GENERIC DRUG SUBSTITUTION: FEASIBILITY FOR HAWAII

CALVIN AZAMA
Researcher

Report No. 1, 1979

Legislative Reference Bureau
State Capitol
Honolulu, Hawaii 96813

FOREWORD

The adoption of a generic drug substitution law for Hawaii is an issue that has been debated for many years in the State Legislature. During the Regular Session of 1978, Senate Resolution No. 272 requested this office to study the feasibility and advisability of adopting a policy of generic drug substitution. The following constitutes a fulfillment of that request.

In carrying out this study, the cooperation of many pharmacies, professional organizations, and government agencies was required and received. To these groups, the Bureau extends its sincerest appreciation. The Bureau especially wishes to acknowledge the assistance of Roy M. Yamauchi, President of the Hawaii Pharmaceutical Association; James K. Asato, Past President of the Hawaii Pharmaceutical Association; Florence A. Huntington, Pharmacist with the State Department of Health; Rebecca A. Kendro of the Hawaii Medical Association; the State Board of Pharmacy and Morris M. Comer, its Executive Secretary; Gene Knapp of the Federal Food and Drug Administration; Peter D. Holmes of the Federal Trade Commission; Roger L. Miller of Eli Lilly and Company and all physicians, pharmacists, and owners of pharmacies who participated in our survey.

The reader who wishes a quick summary of the major points of the report is referred to the Summary appearing in the front of the study.

Samuel B. K. Chang
Director

February 1979

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SUMMARY

Introduction

Generic substitution is the substituting of a generically equivalent drug product made by the same manufacturer or a different manufacturer for the drug product prescribed. In addition, the substitute drug product must be of the same strength and dosage form as the prescribed drug product. Usually, the substitution is made for a drug product with a brand name. A brand name is a trademarked name given to a drug product by its manufacturer.

The Major Issues

The advocacy of generic substitution has been motivated by a desire for cost-savings. Proponents of generic drug substitution maintain that brand name drug products are higher priced than their nonbrand name generic equivalents. Opponents of generic substitution maintain that generically equivalent drug products, in fact, may not be therapeutically equivalent. In addition, whether cost-savings in fact occur is questioned. This report concentrates on two issues:

(1) Whether chemically equivalent drug products are therapeutically equivalent?

(2) Whether cost-savings are realized by permitting generic substitution?

Bioequivalency. "Chemical equivalents" mean drug products which have essentially the same amount of the same active chemical ingredient or ingredients. "Therapeutic equivalents" mean drug products which have essentially the same therapeutic effects. Recently, the subdiscipline of pharmacology called "biopharmaceutics" has generally recognized that the measurement of biological availability of drug products in the body is related closely to therapeutic effect. The term "biological availability" or "bioavailability", meaning the amount of the active chemical ingredient or

ingredients in the blood at a certain time, has come to be used. Therefore, two chemical equivalents which have essentially the same bioavailability are called "biological equivalents" or "bioequivalents", and are assumed to be therapeutically equivalent.

Two governmental bodies, the Task Force on Prescription Drugs established by the United States Secretary of Health, Education, and Welfare in 1967 and the Drug Bioequivalence Study Panel of the Federal Office of Technological Assessment convened in 1974, have studied the issue of therapeutic equivalency. Generally, both found that: (1) bioequivalency cannot be insured among all chemically equivalent drug products; and (2) for many chemically equivalent drug products, minimal differences in bioavailability are not dangerous to the public health.

Cost-Savings. Differences in prices between chemical equivalents exist. Whether cost-savings from generic drug substitution occur depends on the following factors:

(1) That chemical equivalents are available, i.e., there are multiple sources for a drug product.

(2) That although there are multiple sources for a drug product, there are no bioequivalency problem.

(3) That physicians do not generally exercise their prerogative of prohibiting substitution.

(4) That customers understand and support substitution.

(5) That pharmacists practice substitution when they can.

A study conducted in 1977 after the enactment of Delaware's generic substitution law indicated that (1) cost-savings are realized by generic substitution; (2) a substantial percentage of prescriptions prohibited substitution indicating physicians' feelings; and (3) pharmacists substituted in slightly more than half of substitutable situations.

Studies in Michigan and Wisconsin on the effects of their substitution laws indicate that over 50 per cent of the prescriptions examined involved multiple-

source drug products. Michigan's samples indicated about a 20 per cent savings per prescription in the first two years after adoption of the law. Wisconsin's samples indicated about a 17 per cent savings per prescription within the first six months. Both Michigan's and Wisconsin's physicians rarely prohibited substitution in the prescriptions examined; however, the incidence of actual substitution by pharmacists in Michigan was infrequent.

Hawaii Surveys. Four surveys were undertaken between August-November 1978, which were designed to uncover data relating to the base of substitutable drug products, the attitudes of physicians, and the attitudes of pharmacists in Hawaii.

1. Based on a survey of new prescriptions dispensed for randomly selected one-week periods in 1977, it was found:

(1) That of the one hundred most commonly prescribed drug products, ten are for drug products written by their generic names, 37 are for drug products substitutable in at least one of six state formularies, and 53 are not substitutable in any of the six state formularies. The 37 substitutable drug products amounted to over one-third of the prescriptions for the one hundred most commonly prescribed drugs.

(2) That of the total sample, approximately 88 per cent were written by brand name and 12 per cent were written by generic name.

2. Based on a 1978 price survey of nine substitutable drug products, it was found:

(1) That brand name drug products differed in price from pharmacy to pharmacy.

(2) That, for some drug products, there were differences in prices between the commonly prescribed brand name and its chemical equivalent which was kept in stock.

(3) That pharmacies generally do not stock chemical equivalents to brand name drug products almost exclusively prescribed by one brand name, e.g., Actifed.

3. With respect to physicians' attitudes, of the 582 physicians responding to a Bureau survey regarding a nonmandatory substitution law where pharmacists could, but were not required, to substitute if the physicians did not specifically prohibit it, approximately 38 per cent were in favor, 26 per cent were in favor for certain drugs, and 33 per cent were opposed. Reasons for opposition were based mainly on a belief of bioinequivalency, intrusion into physician prerogatives, and stifling of research.

4. With respect to pharmacists' attitudes, of the 175 pharmacists responding to a Bureau survey regarding a substitution law similar to that suggested to the physicians, approximately 37 per cent were in favor, 28 per cent were in favor for certain drugs, and 33 per cent were opposed. The main reasons for opposition were fear of liability suits and a belief of bioinequivalency.

LRB CONCLUSIONS AS TO THE MAJOR ISSUES AND RECOMMENDATIONS

The Bureau concludes based on its study that the therapeutic equivalency issue is not a problem for many drug products because of the findings of the Drug Bioequivalence Study Panel of the Office of Technology Assessment that a list of interchangeable drug products is possible, the endorsement of the Federal Drug Administration (FDA) for generic drug substitution, and the absence of liability suits against pharmacists for substitution or for filling generically written prescriptions.

The Bureau concludes based on its study that cost-savings in Hawaii under a generic drug substitution law are possible. In addition, two future developments will aid in generic drug substitution efforts: the loss of patent protection for approximately 70 per cent of the top two hundred drug products prescribed nationwide by 1983 and the proposed release by the FDA of a publication listing chemical equivalents of brand name drug products.

Accordingly, the Bureau recommends adoption of a generic drug substitution law which is nonmandatory, retains the prerogative of the physician to prohibit substitution, requires consumer consent, is linked to a positive formulary, does not mandate specific cost-savings, and provides a certain amount of physician and pharmacist immunity from liability.

Chapter 1

INTRODUCTION

Senate Resolution No. 272 of the Regular Session of 1978 requests the office of the legislative reference bureau to conduct a study to determine the feasibility and advisability of adopting a "...policy of generic drug substitution...". The request appears to include consideration of the repeal of the State of Hawaii's present antisubstitution law and enactment of a generic substitution law. The key paragraph of the resolution stating what is requested is as follows:

> BE IT RESOLVED by the Senate of the Ninth Legislature of the State of Hawaii, Regular Session of 1978, that the Office of the Legislative Reference Bureau is requested to do a study of the relationship of generic drugs to brand-name drugs to determine the feasibility and advisability of adopting a policy of generic drug substitution; including data on cost savings to consumers if such a policy is implemented on a consumer-option basis and the implications that such a program would have on malpractice liability in the event of undesired side-effects of generic substitution; and
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> * * *

The full text of the resolution may be found in Appendix A.

Generic substitution is the substituting of a generically equivalent drug product made by the same manufacturer or a different manufacturer for the drug product prescribed. Moreover, the substitute drug product must be of the same strength and dosage form as the prescribed drug product.

To further understand generic substitution, the following discussion is necessary.

Each drug product has a chemical name and a generic name.

The chemical name describes the molecular structure of the drug product. It is a complex name and "...usually is understandable to and pronounceable by chemists only".[1]

The generic name is that which is "...most commonly used in the scientific literature, supposedly indicating its general chemical nature...".[2] Legally, there is no such term as "generic name". The Federal Food and Drug Administration (FDA), instead, refers to it as the official or established name.[3] The term "generic name", however, is generally used to describe this name of a drug product.

The FDA has the authority to designate a generic name. It has utilized a private organization to recommend a generic name to it, but retains final veto power.[4] Prior to 1964, the generic name of a drug product was assigned by its original developer or manufacturer. Since then, the developer or manufacturer of a new drug product submits the proposed generic name to the United States Adopted Names Council (USAN). The USAN, consisting of representatives from the United States Pharmacopeial Convention, American Pharmaceutical Association (APhA), American Medical Association (AMA), and the FDA reviews the name and may modify it. The generic name is then recommended to the FDA which has final authority of approval. If approved by the FDA, the generic name is submitted to the World Health Organization which works to standardize generic names throughout the world.[5]

In addition, a drug product may have a brand name. This name is trademarked by the manufacturer and is usually short and easy to remember. In most cases, the original manufacturer assigns a brand name to its new drug product.

To assist in understanding the foregoing, the following are the various names of a popular antibiotic:

(1) Chemical name -- Monopotassium 3, 3-dimethyl-7-oxo-6-(2 - phenoxyacetamido)-4 - thia - 1 -azabicyclo[3.2.0.]heptane - 2 - carbonxylate [132 - 98 - 9];[6]

(2) Generic name - Penicillin V potassium;[7] and

(3) Brand names - V-Cillin K manufactured by Eli Lilly & Co. and Pen-Vee-K manufactured by Wyeth Labs.

The Hawaii law currently reads as follows:[8]

> The following acts and the causing thereof within the State by any person are prohibited:
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> * * *
>
> (15) Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without express permission in each case of the person ordering or prescribing;

Under Hawaii's law, a pharmacist receiving a prescription written for a drug product by its generic name may dispense the drug product of any approved manufacturer; provided it has the same generic name.

The situation is different when a prescription is written for a brand name drug product. If a pharmacist receives a prescription for twelve 250 mg. tablets of V-Cillin K, the pharmacist must dispense V-Cillin K. This prescription is written for a brand name drug product and the pharmacist is required to dispense only that drug product unless the prescriber allows otherwise.

Under a generic substitution transaction, however, the pharmacist receiving the same prescription may instead dispense twelve 250 mg. tablets of Pen-Vee-K or the generic equivalent of any other manufacturer if the prescriber does not prohibit.

