by consumers, the Department feels they should be eliminated."

In a speech before the 1972 Pharmaceutical Conference of the National Association of Chain Drug Stores, Inc., Virginia Knauer, Special Assistant to the President for Consumer Affairs, stated her opinions on advertising:

> "It is true that there is a distinction between prescription drugs and other drug store items. The consumer does not have the choice of <u>what</u> to buy. But this does not mean that the consumer should not have the right to choose <u>where</u> to buy, taking into consideration both the price and the services he is offered by various drug stores."

and more bluntly,

> "Pharmacy laws are widely recognized as a means of protecting the independent drug store from his larger competitors. While it is true that large operations have an advantage in price competition, the economies of scale offer no superiority on such vital elements of competition as the convenience of the location or of the friendliness of the service."

Some local agencies[6] are actively pursuing solutions to this problem. The Director of the Seattle Consumer Protection Office has raised the issue of price disclosure in the state of Washington. He became interested in this aspect of consumer affairs after he encountered great reluctance on the part of Seattle pharmacists to price prescriptions over the telephone.[6]

What exactly is the cost of price secrecy and lack of competition among drug stores? Logically, one could expect that pricing would be arbitrary. Prices would vary widely from store to store, even well beyond what could be expected from variations in overhead costs. The implication is that the consumer will often have to pay more than he should.

To determine the effects of price secrecy in Houston, members of the Texas Public Interest Research Group conducted a price survey of Houston drug stores. Twenty-four pharmacies were randomly selected from those within the Houston city limits. Valid prescriptions were obtained from sympathetic physicians. The prescriptions consisted of four common brand-name prescriptions and four equivalent

generic prescriptions, as indicated below:

Pentids	250 mg.	40 tabs	antibiotic
Potassium Penicillin G	250 mg.	40 tabs	antibiotic (generic)
Equanil	400 mg.	42	tranquilizer
Meprobamate	400 mg.	42	tranquilizer (generic)
Sumycin	250 mg.	40 caps	antibiotic
Tetracycline	250 mg.	40 caps	antibiotic (generic)
Nembutal	30 mg.	14	sedative
Sodium Pentobarbital	30 mg.	14	sedative (generic)

Student volunteers were organized into twelve two-man teams, each team member having one valid prescription. A team would visit a store, present its prescriptions, and ask the prices. Each team member witnessed the price quoted to the other. With each team visiting eight stores, a total of four prescriptions, two brand name drugs and their generic equivalents, were priced in each store. Consequently, price data for each drug is drawn from a sample of twenty-four pharmacies.

The need to resort to the complicated (some would say devious) data-collecting procedure outlined above underscores the inaccessibility of information. A telephone survey was impossible. Only four of ten pharmacies contacted would price a Potassium Penicillin G prescription over the telephone. The first team to visit a given pharmacy would invariably obtain the desired information. However, the second team was not as fortunate. By this time, some druggists realized what our intentions were; this realization was occasionally accompanied by missing data. On the whole, however, data-gathering was successful using this procedure.

The results of this survey speak for themselves. Table 1 shows the average price, price range, and the number of pharmacies consenting to quote prices. Unfortunately, the Nembutal and Sodium Pentobarbital prescriptions were written for an uncommon dosage, the 50 milligram tablets being the common dosage. This explains the relatively scarce data for these prescriptions.

Table 1 Range of Prescription Drug Costs *

Pentids Average: $6.40 Range: $4.86 - $10.49 23 pharmacies	Potassium Penicillin G Average: $4.71 Range: $0.88 - $8.00 23 pharmacies
Equanil Average: $4.37 Range: $3.56 - $6.20 23 pharmacies	Meprobamate Average: $3.23 Range: $1.53 - $7.20 21 pharmacies
Sumycin Average: $3.55 Range: $1.99 - $5.50 23 stores	Tetracycline Average: $3.47 Range: $1.93 - $6.00 23 stores
Nembutal Average: $1.66 Range: $0.76 - $3.00 12 stores	Sodium Pentobarbital Average: $1.31 Range: $0.88 - $2.25 11 stores

It is fair to assume that the average Houston consumer would not pay $8.00 for 40 penicillin tablets if he were aware that the same prescription cost $0.88 elsewhere. This particular case represents a variation in price of over 900%. If the drugstores in the sample were openly competing with each other for business, this variance, as well as the large variances for the other seven prescriptions, could not possibly exist.