It should be emphasized that the pharmacist may only substitute a generic equivalent. The pharmacist, for example, cannot substitute penicillin G potassium because it is not a generic equivalent of penicillin V potassium. Nor can the pharmacist substitute a drug product of any other strength besides 250 mg. or of any other dosage form other than tablet form. Thus, dispensing of 125 mg. or 500 mg. tablets or a drug product in its liquid form is prohibited without the prescriber's permission.

Reason For and Opposition to Generic Substitution

The main reason for the advocacy of generic substitution is cost-savings. It is maintained that brand name drug products are higher-priced than their nonbrand name generic equivalents. Dispensing of lower cost, nonbrand name drug products would then save consumers money. To understand this reason more fully, an understanding of drug development and marketing is essential.

Under the federal patent law, the discoverer of a new "invention", "discovery", or process of manufacture has exclusive rights to that invention, discovery, or process[9] for a seventeen-year period if patented with the U.S. Patent Office.[10] No other person may manufacture that product or artifact unless authorized by the patent holder.

This patent protection also applies to the development of a new drug product. A manufacturer of a new drug product patents that product for the seventeen-year period. After the new drug product is approved by the FDA, the manufacturer then has exclusive rights to market the product for the remainder of the patent protection period. In marketing the drug product, the manufacturer assigns it a brand name. At the expiration of the patent protection period, any manufacturer may market the drug product under its generic name or a brand name other than that used by the original manufacturer. The original brand name remains exclusively the property of the original manufacturer as long as it is in use.[11]

Proponents of generic substitution maintain that the original manufacturer utilizes the patent protection period to hammer the brand name into the minds of prescribers.[12]

> It is a matter of accepted business strategy that a company introducing a new, patented drug product will use the period of patent protection to mount a full-scale promotion campaign. This is aimed not only at selling the drug under its brand name while the patent lasts, but also at permanently imprinting that brand name on the memories of prescribing physicians. The goal is obvious: to associate the brand name with the product so that the physician will continue to prescribe it by that name long after the patent has expired.

The simplicity of the brand name as compared to the generic name of a drug product also appears to contribute to prescribing by brand name. For example, a prescriber would probably remember and prescribe Gantrisin, the brand name of an antibacterial agent manufacturered by Roche Labs, rather than sulfisoxazole, its generic name. The difference in complexity between brand name and generic name is more obvious in combination drug products; that is, drug products which contain two or more active chemical ingredients. For example, the generic name of the analgesic Tylenol with Codeine No. 3 manufactured by McNeil Laboratories is acetaminophen 325 mg. with codeine phosphate 30 mg.[13]

Proponents also maintain that the brand name manufacturers spend a considerable amount of money on advertising and promotion to convince prescribers to prescribe their brand name drug products. Figures have been submitted by proponents which portray an enormous amount of spending on advertising and promotion on a per physician basis.[14] Further, proponents argue that far more is spent on advertising and promotion than on research and development.[15]

In the prescription drug trade, control of prescription writing is crucial. The consumer does not buy the drug product on the consumer's initiative. Instead, the consumer buys what the prescriber prescribes. Conversely, the prescriber does not pay for what the prescriber selects. In this unique situation, price and "rational purchasing"[16] are usually not factors in buying prescription drug products. The consumer has no selection prerogative, and, with little or no price posting information, the consumer's ability to shop around is limited. Control of prescription writing is important and proponents feel that the brand name manufacturers have succeeded in guiding prescription writing towards the more expensive brand name drug products.

Thus, proponents feel that the consumer should not be forced to pay for a much promoted, higher-priced, brand name drug product when a lower cost generic equivalent is available.

Opponents of generic substitution, however, have one main argument. They maintain that generically equivalent drug products may not be, in fact, therapeutically equivalent.

It is argued that generic drug products of different manufacturers may differ although all meet the standards of the FDA. They argue that, although the drug products of different manufacturers have essentially the same amount of active chemical ingredient or ingredients and meet official evaluation tests, therapeutic effects may differ because of the nonactive excipients used to add bulk, flavor, or color to the drug product and different manufacturing techniques and quality control procedures. Thus, opponents maintain that generic equivalency does not insure therapeutic equivalency, making substitution dangerous to the public health.

Because of this argument, this report will no longer use the term "generic equivalents". Instead, the terms "chemical equivalents" and "therapeutic equivalents" shall be used. "Chemical equivalents" mean drug products which have essentially the same amount of the same active chemical ingredient or ingredients. "Therapeutic equivalents" mean drug products which have essentially the same therapeutic effects.

In the controversy over generic substitution, one other issue has recently emerged. Cost-savings are being questioned. Simple price comparisons between brand name drug products and their chemical equivalents do show large differences. Cost-savings, however, are being questioned because of two factors:

(1) Many of the drug products on the market are "single-source" as opposed to "multiple-source". "Single source" drug products are available only from one manufacturer because of patent protection or other reasons. "Multiple-source" drug products are chemical equivalents which are available from more than one manufacturer; and

(2) The physician and pharmacist, who are pivotal in generic substitution, may blunt the intent of the legislation by not permitting substitution or not substituting.

This report, therefore, concentrates upon two issues: whether chemical equivalents are therapeutically equivalent, and whether cost-savings may be realized.

This report does not consider other much discussed issues relative to the prescription drug trade such as:

(1) Alleged excessive profits of pharmaceutical manufacturers;

(2) Alleged improper promotion and advertising by pharmaceutical manufacturers;

(3) The relationship of profits to further research and the allegation that more is spent on advertising and promotion than on research and development;

(4) Dangers of drug products in general;

(5) Usefulness of combination drug products;

(6) Allegations by some that the FDA is too restrictive; and

(7) Alleged "irrational prescribing" by physicians.

For these issues, interested persons may wish to refer to Milton Silverman's and Philip R. Lee's book, entitled Pills, Profits, and Politics, Burack's book, entitled The New Handbook of Prescription Drugs, the reports issued by the Task Force on Prescription Drugs, or the record of the hearings by Senator Gaylord Nelson's Subcommittee on Monopoly of the Senate Select Committee on Small Business.

Chapter 2

THERAPEUTIC EQUIVALENCY

Therapeutic equivalency is the most important issue in generic substitution. For, if chemical equivalents are therapeutically equivalent, there should be no hesitation on the part of physicians, pharmacists, and consumers to accept generic substitution. If, however, chemical equivalents are not therapeutically equivalent, then generic substitution should not be encouraged because of the potential adverse effect on the public health.

To examine the issue of therapeutic equivalency, an overview of the problem is presented first. Secondly, pertinent regulatory activities of the FDA are summarized. Lastly, the findings of two expert bodies which examined the issue are reviewed.

Overview

The prescription drug industry is one of the most regulated. Even with the intense regulation, opponents of generic substitution maintain that compliance with the regulations is not enough to assure quality. Rather, quality can only be assured by the manufacturer's manufacturing techniques and quality control procedures.[1] This is the primary argument of the Pharmaceutical Manufacturer's Association (PMA) which consists of approximately one hundred thirty pharmaceutical manufacturers in the country.[2] PMA members account for approximately ninety-five per cent of the prescription sales in the United States and are heavily involved in the research for new drug products.[3] It should be emphasized the PMA does not maintain that only its members are capable of producing quality drug products. Rather, it maintains that quality is a function of the individual manufacturer, whether PMA member or not.[4]

The manufacturing of solid dosage forms of drug products to be taken orally, i.e., tablets and capsules, involves many different formulation factors. Generally, drug products must contain approximately the amount of active chemical ingredient or ingredients stated; it must also contain nonactive ingredients called excipients or adjuvants to add bulk, flavor, or color or to promote disintegration; finally, the drug product must be compressed into form. Differences in the formulation factors may affect the performance of the drug products of different manufacturers.[5]

Under the Federal Food, Drug, and Cosmetic Act, certain drug products must meet standards established by privately published compendia in order to move in interstate commerce. These compendia are the United States Pharmacopeia (USP), National Formulary (NF), the Homeopathic Pharmacopeia of the United States.[6] The last compendium deals with homeopathic drugs and shall not be further discussed.

The USP is published by the United States Pharmacopeial Convention, Inc. The convention is composed of delegates representing all schools of medicine and pharmacy in the United States, all state and national medical and pharmaceutical associations, several federal agencies (including the Food and Drug Administration and the Public Health Service), and professional or trade associations.[7] It was first published in 1820 and adopted as an official compendium in 1906. It includes drug products "...that represent the best teaching and practice of medicine and pharmacy..." and only those fixed combinations in which each component contributes unequivocally to the intended effect.[8] Medical members of the convention select the drug products to be included in the USP. Pharmacist members then establish the standards.[9]

The NF is published by the American Pharmaceutical Association. It was first published in 1888 and, like the USP, adopted as an official compendia in 1906.[10]

For much of its existence, the selection of drug products was based on the extent of use. The fourteenth edition, 1975, of the NF now states that:[11]

> ...Therapeutic value has served as the sole criterion for recognition of drug substances in this edition of the National Formulary.

In addition, the NF includes combination drug products:[12]

> ...for which there is a therapeutic advantage to the patient, as contrasted with administration of the individual active ingredients separately.

In 1970, the NF and USP were merged. The NF is now published by the United States Pharmacopeial Convention.[13]

Both compendia provide essentially the same type of standards. Generally, the standards provide for the:[14]

> ...chemical identity of the active ingredient, the uniformity of content of the active ingredient from tablet-to-tablet or capsule-to-capsule, the time of disintegration, and the time of dissolution.

The most important standards are those for disintegration and dissolution. Both involve placing a tablet or capsule in certain solutions and timing the rate of disintegration and dissolution. Disintegration is the breaking up of the tablet or capsule into granules.[15] Dissolution is, simply, the dissolving of the tablet or capsule in the solution. These standards are meant to correspond with the dissolving of the tablet or capsule in the stomach.[16]

No information on excipients or formulation of a drug product is presented. It is presumed that the disintegration and dissolution tests will determine their effects.[17]

The standards are updated periodically to reflect advances in science.[18]

To combat illness or infection, drug products which are taken orally must be dissolved in the stomach, absorbed into the bloodstream, and delivered to the sites of action in adequate concentration. Prior to the 1960s, it was assumed

that drug products which met the official compendial standards adopted under the Federal Food, Drug, and Cosmetic Act were therapeutically equivalent. The recognition of the subdiscipline of pharmacology called "biopharmaceutics", however, raised questions as to whether the "in vitro" or "out-of-body" tests of the compendia were adequate. "Biopharmaceutics", in short, is the measurement of the biological effects of drug products in the body.[19] The measurement is generally achieved by "in vivo" or "in-body" tests. The drug product is actually administered and its effects are measured.

Biopharmaceutics today generally recognizes that the measurement of "biologically availability" or "bioavailability" is related closely to therapeutic effect. "Bioavailability" means:[20]

> ...the rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action.

In short, it is the amount of the active chemical ingredient or ingredients in the blood at a certain time. It is measured in several ways, including measurement of the concentration of the drug product in the blood or urine.[21] Measurements, called "blood levels", are taken at intervals and the results are plotted in a time versus concentration curve.

Hence, two chemical equivalents which have essentially the same bioavailability are termed "biological equivalents" or "bioequivalents". It is assumed that both are therapeutically equivalent. Conversely, chemical equivalents which have different bioavailabilities are termed "biological inequivalents" or "bioinequivalents", and are assumed to be therapeutically inequivalent.