Attempts were made to correlate prices with three factors thought to influence drug prices: whether or not the pharmacy was located in a disadvantaged socio-economic area, whether the pharmacy was a chain member or an independent, and whether the pharmacy provided minimal, some, or most drugstore services. The evidence for the influence of these three factors was either inconclusive or insufficient. If these conditions indeed do influence price, they fall far short of justifying the price variation described.

*See Appendix for complete data

Is the Repeal of the Advertising Prohibition the Answer?

Our primary objective is to make drug price information available to the public. Ideally, every drugstore's prescription prices should be accessible to the consumer. The choice of a drugstore would then be determined by balancing the important factors: convenience, services, and price.

Advertising per se would have two important effects: advertisements would provide consumers with a general idea of what specific prescriptions should cost, and pricing would become more competitive. This situation, although far from ideal, would certainly be preferable to what exists now. The problems with advertising are worth mentioning. First, it is already practice among a few pharmacists to sell a very common prescription drug such as birth control pills at a loss. Through this practice, the pharmacist hopes to attract the regular business of a customer. We could expect the same situation with advertising. A few drugs will be advertised at very low prices, thus attracting consumers to a store which may sell all other drugs at excessive prices.

In general, advertising will not provide consumers with all the necessary data to make sound decisions. They will only know the prices in those stores which can afford to advertise, and then only for selected drugs.

There is only one truly effective means of providing the public with the information it needs. A statute must be enact which would require each drugstore to post on the premises the prices of the 100 drugs most commonly prescribed nationwide. This formulary, which would list drugs according to generic class, would be drawn up by the state board of pharmacy and the health department. This program has already been put into effect in Vermont, and legislation has been introduced in several other states.

In addition, we recommend that the state board of pharmacy, HEW, and representatives of consumer groups establish maximum prices for all drugs. (This would be quite similar to what already exists in the Vendor Drug Program within the Welfare Department.) The Attorney General should be empowered to levy fines whenever a drug was sold for more than the maximum established price.

The Case for Substitution

The American Pharmaceutical Association defines substitution as "the substitution of one manufacturer's therapeutically effective and chemically equivalent drug product for the product of another prescribed by trade name alone."[7]

-Trade name (brand name): The name coined and usually registered by the manufacturer to describe a specific drug product made by him alone
-Established name (generic or nonproprietary name): established names include:

1) Names used in the National Formulary and the United States Pharmacopeia to describe drug entities
2) Names promulgated by the Secretary of HEW to describe drug entities
3) In the absence of a name in category (1) or (2), the common name of the drug entity if it has one

(Definitions provided by A. Ph. A.)

Very simply, generic refers to an entire class of drugs; the brand name drugs within the class as well as the non-proprietary drugs, those which are not given names by their manufacturers. All the unnamed drugs are called by the generic name.

Currently, pharmacists are not allowed to stustitute a generic drug for a brand name drug when the two drugs are chemically identical. For instance, Pentids is the Squibb brand name for penicillin G. When a pharmacists receives a prescription for penicillin G, he may fill it with Pentids or any brand name of his choice. However, if a doctor prescribes a specific brand name, such as Pentids, the pharmacist is not allowed to substitute an equivalent but cheaper brand. Simple statistical analysis indicates that generically filled prescriptions can be expected to cost less than equivalent brand names virtually 100% of the time.

Today, pharmacists, almost without exception, are in favor of generic substitution. They would like to see the anti-substitution laws repealed. This would grant them more professional responsibility in making drug therapy decisions for their patients. The American Pharmaceutical Association's Policy Committee on Public Affairs is clear on this issue:

"The pharmacist's training and expertise qualify him as an expert on drugs and permit him to make judgments about quality drug products. Thus, in the Committee's view, antisubstitution laws serve for the most part to eliminate the pharmacist as a decision-maker in providing rational drug therapy for patients. To state the proposition in other terms, a major effect of antisubstitution laws is to make the pharmacist's function more mechanical than professional..."

The APhA further argues that allowing generic substitution would increase efficiency; lower the cost of widely-used drugs, permit reduction of inventories of generic drugs manufactured by many different companies, force drug manufacturers to compete, and require physicians to obtain drug information from sources other than medical journal advertisements.[8] The Texas Pharmaceutical Association favors modification of the Texas antisubstitution law to allow generic substitution and is currently engaged in legislative activity toward that end.[9] A director of the Texas Pharmaceutical Association states "...this would allow the pharmacist the professional perogative of selecting from a wide variety of quality drugs of identical chemical composition the one which provided the most reasonable price consistent with high standards."[10]