FDA Regulations

Under the Federal Food, Drug, and Cosmetic Act, the FDA is responsible for the regulation of the drug industry. Regulation, among other things,

involves the registration of manufacturers, inspection of manufacturing techniques, approval for the manufacture of new drugs, establishment of bioavailability standards, and product surveillance.

These regulations are important because opponents of generic substitution maintain that they are not adequate enough to insure therapeutic equivalency among chemical equivalents of different manufacturers. As stated previously, these opponents maintain that quality can only be assured by the individual manufacturers.

While the regulations are complex and difficult for the lay person to thoroughly understand, the following presents summaries of some of the different areas of FDA drug regulations.

Registration and Inspection. Owners or operators of "establishments" which manufacture, prepare, propagate, compound, process, or repackage drugs or drug products must register with the FDA. Owners or operators must also submit a list of all drugs in commercial distribution, whether or not in interstate commerce, which it manufactures.[22] Registration must be made within five days after the beginning of operation or, if the owners or operators have not started operation, within five days after submission of a new drug application.[23] Thereafter, owners or operators must re-register annually within thirty days of receipt of the registration forms from the FDA.[24]

Establishments are required to be inspected by the FDA:[25]

> ...at least once in the two-year period beginning with the date of registration of such establishment...and at least once in every successive two-year period thereafter.

Inspections are designed to assure compliance with FDA's current "good manufacturing practice" (CGMP) regulations.[26] These regulations are broad parameters within which each manufacturer must comply:[27]

> The Good Manufacturing Practices regulations deal with the nitty-gritty of good production, that is, a proper building, proper equipment, proper cleaning of the equipment, proper controls of the raw materials going into the mixing batch, proper control over the labeling, regulation of the type of personnel, and so forth.
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> * * *
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> They are designed to be compliable by the small manufacturer as well as the large but there are certain minimum things that must be observed by all manufacturers to assure drug quality.
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> * * *
>
> So the Good Manufacturing Practices are the basic rules that apply to every drug manufacturer, large or small.

Good manufacturing practice regulations address, among other things, the following:

(1) Personnel -- Direction that personnel responsible for the manufacture and control of drug products be "adequate and have education, training, experience, and capability to assure the safety, identity, strength, quality, and purity of the drug products".[28]

(2) Buildings -- Direction that the buildings be maintained in a clean and orderly manner and be of suitable size, construction, and location for their function. Specifications that the buildings must have adequate space for certain functions and controls to minimize contamination by microorganisms.[29]

(3) Equipment -- Direction that equipment in contact with products be nonreactive, nonaddictive, or nonabsorptive so as not to alter the drug products; no lubricants or coolants required for operation of equipment be in contact with drug products; be constructed and installed to facilitate adjustment, cleaning, and maintenance to assure reliability of control procedures, uniformity, and noncontamination of drug products.[30]

(4) Production and control procedures -- Direction that each significant step in the manufacturing process be double checked with written recordation of the checks; direction for adequate in-process controls to assure uniformity and integrity of the drug products; requirement that representative samples be tested; requirements that procedures be instituted to review production and control records prior to

release of a batch of drug products; requirements for investigation of failure of a batch; provision for the return of goods and their disposition; procedures to properly identify all equipment for the manufacture of a batch; prevention of mixup of equipment and procedures to minimize cross-contamination.[31]

(5) Components -- Requirements of procedures for the storage and handling of components and materials used in manufacturing and packaging. Requirements of procedures for the testing of "an adequate number of samples" to establish specific identity; testing for filth and other extraneous components; testing of active ingredients for strength; testing for microbiological contamination when necessary; identification of the manufacturer of components. Requirement that drug product samples be retained for possible testing after it goes on the market.[32]

(6) Product containers and their components -- Direction that suitable tests and cleaning procedures be used to assure containers are suitable for intended use; direction that container shall not be reactive, addictive, or absorptive so as to alter drug products.[33]

(7) Laboratory controls -- Direction that laboratory controls include the "establishment of scientifically sound and appropriate specifications, standards, and test procedures to assume that components, in-processed drugs, and furnished products conform to appropriate standards of identity, strength, quality, and purity".

This includes keeping records of tests conducted; procedures to test samples for identity and strength; auditing of procedures and instruments; retention of samples and records of drug products for specified periods after distribution; and testing for contamination of nonpenicillin drug products with penicillin.[34]

New Drug Application and Abbreviated New Drug Application. The FDA is empowered to approve a new drug for its safety and effectiveness prior to public distribution.[35] A "new drug" is defined as:[36]

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the

> labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Pursuant to the definition, a new drug is considered to be one for which the scientific literature does not provide sufficient information as to its safety and effectiveness.[37]

In order to market a new drug, a manufacturer must usually proceed through two steps: the investigational new drug (IND) plan and the new drug application (NDA) process.[38]

The manufacturer of the new drug must submit an IND to the FDA to conduct testing of that product. Submission of the IND must be accompanied by:[39]

> Such information as the physical and chemical properties of the drug, the process by which it was to be manufactured, the results of all preliminary test-tube and animal studies, a proposed plan for clinical trials in human subjects, and information on the training and experience of the proposed investigator.

When the IND study is completed, the manufacturer submits an NDA:[40]

> When the IND study has been completed, the manufacturer may submit a New Drug Application (NDA), upon which FDA is required to act within 180 days. The NDA involves additional data relating to manufacturing, marketing, and promotional plans. Methodology for process controls must be outlined, and the manufacturer must assure that each batch of the drug will be equivalent to that upon which the NDA is based. In most cases, the manufacturing facility must be inspected. The proposed labeling (including the required package

> insert) must be approved by FDA. After NDA clearance, the manufacturer must submit periodic reports upon ongoing clinical studies and prompt report of any unexpected adverse reactions.

In addition, the FDA allows manufacturers of chemical equivalents which are already marketed by another manufacturer and which are generally recognized to be safe and effective to submit an abbreviated new drug application (ANDA).[41] The ANDA, as its name suggests, does not require the full information of the NDA. Much of the detailed information required by the NDA may be only summarized in the ANDA.

Bioavailability. Previous to 1977, the NDA and ANDA process did not require all manufacturers to submit bioavailability data; although the FDA did require some manufacturers to do so. The situation is somewhat confusing as to who did submit bioavailability data.

In answers to two questions posed by the State of Delaware, the FDA responded in the following. The questions were:

(1) Whether companies holding approved ANDAs cited in an FDA publication listing holders of NDAs and ANDAs for drug products with bioequivalence problems have submitted bioequivalence data; and

(2) Where bioavailability data are required by the originator of the drug product which holds the full NDA, whether the requirement is required for ANDA holders.

The FDA responded as follows:[42]

> As we have discussed over the phone the questions you have raised can neither be answered by "yes" or "no" as dealt with on a full NDA, ANDA basis. In this connection the answer to the first question you pose is, "All firms holding approved ANDA's have not submitted bioequivalence data; however, all firms holding approved NDA's have not done so either." The answer to question two is "where an NDA holder is required to demonstrate product bioavailability subsequent ANDA holders must usually also provide such information. Except there are instances where the NDA holder did not originally provide such information for his product, whereas the subsequent ANDA holders did. There are additional situations where neither the NDA or ANDA holders submitted such information.

The FDA has recently issued regulations requiring data on the bioavailability of certain drug products. It requires any person submitting an NDA or an ANDA after July 7, 1977 to include either:[43]

(1) Evidence of demonstrating the in vivo or in-the-body bioavailability of the drug product that is the subject of the application; or

(2) Information to permit the Food and Drug Administration to waive demonstration of in vivo bioavailability.

Presumably, the FDA would require bioavailability data for drug products which are identified as having bioequivalence problems.

Certification of Insulin and Antibiotics. The FDA is required to certify each batch of insulin and antibiotic drug products. A batch is only certified if the drug products have:[44]

> ...such characteristics of identity...strength, quality, and purity as the Secretary ±of the Department of Health, Education, and Welfarel prescribes by regulation as necessary to adequately insure safety and efficacy for use.

FDA standards for the testing of antibiotics supersede those of the official compendia.[45]

Product Surveillance. The FDA conducts surveillance of drug products which are on the market.[46] Representative samples of drug products are taken from the shelves of pharmacies and assayed. Manufacturers of defective drug products are allowed to voluntarily recall them or, failing that, face court action forcing removal. The FDA also conducts a drug problem reporting program in which drug products of which someone complains are investigated.

Lannet Case. The United States Court of Appeals of the Third Circuit has handed down a decision affecting the FDA's authority to gather bioavailability evidence. The decision is being appealed by the FDA. This office has not had a chance to review the decision at this writing. Please see Appendix K for the PMA view.

Findings of Task Force on Prescription Drugs and Drug Bioequivalence Study Panel Regarding Therapeutic Equivalence

The question of therapeutic equivalency is a great concern of Congress and the pharmacology community. In the 1960s, the question of therapeutic equivalency was greatly debated in Congressional hearings. Until 1967, however, no governmental body received an official mandate to examine and report on the question of therapeutic equivalency. In 1967, the Task Force on Prescription Drugs was formed to examine certain aspects of the prescription drug industry. In its report, it touched upon the question of therapeutic equivalency. In 1974, the Drug Bioequivalence Study Panel was established to specifically examine therapeutic equivalency.

The Task Force and the Panel, to the extent of our knowledge, were the only official governmental bodies with the mandate to study or touch upon the issue of therapeutic equivalency.

Task Force on Prescription Drugs. The Task Force on Prescription Drugs was established in May of 1967 by the Secretary of Health, Education, and Welfare. Its major purpose was to undertake a comprehensive study of the problems of including prescription drug costs under the Medicare program.[47] The issue of therapeutic equivalency, which the Task Force termed "clinical equivalency", became involved because of the potential cost-savings of generic substitution under Medicare.[48]

The Task Force examined the compendia standards and found the "full agreement among informed scientists and clinicians" that:[49]

> The existing standards do not provide complete assurance of clinical and biological equivalency.

The Task Force, however, qualified the statement by finding that:[50]

(1) The issue of nonequivalency should not be overexaggerated because about eighty per cent of the drug products were single-source and equivalency was not a question for these;

(2) Among the multiple-source drug products, some were not required for serious or critical illness and exact equivalency did not appear to have major clinical importance. Others, however, that were required for serious illness and precise absorption rates would seem to call for particular study under controlled, scientific conditions; and

(3) Consideration should be given to the instance where two chemical equivalents produce different absorption rates but still have therapeutic value. This would happen when one drug product is absorbed rapidly with a high initial peak then rapid decrease in blood levels, while its chemical equivalent is absorbed more slowly, but has a more extended presence in the body.

Finally, in its major finding regarding therapeutic equivalency, the Task Force stated:[51]

> ...that on the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health.

Drug Bioequivalence Study Panel. The Drug Bioequivalence Study Panel of the Federal Office of Technology Assessment was convened in 1974 to:[52]

(1) Examine the relationships between chemical and therapeutic equivalence in drug products; and

(2) Assess the capability of current technology--short of therapeutic trials in man--to determine whether drug products with the same physical and chemical composition produce comparable therapeutic effects.