Doctors have mixed feelings on the issue of generic substitution. Although they recognize that there is little if any clinical difference among brands of a generic drug to justify large price differences, they are reluctant to allow pharmacists to assume what has been a doctor's responsibility. There have been some instances however, where doctors have voluntarily co-operated in plans which would allow substitution. In Charlottesville, Virginia, a plan was worked out between the pharmaceutical association and the medical society whereby "physicians agreed to prescribe by nonproprietary (generic) name, and pharmacists agreed to dispense accordingly and pass on cost savings to the patient."[11]

The only serious opposition to repeal comes from the major drug manufacturers. They are the people who successfully pushed for the adoption of antisubstitution laws in 44 of the 50 states during the 1950's. These laws now serve to protect the large profits of the big drug manufacturers. "About 90-95% of all drugs sold by manufacturers are brand name products protected by patents or supported by highly promotional expenses."[12] The drug manufacturers use 'the necessity for quality control' as their central argument. Yet the stringent testing and regulation by the FDA in recent years removes the basis for these arguments; there are few generic drugs on the market today of inferior or detrimental quality.[13]

It is generally believed by consumer groups that if pharmacists were allowed to substitute generic equivalents in the case of brand name prescriptions that they could pass on cost savings from stock reduction and competition among manufacturers to their customers. There is no reason to believe that this would not be the case. There would be other benefits to the consumer as well. A customer would no longer be inconvenienced by a pharmacist not having the specific brand name drug that was prescribed.

If, however the consumer is to benefit in any <u>major</u> way, there are two critical questions which must be answered.

1) IF A PHARMACIST IS ALLOWED TO SUBSTITUTE, IS THERE ANY INDICATION THAT HE WILL SUBSTITUTE A LOW PRICED GENERIC EQUIVALENT?

The most disturbing fact revealed by the Houston survey relates directly to this. One of the drugs used in our survey was Tetracycline, the generic name for an inexpensive commonly prescribed antibiotic. Sumycin, brand name tetracycline, of slightly higher than average cost, was also used. In 8 of the 24 drug stores surveyed, the price quoted for generic tetracycline was higher than the price quoted for Sumycin. This means that 1/3 of the pharmacists were filling generic prescriptions with one of the most expensive brand names, even when cheaper brand name drugs were available. It is conceivable then that the repeal of the antisubstitution law by itself could actually serve to increase drug costs.

2) IF PHARMACISTS WERE SUBSTITUTING GENERALLY LOW PRICED GENERIC EQUIVALENTS, IS THERE ANY INDICATION THAT THEY WOULD NOT ENGAGE IN HUGE MARKUPS?

A pharmacy professor at the state university of New York conducted a survey similar to TexPIRGs. Professor Wertheimer concluded that "prices varied according to the customer's dress, his age, his race, the time of day or week he purchased

the prescription, and other irrelevant factors."[14]

There is evidence enough that repeal of the substitution laws might act only to increase the pharmacists' margin of profit and actually result in even greater financial burden for the consumer. We believe that the only means for assuring that both pharmacist and consumer benefit from repeal of the law is if it goes hand in hand with the requirement that every drug store post prices. This will not only avoid excessive markups, but a consumer can then ask the pharmacist to substitute according to the prices posted in the store.

TexPIRG will lobby extensively for passage of a posting requirement. We will urge that the antisubstitution law be repealed, but only after the posting requirement has become law. We will actively support any other legislation which provides for a more clinical orientation to the pharmacy profession.

The drug pricing survey was developed and carried out by TexPIRG members at the University of Houston and Rice University, with the help of Ms. Sandra Dement of the Citizen Action Group in Washington, D.C. The report was done by Paul Sanner, Rice University senior, and TexPIRG staff.

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NOTES

1 HEW, "Prescription Drug Data Summary," p. 6.

2 Vordenbaum, Statement to the Texas Senate Interim Committee on Rising Medical Costs, Dec. 5, p. 1.

3 Sav-a-lot vs. Commissioners of Pharmacy, p. 9.

4 "Prescription Drug Pricing," CFA, p. 4.

5 Sav-a-lot vs. Commissioners of Pharmacy, p. 16.

6 The Post-Times, Seattle, Sat. Nov.4.

7 "Pharmacist's Role in Product Selection," p. 6.

8 Ibid., p. 5.

9 Vordenbaum, Statement, Dec. 5, p. 5.

10 Ibid.

11 "Pharmacist's Role in Product Selection," p. 8.

12 "Controlling Health Care Costs in Illinois," p. 9.

13 Burack, The New Handbook of Prescription Drugs, p. 13.

14 "Prescription Drug Pricing," p. 5.