From the beginning, the Panel recognized two factors also recognized by the Task Force on Prescription Drugs and the pharmaceutical science community in general:[53]

(1) That certain chemical equivalents have produced clinically important and measurable differences in therapeutic effect because of bioavailability differences; and

(2) That differences in bioavailability among some drug products may not be a critical concern regarding their therapeutic effects.

The following summarizes some of the pertinent findings and recommendations of the Panel:

(1) Current standards and regulatory practices do not insure bioequivalence for drug products.[54]

The Panel found that there was considerable literature which suggested differences in the bioavailabilities of chemical equivalents. It stated that since the studies involved marketed products which met compendial standards, the present standards and specifications for materials, manufacturing processes, and controls were not adequate to insure equivalency in bioavailability.

(2) It is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products. Certain classes of drugs for which evidence of bioequivalence is critical should be identified. Selection of these classes should be based on clinical importance, ratio of therapeutic to toxic concentration in blood, and certain pharmaceutical characteristics.[55]

The Panel recommended that bioavailability tests not be conducted for all drug products because of practical infeasibility and ethical reasons. Rather, it identified criteria under which drug products should be tested for bioavailability:[56]

(1) The drug products are used for serious illness;

(2) The drug products are relatively insoluble which may pose problems in their dissolution in the gastrointestinal tract; and

(3) The drug products for which the therapeutic level and toxic levels are relatively close.

In the last criterion, the Panel stated that some drug products have wide ranges between the therapeutic level, that is, the level necessary for the desired therapeutic effect, and the toxic level, the level which would prove dangerous to the patient. The Panel found that:[57]

> Clearly, under such circumstances a wide range in bioavailability could be tolerated without hazard of therapeutic failure.

(3) Present compendial standards and guidelines for current good manufacturing practice do not insure quality and uniform bioavailability for drug products. Not only may the products of different manufacturers vary, but the product of a single manufacturer may vary from batch to batch or may change during storage.[58]

The Panel criticized the compendia standards, particularly the statistical methods used to test the final manufactured batch of drug products. The Panel also found that the current good manufacturing practice guidelines were "...limited to rather general statements that may be subject to wide differences of interpretation".[59] It found that the practices do little to minimize lot-to-lot variation of bioequivalence among chemically equivalent products.

The Panel was also critical of the disparity in regulation between holders of the NDA and ANDA. It stated that holders of the NDA were subject to much stricter specifications and quality controls than holders of the ANDA making chemical equivalents.[60]

(4) A system should be organized as rapidly as possible to generate an official list of interchangeable drug products. In the development of the list, distinctions should be made between two classes of drugs and drug products:[61]

(1) Those for which evidence of bioequivalence is not considered essential and that could be added to the list as soon as standards of pharmaceutical equivalence have been established and satisfied.

(2) Those for which evidence of bioequivalence is critical. Such products should be listed only after they have been shown to be bioequivalent or have satisfied standards of pharmaceutical equivalence that have been shown to insure bioequivalence.

Thus, the report appeared to make two contradictory points.

First, it appeared that the quality of drug products is not guaranteed by existing standards and regulation. Dr. William S. Apple, Executive Director of the American Pharmaceutical Association, apparently, received the same impression. He stated in subsequent testimony to the Senate Subcommittee on Health which examined the report:[62]

> Mr. Chairman, I must publicly admit that when I first read the Panel report, my initial reaction was to ask the pharmacists of our country to immediately quarantine all drug products in their pharmacies and withhold these drugs from patients until the recommendations of the Panel were completely implemented.
>
> After all, APA has been telling the American people, that the pharmacists of this country have confidence in the Nation's drug supply.
>
> When I read the PMA news release which accompanied the report, I became even more concerned.
>
> Read in the abstract, these two documents seemed to be saying that Congress should immediately demand the resignation of the Secretary of HEW and the FDA Commissioner, that Congress should immediately defrock the official compendiums, and that Congress should immediately appropriate funds to replace the Nation's drug supply.
>
> Obviously, if we have no confidence in the U.S. drug industry, the Government would have to take over the industry or the replacement drugs would have to come from foreign sources, which have pharmaceutical manufacturers capable of producing therapeutically equivalent as well as safe and effective drug products.

Second, it appeared that the bioavailability differences are not important in some drug products.

These findings have been used as support by both proponents and opponents of generic substitution. While the Panel did not make an endorsement of generic substitution, it makes it clear that, for some drug products, bioequivalence is without therapeutic significance:[63]

> Moderate variations within that range between effective and toxic levels whether owing to differences in bioavailability or any other factor, are without therapeutic significance.

The Panel did not identify the drug products for which bioequivalence was not significant. Apparently, however, in a news conference, it appears that the Chairman of the Panel stated that eighty-five to ninety per cent of the drug supply would fall into the category where bioequivalence was not significant.[64] Later, the statement was heavily qualified before the Senate Subcommittee on Health. Dr. Robert Berliner, the Chairman of the Panel, stated:[65]

> Well, that was a number, Senator, we sort of grabbed off the top of our heads, and I would not want to stand too close to it, but that is the figure we quoted; that is the group of drugs I am referring to.

Nevertheless, Dr. Berliner further stated that:[66]

> The problem of distinguishing between those drugs for which bioavailability studies should be required and those for which they should not, is one we believe appropriate groups of experts would find it not difficult to deal with.

Conclusion

Thus, it is clear that bioequivalency among chemically equivalent drug products cannot be guaranteed for every drug product. Experts feel, however, that for many chemically equivalent drug products, minimal differences in bioavailability are not dangerous to the public health.

The FDA has also responded to the recommendation of the Drug Bioequivalence Study Panel for a list of drug products for which bioequivalence differences are not essential. The recently published FDA formulary of approved substituable drug products is said to be that response.

Chapter 3

EXAMINATION OF COST-SAVINGS

Introduction

There appears to be little question that significant differences in prices between brand name and nonbrand name chemical equivalents exist. Price surveys have been presented which display and often sensationalize the differences. Some of these price surveys are based on comparisons between the wholesale prices of brand name and nonbrand name chemical equivalents as listed in the Drug Topics Red Book or American Druggists Blue Book.[1] It is commonly understood, however, that the prices in both publications are "umbrella" prices. That is, the prices are the maximum offered. Usually, the retailer obtains the drug products at lower prices because of special arrangements or discounts.[2] Thus, these surveys do not reflect actual savings.

Numerous factors determine if cost-savings from generic substitution is to occur. Basically, these factors serve as barriers to total cost-savings. These factors are:

(1) Many drug products are single-source; that is, they are available from only one manufacturer. No chemical equivalents are available. Thus, no price savings through substitution are possible;

(2) Some multiple-source drug products have bioequivalence problems. Pharmacists may be reluctant to substitute or may be prohibited from substituting for these drug products;

(3) Physicians may prohibit substitution by exercising the prerogative of requiring dispensing of prescriptions as written. All states with generic substitution laws have this provision;

(4) Consumers may not want substitution even if resulting in cost-savings; and

(5) Pharmacists may not substitute even when allowed or may substitute chemical equivalents of comparable prices to the brand names prescribed resulting in no or very little cost-savings.

The Task Force on Prescription Drugs estimated cost-savings if certain drug products were dispensed with nonbrand name drug products. Other studies have also been conducted to determine whether cost-savings occur if prescriptions are written generically. These studies examine generic prescribing and not generic substitution. They are reviewed by this study because generic prescribing is comparable to generic substitution. For, in generic substitution, brand name prescriptions become, in effect, generic prescriptions if physicians do not prohibit substitution.

Task Force on Prescription Drugs

The Task Force on Prescription Drugs estimated the savings which may result from generic prescription in a report issued in December 1968.[3] Using data from 1966, the Task Force found that the total retail cost of four hundred nine of the most commonly prescribed drug products was $682.3 million. Out of the four hundred nine, only sixty-three had low-cost chemical equivalents and were substitutable. The Task Force stated that:[4]

> For these 63 products, the use of low-cost chemical equivalents could have reduced the acquisition cost--the wholesale cost to the retailer--from nearly $74.9 million to $33.4 million, representing a potential savings of $41.5 million, or 55.3 percent at the wholesale level.

To determine savings at the retail level, the total number of prescriptions for all sixty-three drug products was computed. This total was then multiplied by three different retail markups: $1.50; $1.81, which was the average gross profit of the pharmacist per prescription; and $2.00. The amounts were then added to the estimated wholesale cost and potential savings computed. For the various markups, the following were the estimated retail cost-savings which may have resulted in 1966 out of a total expenditure of $682.3 million:

(1) $1.50 markup -- 8.0 per cent savings;

(2) $1.81 markup -- 6.1 per cent savings; and

(3) $2.00 markup -- 5.0 per cent savings.

These estimations were based on across-the-board substitution of low-cost chemical equivalents. Other studies, which have compared actual retail prices and dispensing practices have also indicated cost-savings.

Other Studies

In 1966, Daniel L. Azarnoff,[5] et al., compared retail prices for prescriptions written for Miltown, a tranquilizer made by Wallace Laboratories, and meprobamate, the generic name of Miltown. Bona fide prescriptions for fifty 400 mg. tablets of Miltown were presented at twenty-three pharmacies. One week later, prescriptions for the same amount and strength of meprobamate were presented at the same pharmacies. Findings showed that:[6]

> The mean cost of Miltown at the 23 pharmacies was $4.94 while meprobamate purchased by generic name was $3.88, a savings of 21 per cent.

In 1974, A. K. Gumbhir and C. A. Rodowskas, Jr.[7] compared the retail prices of prescriptions written for seven drug products by their generic name and brand name chemical equivalents of those drug products. It was found that consumer price differentials were statistically significant for five of the seven drug products. The following were the mean prices per unit for generic prescriptions and brand name prescriptions and the differences between both.

Drug Product	Mean Brand Price	Mean Generic Price	Difference
Tetracycline	$0.126	$0.095	$0.031
Penicillin G	0.124	0.085	0.039
Prednisone	0.071	0.066	0.005
Meprobamate	0.096	0.074	0.022
Reserpine	0.069	0.038	0.031
Digoxin	0.024	0.024	--
Chloral Hydrate	0.096	0.078	0.018

Thus, the results showed that prescriptions written and dispensed by generic name were generally priced lower to the consumer than prescriptions written by brand name for the same drug product.

In 1975, Richard A. Horvitz,[8] et al., compared the retail prices of prescriptions written for brand name drug products with prescriptions written by their generic names. Twelve drug products were chosen from the following criteria:

(1) The drug products must have been among the top two hundred most frequently prescribed;

(2) They must have been multiple-source; and

(3) The wholesale price differences between the brand names and their chemical equivalents must have been significantly different according to the Red Book.

The twelve drug products chosen, their comparative brand names, and the prescriptions presented were:

(1) Ampicillin compared with the brand name Polycillin manufactured by Bristol Laboratories; prescriptions written for twenty-eight, 250 mg. capsules;

(2) Erythromycin compared with the brand name Erythrocin manufactured by Abbott Laboratories; prescriptions written for twenty-eight, 250 mg. tablets;

(3) Penicillin V compared with the brand name Pen-Vee K manufactured by Wyeth Labs; prescriptions written for forty, 250 mg. tablets;

(4) Propoxyphene compared with the brand name Darvon manufactured by Eli Lilly and Co.; prescriptions written for thirty, 65 mg. capsules;

(5) Chlorpheniramine maleate compared with the brand name Chlor-Trimeton manufactured by Schering Corp.; prescriptions written for one hundred, 4 mg. tablets;

(6) Diphenylhydantoin compared with the brand name Dilantin manufactured by Parke, Davis & Co.; prescriptions written for one hundred, 100 mg. capsules;

(7) Dioctyl sodium sulfosuccinate compared with the brand name Colace manufactured by Mead Johnson Laboratories; prescriptions written for sixty, 100 mg. capsules;

(8) Papaverine compared with the brand name Pavabid manufactured by Marion Labs, Inc.; prescriptions written for sixty, 100 mg. capsules;

(9) Pentaerythritol tetranitrate compared with the brand name Peritrate manufactured by Warner-Chilcott Laboratories; prescriptions written for one hundred, 20 mg. tablets;

(10) Conjugated estrogens compared with the brand name Premarin manufactured by Ayerst Labs; prescriptions written for sixty, 125 mg. tablets;

(11) Sulfisoxazole compared with the brand name Gantrisin manufactured by Roche Labs; prescriptions written for eighty, 500 mg. tablets; and

(12) Methenamine mandelate compared with the brand name Mandelamine manufactured by Warner-Chilcott Laboratories; prescriptions written for sixty, 1.0 g. tablets.

The study found that:

(1) Generic prescriptions frequently cost less in four of the twelve drug products. The drug products and mean price differences per prescription between brand name and generic prescriptions were: ampicillin, mean price difference of $1.54; erythromycin, mean price difference of $1.18, propoxyphene, mean price difference of $0.59; and dioctyl sodium sulfosuccinate, mean price difference of $2.49;

(2) With three others, papaverine, pentaerythritol tetranitrate, and conjugated estrogens, occasional savings were encountered, but they were substantial; and

(3) For the remainder, chlorpheniramine maleate, penicillin V, diphenylhydantoin, sulfisoxazole, and methenamine mandelate, no significant differences were available because most pharmacies stocked only the brand names and no chemical equivalents.

The study concluded with the finding that savings were most frequent among drug products that were often prescribed generically. This induced pharmacists to keep nonbrand name drug products on stock. Savings for drug products which were prescribed infrequently by generic name were nonexistent or only occasional because pharmacists had no incentive to stock nonbrand names.

Thus, the studies showed that generic prescribing did save money for some drug products. They also identified one important element which is necessary if cost-savings is to occur; that the pharmacists dispense lower cost drug products when receiving generic prescriptions rather than the higher priced, frequently prescribed, brand name drug products.

Studies on Actual Effects of Generic Substitution

Two studies examined the impact of generic substitution laws. These studies, as will be seen, show that cost-savings do result from generic substitution although the cost-savings do not approach the potential maximum.

Delaware. A generic substitution law became effective in the State of Delaware on December 22, 1976. Delaware's law, entitled the Delaware Drug Product Selection Act, allows pharmacists to substitute subject to legal constraints common to other generic substitution laws. Among these constraints are:

(1) A nonequivalent formulary. Drug products in the formulary cannot be substituted; and

(2) Authority of physicians to prohibit substitution.

Professors Joseph L. Fink III and Maven J. Myers[9] of the Philadelphia College of Pharmacy and Science conducted a study on the effects of the Delaware Drug Product Selection Act. The study was designed to collect data on areas grouped under two general objectives. These areas were as follows:

Objective 1

(1) Drug prices to consumers for selected multiple-source drug products prior to the effective date of the Act;

(2) Drug prices to consumers for these drug products at some time subsequent to the effective date of the Act;

(3) Savings, if any.

Objective 2

(1) Incidence of authorization to substitute by prescribers;

(2) Incidence of prescriptions for multiple-source drug products; and

(3) Incidence of actual substitution by pharmacists.

Twelve frequently prescribed, multiple-source drug products were selected for study: ampicillin, 250 mg. (any salt); chlordiazepoxide hydrochloride, 10 mg.; erythromycin, 250 mg. (base of any salt); hydrochlorothiazide, 50 mg.; meprobamate, 400 mg.; papaverine hydrochloride, 150 mg. (sustained release); penicillin G, 400,000 units; penicillin V potassium, 250 mg.; prednisone, 5 mg.; propoxyphene hydrochloride compound-65; sulfisoxazole, 500 mg.; tetracycline hydrochloride, 250 mg.

Thirty community pharmacies were selected randomly for participation.

In Phase I, data were collected from these pharmacies for the period September 1, 1976 to December 20, 1976; a period just prior to the effective date

of the Act. The data involved the examination of five prescriptions for each of the drug products under study and recordation of the brand and quantity prescribed and the consumer price.

In Phase II, similar data were collected for the period October 1, 1977 to December 1, 1977. In addition, data were collected as to whether physicians allowed or prohibited substitution for each of the examined prescriptions.

These data were designed for objective 1.

Phase II also involved the collection of other data to address objective 2. The first one hundred new prescriptions were examined at each of the pharmacies and data on the incidence of physicians' authorization to substitute, incidence of prescriptions for multiple-source drug products, and incidence of actual substitution by pharmacists was collected.

The results are displayed in the following tables.

Table I

MEAN CONSUMER PRICE PER DOSAGE FOR STUDIED DRUGS
PHASES I AND II

Drug	Mean, Dollars		Difference
	Phase I	Phase II	
Ampicillin	0.159	0.159	0
Chlordiazepoxide	0.098	0.096	−0.002
Erythromycin	0.210	0.201	−0.009
Hydrochlorothiazide	0.077	0.069	−0.008
Meprobamate	0.064	0.058	−0.006
Papaverine	0.109	0.104	−0.005
Penicillin G	0.103	0.102	−0.001
Penicillin V potassium	0.152	0.136	−0.016
Prednisone	0.075	0.071	−0.004
Propoxyphene	0.132	0.126	−0.006
Sulfisoxazole	0.078	0.074	−0.004
Tetracycline	0.092	0.096	+0.004

Table I shows the mean consumer price per dosage unit for the studied drug products in Phases I and II. In other words, this table shows the average price for one tablet or capsule for each of the drug products studied. Although the results show that the mean dosage unit prices of ten of the twelve drug

products decreased, the differences were not considered statistically significant. The results, however, display the fact that:[10]

> The Bureau of Labor Statistics Consumer Price Index for prescriptions increased from 116.4 in September 1976 to 124.6 in October 1977 (13), a 7.04% increase. A similar increase would have been expected in Delaware but was not evidenced in this study.

Table II

MEAN PRICES PER UNIT FOR STUDIED DRUGS IN PHASE II
(SUBSTITUTION NOT AUTHORIZED VERSUS SUBSTITUTION AUTHORIZED)

Drug	Mean, Dollars		Difference
	Not Authorized	Authorized	
Ampicillin	0.234	0.153	−0.081
Chlordiazepoxide	0.113	0.061	−0.052
Erythromycin	0.280	0.148	−0.132
Hydrochlorothiazide	0.101	0.057	−0.044
Meprobamate	0.111	0.071	−0.040
Papaverine	0.131	0.047	−0.084
Penicillin V potassium	0.144	0.126	−0.018
Propoxyphene	0.146	0.098	−0.048
Sulfisoxazole	0.075	0.048	−0.027
Tetracycline	0.133	0.081	−0.052

Table II displays the mean price per unit of the twelve drug products in Phase II differentiated by when substitution was not authorized and when it was. This table does not include generic prescriptions since they are not affected by the generic substitution law.

The table shows that:[11]

> The effects of the Delaware legislation are seen best in Table 2, which shows the differences in mean price per dosage unit for the studied drugs under two conditions, where substitution was authorized and where it was not (generically written prescriptions are excluded). Statistically significant savings at the 95% confidence level were found for 7 of the 10 drugs for which data could be collected:

chlordiazepoxide hydrochloride
erythromycin
hydrochlorothiazide
papaverine hydrochloride
propoxyphene hydrochloride compound-65
sulfisoxazole
tetracycline

Table III

INCIDENCE OF AUTHORIZATION TO SUBSTITUTE, PRESCRIBING OF SINGLE-SOURCE PRODUCTS, AND ACTUAL SUBSTITUTION IN 27 DELAWARE PHARMACIES (PHASE II)

	Single-Source Products	Multisource Products	Total
Dispense as written	955 (35.4)	722 (26.7)	1677 (62.1)
Substitution permissible			
Did substitute		304 (11.2)	
Did not substitute		237 (8.8)	
Total	482 (17.8)	541 (20.0)	1033 (37.9)
Total	1437 (53.2)	1263 (46.8)	2700 (100.0)

Numbers in parentheses are percentages.

Table III shows the results of the data examined for objective 2. As stated previously, the first one hundred prescriptions on or after October 1, 1977 were examined in each of the pharmacies. Three pharmacies, however, could not participate so the total number of prescriptions examined was 2,700. The results were as follows:

(1) Incidence of authorization to substitute by prescribers.

Pharmacists were authorized to substitute in 1,033, or 37.9 per cent, of the total prescriptions examined. For 482 of the prescriptions, however, the prescriptions were for single-source drug products and no substitution could be made.

(2) Incidence of prescriptions for multiple-source drug products.

Multiple-source drug products were prescribed in 1,263, or 46.8 per cent, of the total prescriptions examined. For 722 of these prescriptions, however, physicians prohibited substitution. Thus, in actuality, pharmacists had the opportunity to substitute in 541, or 20.0 per cent, of the total prescriptions examined.

(3) Incidence of actual substitution by pharmacists.

> Although pharmacists had the opportunity to substitute in 541, or 20.0 per cent, of the total prescriptions examined, they only did so in 304 instances. This amounted to an incidence of 11.2 per cent of the total prescriptions examined.

This study demonstrated three main findings: (1) savings may be realized by generic substitution; (2) a substantial percentage of prescriptions prohibited substitution indicating physicians' feelings; and (3) pharmacists substituted in slightly more than half of the instances when substitution was authorized and chemical equivalents were available.

Thus, in Delaware, savings were demonstrated. But more importantly, it was shown that greater savings could have been realized.

Michigan and Wisconsin

Professor Theodore Golderberg[12] of the Wayne State University School of Medicine conducted a comprehensive study of the effects of the generic substitution laws of Michigan and Wisconsin.

Both Michigan's and Wisconsin's generic substitution laws allow physicians to prohibit substitution. Michigan's law, however, does not contain a formulary of equivalent or nonequivalent drug products to define parameters of substitutability whereas Wisconsin has a formulary of equivalent drug products.

In Michigan, data were collected on approximately 31,000 prescriptions for the year prior to the implementation of the generic substitution law and 33,000 and 22,000 in each of the two years following implementation. In Wisconsin, data were collected for 25,000 prescriptions in the first and second years and 18,000 in the third. Of the prescriptions collected for Wisconsin, only those collected for the last six months of the last year were after the effective date of its generic substitution law.

The study, among other things, analyzed the following:

(1) What proportion of prescriptions fall into the category of "multiple-source drug entities"?

(2) Is there a significant differential in prices of chemically equivalent drug products?

(3) To what extent do physicians prohibit substitution?

(4) To what extent do pharmacists actually substitute when authorized to do so?

(5) What is the range of actual and potential savings from generic drug substitution?

The following are the findings of the study.

(1) What proportion of prescriptions fall into the category of "multiple-source drug entities"?

It was found that over 51 per cent of the prescriptions examined in Michigan and 52 per cent of the prescriptions examined in Wisconsin were for multiple-source drug products in each of the years studied. The study, however, did not indicate whether all of the multiple-source prescriptions in Wisconsin were substitutable under the Wisconsin formulary.

(2) Is there a significant differential in the prices of chemically equivalent drug products?

The study examined the differences in prices between the drug products prescribed and the drug products actually dispensed when substitution occurred. Since only the prices of the dispensed drug products were actually known, a technique was used to estimate the prices of the prescribed drug products. This technique, termed "matching", matched each of the prescriptions for which substitution occurred to comparable prescriptions which were dispensed as written. Three characteristics were identified as important for matching: the "matched" prescriptions should have been from the same time

period; they should be for approximately the same quantity; and they should be from the same pharmacy of from another with similar characteristics.

The differences in prices were then computed and averaged.

Savings calculated were as follows:

For Michigan --

(1) First year after effective date -- $1.14, or 21 per cent, per prescription when substitution actually occurred;

(2) Second year after effective date -- $1.15, or 20 per cent, per prescription when substitution actually occurred.

For Wisconsin --

First six months after effective date -- $.87, or 17 per cent, per prescription when substitution occurred.

It should be emphasized that the above savings were computed only for prescriptions in which substitution occurred and not for all prescriptions in the sample or the total drug expenditures of the State.

(3) To what extent do physicians prohibit substitution?

Contrary to the findings of the Delaware study where substitution was prohibited for 62.1 per cent of the total prescriptions examined, physicians prohibited substitution only rarely in Michigan and Wisconsin. In Michigan, only 6.4 and 4.0 per cent, respectively, of the prescriptions examined prohibited substitution in the first two years following effectiveness of the law. In Wisconsin, only 3.6 per cent of the prescriptions examined prohibited substitution.

(4) To what extent do pharmacists actually substitute when authorized to do so?

Again, the data are contrary to the findings of Delaware where pharmacists substituted in 11.2 per cent of the total prescriptions examined. The incidence of actual substitution in Michigan was infrequent. The study states:[13]

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

Similar data were not available for Wisconsin.

(5) What is the range of actual and potential savings from generic drug substitution?

The study estimated the actual savings in Michigan. The estimation was based on a range of 26 million to 34 million total annual prescriptions in Michigan. Using this estimate, the study then calculated the actual savings by using the discovered data; 0.67 per cent incidence of substitution and $1.15 savings per actual substituted prescription. The savings were estimated to have been "...within the range of $200,000 and $300,000 a year".

The study also estimated the potential savings. Potential savings were estimated by multiplying the $1.15 savings per actual substituted prescription by the number of prescriptions where substitution was possible.

The number of prescriptions where substitution was possible was calculated in the following manner:

Estimated total volume of prescriptions

x Per cent of prescriptions which were discovered to be multiple-source

---

Estimated total of multiple-source prescriptions

x Per cent of prescriptions written generically for which generic substitution has no effect

x Per cent of prescriptions for which physicians prohibited substitution

---

Estimated total of multiple-source prescriptions where substitution was possible

x Actual savings per prescription where substitution actually occurred

---

Total potential savings

When placing the values, the results were:

26 million to 34 million
x 51%

13.3 million to 17.3 million
x 20%
x 4%

10.2 million to 13.3 million
x $1.15

$11,730,000 to $15,295,000

Thus, if substitution occurred for each multiple-source prescription when possible, potential savings was in the range of $11,730,000 to $15,295,000. If true, actual savings was much less than the potential savings.

Both the Delaware and Michigan studies have shown that cost-savings is greatly dependent on the actions of physicians and pharmacists. If these professionals do not allow substitution or do not substitute, as the case may be, generic substitution laws are of no value.

The following chapter will examine the feelings of Hawaii's physicians and pharmacists regarding generic substitution and other barriers to cost-savings.

Chapter 4

RESULTS OF SURVEYS

As discussed in chapter 3, it appears that certain factors must be present if generic drug substitution is to result in cost-savings. These factors are:

(1) A portion of the commonly prescribed drug products in Hawaii must be "substitutable", that is, they must not be single-source or have bioequivalence problems;

(2) There must be a difference in retail prices between commonly prescribed, "substitutable" brand name drug products and their chemical equivalents;

(3) Physicians must give some support to a generic drug substitution law; and

(4) Pharmacists must give some support to a generic drug substitution law.

Four surveys were taken to obtain a general idea of these factors in Hawaii:

(1) An examination of a sample of prescriptions dispensed by retail pharmacies in the city and county of Honolulu.

(2) A price survey of nine "substitutable" drug products.

(3) A sample of attitudes of physicians regarding generic substitution.

(4) A sample of attitudes of pharmacists regarding generic substitution.

Survey 1 - Examination of Prescriptions

In August and September of 1978, data on prescriptions dispensed in Hawaii during the year 1977 were gathered with the objective of obtaining a general idea of the most commonly prescribed drug products in the State. Based on these data, a general determination of the "substitutability" of commonly prescribed drug products was made.

Each of the retail pharmacies in the city and county of Honolulu's telephone directory was assigned a randomly selected one-week period in 1977. Forty of these pharmacies were arbitrarily selected on the basis of type of operation and location. These pharmacies and their one-week periods are listed in Appendix B. All original prescriptions dispensed by each of the pharmacies during the assigned one-week periods were examined. If a prescription form prescribed more than one drug product, each of the drug products was considered separate prescriptions. The following data were noted for each prescription:

(1) The drug products prescribed;

(2) Dosage forms;

(3) Strengths; and

(4) For solid oral dosage forms, the number of units prescribed.

Data were also noted regarding prescriptions for nondrug products such as eye patches and pads. No data were gathered regarding the prescriber, the patient, or prescription prices.

This survey was not attempted on the neighbor islands because of logistics and expense.

Before presenting the results, some caveats as to its limitations must be set forth:

(1) The prescriptions examined were original prescriptions; no data on refills were taken. Thus, the number of prescriptions for drug products for which refills are not unusual, such as the oral contraceptives or long-term maintenance drug products, is probably conservative.

(2) Prescriptions for Schedule II drug products were not examined at some pharmacies, since these prescriptions were not immediately available or on file elsewhere. Thus, the number of prescriptions for these drug products is also conservative.

(3) Some prescriptions were rather illegible. The surveyor copied them as closely as possible but could not determine what they were. These prescriptions are presented in the form copied. They are not, however, considered as brand name or generic prescriptions in Appendix C. Rather, they are considered to be "unknowns".

(4) For other prescriptions, the strengths of the drug products were missing or illegible. Question marks are provided in the appropriate places when these data were missing or illegible for these prescriptions.

(5) For some prescriptions, the strengths did not conform to recognized strengths of the drug products. These strengths are presented as copied.

In all, 21,509 prescriptions were examined. Of this total:

(1) 18,875, or 87.8 per cent, were written by brand name;

(2) 2,550, or 11.8 per cent, were written by generic name. Of these, 132 were written for drug products available from only one manufacturer. Thus, pharmacists had no choice but to dispense the drug products of that manufacturer although the prescriptions were written generically;

(3) 61, or 0.3 per cent, were written by a nongeneric name for multiple-source drug products. These prescriptions were similar to generic prescriptions because pharmacists had the choice of dispensing the products of any qualified manufacturer. Examples of these types of prescriptions include those for "analgesic balm" and "vitamin C"; and

(4) 23, or 0.1 per cent, could not be determined. These are regarded as "unknowns".

When categories (2) and (3) are combined and category (4) disregarded, the percentages are:

(1) 18,875, or 87.5 per cent, brand name prescriptions; and

(2) 2,611, or 12.2 per cent, generic or other multiple-source prescriptions.

These percentages correspond to a 1977 nationwide survey reported by the Pharmacy Times magazine. It reported that 12.5 per cent of the new prescriptions were written generically. It should be noted that the percentage of generic prescriptions for the sample is approximately 8 per cent less than the percentage found by Professor Goldberg in his previously discussed study.

Appendix C provides the results of Survey 1.

From the data received, the following table of one hundred most commonly prescribed drug products of the sample has been compiled. The top one hundred represents 10,973 prescriptions, or 51.1 per cent, of the sample.

The effectiveness of generic substitution is greatly dependent on the number of substitutable drug products among the commonly prescribed ones. The survey data may be used to determine whether Hawaii has a base of substitutable drug products. As stated previously, substitutable drug products are those which are multiple-source and do not have bioequivalence problems. To our knowledge, there is no single document which provides information on the multiple- or single-source status of drug products. However, a method utilizing the formularies of other states can be devised to determine the substitutable base in Hawaii. In using the formularies, the assumptions are that these states would not approve substitution of drug products which have bioequivalence problems and cannot approve substitution of drug products which are single-source.

The state formularies of New York, Illinois, Kentucky, Pennsylvania, Rhode Island, and Wisconsin are positive formularies. That is, they list the drug products which may be substituted. Table V lists each of Hawaii's one hundred most commonly prescribed drug products and whether they are substitutable in these states.

Delaware and Florida have negative formularies. That is, they list the drug products which may not be substituted. According to these formularies, some of the drug products which are substitutable in some of the other states

Table IV

100 MOST COMMONLY PRESCRIBED DRUG PRODUCTS

Drug Products (Generic Name)	No. of Prescriptions
1. Valium (Diazepam)	766[a]
2. TETRACYCLINE (GENERIC)	355
3. Tylenol Comp. No. 3 (Acetaminophen + Codeine Phosphate)	315
4. AMPICILLIN (GENERIC)	259
5. Dimetapp Elix. (Brompheniramine Maleate + Phenylpropanolamine + Phenylephrine HCl)	234
6. Actifed (Triprolidine HCl + Pseudoephedrine HCl)	227
7. Darvocet N 100 (Propoxyphene Napsylate + Acetaminophen)	223
8. ERYTHROMYCIN (GENERIC)	212
9. AMPICILLIN SUSP. (GENERIC)	207
10. V-Cillin K (Penicillin V Potassium)	202
11. Dyazide (Triamterene + Hydrochlorothiazide)	198
12. Actifed Syr. (Triprolidine HCl + Pseudoephedrine HCl)	190
13. Zyloprim (Allopurinal)	175[b]
14. Aldomet (Methyldopa)	174[c]
15. Marax (Hydroxyzine HCl + Ephedrine Sulfate + Theophylline)	166
16. Inderal (Propanolol HCl)	161[d]
17. Premarin (Conjugated Estrogens)	158
18. Aldactazide (Spironalactone + Hydrochlorothiazide)	157
19. Dalmane (Flurazepam HCl)	157[e]
20. Lasix (Furosemide)	156
21. Erythrocin (Erythromycin)	153
22. Lomotil (Diphenoxylate HCl + Atropine Sulfate)	133

Drug Products (Generic Name)	No. of Prescriptions
23. Phenergan Expect. w/Codeine (Promethazine HCl + (Potassium Guaiacolsulfonate + Chloroform + Citric Acid + Sodium Citrate + fluid extract of ipecac + Alcohol + Codeine Phosphate)	133
24. Keflex (Cephalexin Monohydrate)	127
25. Benadryl (Diphenhydramine HCl)	126
26. PREDNISONE (GENERIC)	123
27. Ilosone (Erythromycin Estolate)	123
28. Indocin (Indomethacin)	123[f]
29. Atarax (Hydroxyzine HCl)	116
30. PENICILLIN V POTASSIUM (GENERIC)	115
31. Ilosone Susp. (Erythromycin Estolate)	113
32. Diabinese (Chlorpropamide)	108
33. Achromycin V (Tetracycline HCl)	107
34. Mycolog Cream (Triamcinolone Acetonide + Neomycin Sulfate + Gramicidin + Nystatin)	107
35. Lanoxin (Digoxin)	103
36. Novahistine DH Expect. (Phenylephrine HCl + Chlorpheniramine Maleate + Codeine Phosphate + Chloroform + Alcohol)	101
37. Fiorinal (Butalbital + Caffeine + Aspirin + Phenacetin)	95
38. Pediamycin Liq. (Erythromycin Ethylsuccinate)	94
39. Phenergan Expect. (Promethazine HCl + Potassium Guaiacolsulfonate + Chloroform + Citric Acid + Sodium Citrate + fluid extract of ipecac + Alcohol)	94
40. Poly Vi Flor Chews (Vit. A + Vit. D + Vit. E + Vit. C + Vit. B-1 + Vit. B-2 + Vit. B-6 + Vit. B-12 + Niamcinamide + Fluoride + Folic Acid)	92
41. Tranxene (Clorazepate Dipotassium)	86
42. Ionamin (PHentermine Resin)	86
43. Vibramycin (Doxycycline Hyclate)	84

Drug Products (Generic Name)	No. of Prescriptions
44. Sudafed (Pseudoephedrine HCl)	84
45. Librax (Chlordiazepoxide HCl + Clidinium Bromide)	83
46. Tenuate Dospan (Diethylpropion HCl)	83
47. Vi Daylin F Drops (Vit. A + Vit. B-1 + Vit. B-2 + Vit. B-6 + Vit. C + Vit. D. + Niamcinamide + Vit. E + Sodium Fluoride)	82
48. Ornade Spansule (Isopropamide Iodide + Phynylpropanolamine HCl + Chlorpheniramine Maleate)	81
49. Darvon Compound-65 (Propoxyphene HCl + Aspirin + Phenacetin + Caffeine)	80
50. Benylin Syrup (Diphenhydramine HCl + Ammonium Chloride + Sodium Citrate + Chloroform + Menthol + Alcohol)	78
51. Donnagel PG Susp. (Po. Opium + Kaolin + Pectin + Hyoscyamine Sulfate + Atropine Sulfate + Hyoscine HBr + Sodium Benzoate + Alcohol)	78
52. Drixoral (Dexbrompheniramine Maleate + d-isoephedrine sulfate)	77
53. Kwell Lot. and Shamp. (Gamma Benzene Hexachloride + others)	77
54. V-Cillin K Susp. (Penicillin V Potassium)	77
55. Hydrodiuril (Hydrochlorothiazide)	77
56. Marax Syr. (Hydroxyzine HCl + Ephedrine Sulfate + Theophylline + Alcohol)	75
57. Motrin (Ibuprofen)	75
58. Rondex DM Syr. (Carbionoxamine Maleate + Pseudoephedrine HCl + Dextromethrophan HBr + Guaifenesin + Alcohol)	74
59. Dimetane Elix. and Expect. (Brompheniramine Maleate)	72
60. Cortisporin Otic (Polymyxin B Sulfate + Neomycin Sulfate + Itydrocortisone Free Alcohol + Cetyl Alcohol + Propylene Glycol + Polysurbate + Thimerosal)	71
61. Cordran Cream (Flurandrenolide)	71

Drug Products (Generic Name)	No. of Prescriptions
62. Dimetapp Extentabs (Brompheniramine Maleate + Phenylephrine HCl + Phenylpropanolamine HCl)	71
63. Tegopen (Cloxacillin)	71
64. Apresoline (Hydralazine HCl)	70
65. Parafon Forte (Chlorzoxane + Acetaminophen)	70
66. Librium (Chlordiazepoxide HCl)	69
67. Valisone Cream (Betamethasone Valerate)	69
68. Pen-Vee K (Penicillin V Potassium)	68
69. Kenalog Cream (Triamcinolone Acetonide)	67
70. Antivert (Meclizine HCl)	66
71. THYROID (GENERIC)	65
72. AMOXICILLIN SUSP. (GENERIC)	65
73. Benadryl Elix. (Diphenhydramine HCl)	65
74. Tylenol (Acetaminophen)	65
75. Desquam x 5 and 10	64
76. Erythrocin Susp. (Erythromycin)	63
77. Butazolidin Alka (Phenylbutazone + Aluminum Hydroxide Magnesium Trisilicate)	62
78. Dilantin (Diphenylhydantoin)	62
79. Lidex Cream (Fluocinonide)	62
80. Bendectin (Dycyclomine HCl + Doxylamine Succinate + Pyridoxine HCl)	60
81. Clistin RA (Carbinoxamine Pyridine Maleate)	60
82. Mellaril (Thioridazine HCl)	58
83. Empirin Compound #3 (Aspirin + Phenacetin + Caffeine + Codeine Phosphate)	58
84. DIGOXIN (GENERIC)	57
85. Bentyl (Dicyclomine HCl)	57

Drug Products (Generic Name)	No. of Presciptions
86. Neosporin Oint. (Polymyxin B Sulfate + Zinc Bacitracin + Neomycin Sulfate)	56
87. Actifed C Syrup (Triprolidine HCl + Pseudoephedrine HCl + Glyceryl Guaiacolate + Codeine Phosphate)	56
88. Lo Ovral (Norgestrol + Ethinyl Estradiol)	56
89. Monistat Cream (Miconazole Nitrate)	55
90. Phenergan VC Expect. (Promethazine HCl + Potassium Guaiacolsulfonate + Chloroform + Citric Acid + Sodium Citrate + Alcohol + fluid extract of ipecac + Phenylephrine HCl)	55
91. PHENOBARBITAL (GENERIC)	54
92. Atromid-S (Clofibrate)	54
93. Fastin (Phentermine HCl)	53
94. Poly Vi Flor Drops	53
95. Novahistine Expect. (Phenylephrine HCl + Chlorpheniramine Maleate + Codeine Phosphate + Glyceryl Guaiacolate + Chloroform + Alcohol)	52
96. Ortho Novum - 21 (Norethindrone + Mestranol)	52
97. Ser Ap Es (Reserpine + Hydralazine HCl + Hydrochlorothiazide)	52
98. Enduronyl (Methyclothiazide + Deserpidine)	51
99. Vioform HC Cream and Lot. (Hydrocortisone + Iodochlorhydroxyquin)	51
100. Darvocet N (Propoxyphene Napsylate + Acetaminophen)	50

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a. Includes 10 prescriptions for diazepam. Valium is a single-source drug product. Only it can be dispensed if diazepam is prescribed.

b. Includes 18 prescriptions for allopurinal. Zyloprim is a single-source drug product. Only it can be dispensed if allopurinal is prescribed.

c. Includes 1 prescription for methyldopa. Aldomet is a single-source drug product. Only it can be dispensed if methyldopa is prescribed.

d. Includes 31 prescriptions for propanolol HCl. Inderal is a single-source drug product. Only it can be dispensed if propanolol HCl is prescribed.

e. Includes 1 prescription for flurazepam HCl. Dalmane is a single-source drug product. Only it can be dispensed if flurazepam HCl is prescribed.

f. Includes 2 prescriptions for indomethacin. Indocin is a single-source drug product. Only it can be dispensed if indomethacin is prescribed.

Table V

SUBSTITUTABLE DRUG PRODUCTS

Drug Product	Substitutable in					
	N.Y.	Ill.	Ky.	Penn.	R.I.	Wis.
Valium						
TETRACYCLINE	----------GENERIC----------					
Tylenol Comp. No. 3	x	x	x		x	
AMPICILLIN	----------GENERIC----------					
Dimetapp Elix.				x		
Actifed				x		
Darvocet N 100						
ERYTHROMYCIN	----------GENERIC----------					
AMPICILLIN SUSP.	----------GENERIC----------					
V-Cillin K®	x	x	x	x	x	
Dyazide						
Actifed Syr.			x	x		
Zyloprim						
Aldomet						
Marax						
Inderal						
Premarin	x					
Aldactazide						
Dalmane						
Lasix						
Erythrocin[g]	x	x	x	x	x	x
Lomotil	x	x			x	

Drug Product	Substitutable in					
	N.Y.[a]	Ill.[b]	Ky.[c]	Penn.[d]	R.I.[e]	Wis.[f]
Phenergan Expect. w/Cod.				x		
Keflex						
Benadryl	x	x	x	x	x	x
PREDNISONE	----------GENERIC----------					
Ilosone[g]						
Indocin						
Atarax						
PENICILLIN V POTASSIUM	----------GENERIC----------					
Ilosone Susp.[g]						
Diabinese						
Achromycin V	x	x	x	x	x	x
Mycolog Cream						
Lanoxin						
Novahistine DH Expect.						
Fiorinal						
Pediamycin Liq.[g]			x		x	
Phenergan Expect.	x	x		x		
Poly Vi Flor Chews						
Tranxene						
Ionamin						
Vibramycin	x		x			
Sudafed			x	x		
Librax						
Tenuate Dospan	x					
Vi Daylin F Drops						

Drug Product	Substitutable in					
	N.Y.	Ill.	Ky.	Penn.	R.I.	Wis.
Ornade Spansule						
Darvon Compound - 65	x	x	x		x	x
Benylin Syrup	x				x	
Donnagel PG Susp.						
Drixoral						
Kwell Lot. and Shamp.[h]	x	x				
V-Cillin K Susp.	x	x	x		x	x
Hydrodiuril	x	x	x	x		x
Marax Syr.						
Motrin						
Rondec DM Syr.						
Dimetane Elix. and Expect.	x	x		x		
Cortisporin Otic	x	x				
Cordran Cream						
Dimetapp Extentabs				x		
Tegopen	x	x				
Apresoline						
Parafon Forte						
Librium	x	x	x		x	x
Valisone Cream						
Pen-Vee K	x	x	x	x	x	x
Kenalog Cream	x	x		x		
Antivert	x	x	x			x
THYROID	----------GENERIC----------					
AMOXICILLIN SUSP.	----------GENERIC----------					

Drug Product	Substitutable in					
	N.Y.[a]	Ill.[b]	Ky.[c]	Penn.[d]	R.I.[e]	Wis.[f]
Benadryl Elix.	x	x	x	x		x
Tylenol				x		
Desquam x 5 and 10						
Erythrocin Susp.[g]	x		x		x	
Butazolidin Alka						
Dilantin						
Lidex Cream						
Bendectin						
Clistin RA						
Mellaril						
Empirin Compound #3				x		
DIGOXIN	----------GENERIC----------					
Bentyl						
Neosporin Oint.	x	x				
Actifed C Syrup				x		
Lo Ovral						
Monistat Cream						
Phenergan VC Expect.						
PHENOBARBITAL	----------GENERIC----------					
Atromid - S						
Fastin		x				
Poly Vi Flor Drops						
Novahistine DH Expect.						
Ortho Novum - 21	x	x				
Ser Ap Es						

Drug Product	Substitutable in N.Y.[a]	Ill.[b]	Ky.[c]	Penn.[d]	R.I.[e]	Wis.[f]
Enduronyl						
Vioform HC Cream and Lot.						
Darvocet N						

a. New York (State), Department of Health, Office of Public Health and Office of Health Systems Management, Safe, Effective and Therapeutically Equivalent Prescription Drugs (Albany: 1978).

b. Illinois, Department of Public Health, Office of Environmental Health, Division of Food and Drugs, Illinois Formulary, Illinois Drug Product Selection Program, First Edition Revised (Springfield: 1978).

c. Kentucky, Department of Human Resources, Kentucky Drug Formulary Council, Kentucky Drug Formulary (Frankfort: 1978).

d. Pennsylvania, Legislative Reference Bureau, Pennsylvania Bulletin, Vol. 7, No. 50 (Harrisburg: 1977).

e. Rhode Island, Department of Health, Rhode Island Formulary Commission, Rhode Island Formulary, First Edition (Providence: 1977).

f. Wisconsin, Department of Health and Social Sciences, Division of Health, Wisconsin Drug Formulary, Vol. 4 (Madison: 1978).

g. Delaware and Florida prohibit substitution for this drug product.

h. Florida prohibits substitution for this drug product.

are not substitutable in Delaware or Florida. Where this occurs, appropriate footnotes have been added to Table V.

Of the one hundred most commonly prescribed drug products:

(1) Ten are for drug products written by their generic names. A generic substitution law will not affect these drug products;

(2) Thirty-seven are substitutable in at least one of the six state formularies.[1] Of these thirty-seven, Florida and Delaware, or both, list six drug products in their negative formularies;

(3) Fifty-three are not substitutable in any of the six state formularies.[2]

The thirty-seven substitutable drug products amount to 3,829 prescriptions in the Hawaii sample. This equals 34.9 per cent of the 10,973 prescriptions for Hawaii's one hundred most commonly prescribed drug products.

Seventeen drug products are substitutable in three or more of the six states equaling 1,834 prescriptions in the Hawaii sample or 16.7 per cent of the prescriptions for the one hundred most commonly prescribed drug products.

Survey 2 - Retail Price Survey/Dispensing Policies

Price Survey. In November of 1978, a survey of retail pharmacies with permits to operate in the State was made to determine retail prices of selected drug products. The chief pharmacists of 96 retail pharmacies were questioned. Forty-one pharmacies, or 42.7 per cent, returned the questionnaires.[3]

Survey 2 was undertaken to determine:

(1) The differences in retail prices between commonly prescribed, "substitutable" brand name drug products and their chemical equivalents;

(2) Retail prices among different pharmacies for each of the drug products surveyed; and

(3) Whether retail pharmacies stock chemical equivalents of drug products commonly prescribed and prescribed by brand name.

Eight brand name drug products among Hawaii's one hundred most commonly prescribed were reviewed. Pharmacies were asked the retail prices of these brand name drug products for the mode strength and number of units discovered in Survey 1. Similar data were requested for the lowest priced chemical equivalent in stock on that date. In addition, retail prices for ampicillin and polycillin, a brand name of ampicillin which was not among the one hundred most commonly prescribed, was also requested.

The nine drug products selected, their strengths, the number of units, and chemical equivalents are:

(1) Achromycin V -- 250 mg., 20 capsules;
Tetracycline HCl -- 250 mg., 20 capsules;

(2) Polycillin -- 250 mg., 20 capsules;
Ampicillin -- 250 mg., 20 capsules;

(3) Erythrocin Stearate -- 250 mg., 20 tablets;
Erythromycin stearate -- 250 mg., 20 tablets;

(4) V-Cillin K -- 250 mg., 20 tablets;
Penicillin V potassium -- 250 mg., 20 tablets;

(5) Tylenol Comp. No. 3 -- 12 tablets;
Acetaminophen + codeine phosphate -- 12 tablets;

(6) Lomotil -- 20 tablets;
Diphenoxylate + atropine sulfate -- 20 tablets;

(7) Benadryl -- 25 mg., 30 capsules;
Diphenhydramine HCl -- 25 mg., 30 capsules;

(8) Hydrodiuril -- 50 mg., 100 tablets;
Hydrochlorothiazide -- 50 mg., 100 tablets;

(9) Actifed -- 20 tablets; and
Triprolidine HCl + pseudoephedrine HCl -- 20 tablets.

The following table presents the results of Survey 2 setting forth the mean, median, and mode retail prices for the drug products surveyed. The differences between the brand name drug products and their chemical equivalents were calculated using only pharmacies which stocked both. Complete results of Survey 2 may be found in Appendix D.

In the attempt to determine the differences in retail prices between commonly prescribed, "substitutable" brand name drug products and their chemical equivalents, the results show:[4]

(1) There are differences in prices of brand name drug products from pharmacy to pharmacy.

(2) For drug products almost exclusively prescribed by one brand name, pharmacies generally do not stock chemical equivalents to that brand name drug product.

(3) For three drug products, Achromycin V (tetracycline), Tylenol Compound No. 3 (acetaminophen + codeine phosphate), and V-Cillin K (penicillin V potassium), the mean price differences between the brand name drug products and their chemical equivalents were less than $1, although the median and mode price was zero for Achromycin V.

(4) For two drug products, Erythrocin (erythromycin) and Hydrodiuril (hydrochlorothiazide), the mean price differences between the brand name drug products and their chemical equivalents were more than $1.

(5) For three drug products, Benadryl, Lomotil, and Actifed, less than 5 per cent of the pharmacies responding stocked chemical equivalents to those almost exclusively prescribed brand name drug products.

Finding (2) above is of interest and a generic substitution law may change the prevailing practice. One reason for the absence of chemical equivalents is that pharmacies do not have the incentive to stock them because they are rarely

Table VI

RESULTS OF SURVEY 2

Name	No. of Pharmacies	Mean	Median	Mode	Range
Brand: Achromycin V	36	$1.97	$1.75	$1.75	$ 4.75 - $1.40
Generic: Tetracycline HCl	29	1.98	1.75	1.75	3.75 - 1.00[a]
Difference	24	0.16	0.00	0.00	1.00 - 0.00
Brand: Polycillin	31	$5.87	$6.10	$6.10	$ 7.00 - $4.00[b]
Generic: Ampicillin	40	3.02	2.925	2.35	5.00 - 1.75
Difference	29	3.03	3.01	3.75	4.20 - 0.80
Brand: Erythrocin Stearate	39	$4.34	$4.05	$4.00	$ 7.40 - $3.00
Generic: Erythromycin Stearate	25	3.38	3.60	3.60	4.25 - 2.15
Difference	25	1.02	1.00	0.90	2.03 - 0.00
Brand: V-Cillin K	39	$3.35	$3.10	$3.05	$ 5.35 - $2.00
Generic: Penicillin V Potassium	32	2.53	2.40	2.30	3.95 - 1.75
Difference	32	0.85	0.80	0.75	1.75 - 0.00
Brand: Tylenol Comp. No. 3	40	$2.35	$2.30	$2.30	$ 3.50 - $1.65
Generic: Acetaminophen + Codeine Phosphate	12	2.08	2.10	1.75	2.80 - 1.75[c]
Difference	12	0.20	0.20	--	0.50 - 0.00
Brand: Lomotil	40	$4.34	$4.20	$3.90	$ 5.75 - $3.40
Generic: Diphenoxylate + Atropine Sulfate	2	2.90	--	--	--[d]
Difference	2	1.83	--	--	--
Brand: Benadryl	40	$2.13	$2.05	$1.75	$ 3.25 - $1.35
Generic: Diphenhydramine HCl	2	2.00	--	--	--[e]
Difference	2	0.50	--	--	--
Brand: Hydrodiuril	39	$8.87	$8.25	$7.70	$16.50 - $7.30
Generic: Hydrochlorothiazide	31	4.52	4.42	3.75	6.25 - 2.20
Difference	30	3.85	3.95	3.95	7.10 - 1.35
Brand: Actifed	40	$2.04	$1.975	$1.75	$ 3.00 - $1.30
Generic: Triprolidine + Pseudophedrine	0	--	--	--	--
Difference	0	--	--	--	--

a. Only 10 pharmacies stocked chemical equivalents cheaper than Achromycin V.

b. Ten pharmacies did not stock and only 15 prescriptions for Polycillin were found in Survey 1.

c. There were no prescriptions for "acetaminophen + codeine phosphate" found in Survey 1 and only 12 pharmacies stocked a chemical equivalent to Tylenol Comp. No. 3.

d. There were no prescriptions for "diphenoxylate + atropine sulfate" found in Survey 1 and only 2 pharmacies stocked a chemical equivalent to Lomotil. Note the manufacturers of the chemical equivalent stocked are not listed in the New York, Illinois, or Wisconsin formularies where Lomotil is substitutable.

e. There were no prescriptions for "diphenhydramine HCl" found in Survey 1 and only 2 pharmacies stocked a chemical equivalent to Benadryl. Note the manufacturers of the chemical equivalent are not listed in the formularies of the 6 states whose formularies were reviewed.

f. There were no prescriptions for "triprolidine + pseudophedrine" found in Survey 1. No chemical equivalent to Actifed was stocked by any of the respondents.

prescribed. The study by Richard A. Horvitz, discussed in chapter 3, came to a similar conclusion. As can be seen in Survey 2, when a drug product is commonly prescribed by a brand name as well as by its generic name, almost all pharmacies carry chemically equivalent drug products of more than one manufacturer. A generic substitution law may encourage pharmacists to stock the cheaper chemical equivalents.

Dispensing Policies. Under a generic drug substitution law, brand name prescriptions would have essentially the same status as generically written prescriptions if physicians do not prohibit substitution. Thus, present dispensing policies for generically written prescriptions may also apply if a generic drug substitution law is enacted. The question asked did not mention generic drug substitution. For this reason, the results are only indicative of, but cannot be used to portray, the attitudes of the respondents under a generic drug substitution law.[5]

The results did not indicate an overwhelming prevailing practice in filling generically written prescriptions among the respondents. They did show that pharmacies fill generic prescriptions:

(1) With the lowest priced brand name chemically equivalent drug in stock which the store has confidence in; or

(2) With a brand name or nonbrand name chemically equivalent drug which the manufacturer backs the pharmacist with good liability coverage.

Physicians' and Pharmacists' Attitudes

Although there are differences in prices between commonly prescribed brand name drug products and their chemical equivalents, the actions of physicians and pharmacists are important if the savings suggested by the price differentials are to be realized. To determine the attitudes of physicians and pharmacists, two separate surveys were conducted.

Survey 3 - Physicians Survey

Survey 3 was conducted in September of 1978 in conjunction with the Hawaii Medical Association. Questionnaires were sent by the Hawaii Medical Association to 1,583 physicians in the State.[6] Five hundred eighty-two questionnaires equaling 36.8 per cent were returned. The completed questionnaire and results may be found in Appendix F.

Among other purposes, Survey 3 attempted to discern:

(1) The attitudes of physicians regarding a generic drug substitution law; and

(2) The reasons for opposition to a generic drug substitution law.

When questioned concerning a nonmandatory substitution law where pharmacists are allowed but not required, to substitute if physicians did not specifically prohibit substitution:[7]

(1) 38.0 per cent were in favor;

(2) 26.3 per cent were in favor for certain drug products;

(3) 33.0 per cent were not in favor; and

(4) 2.7 per cent had no opinion or checked more than one blank.

Physicians who are "not in favor" of a generic drug substitution law were asked why they opposed it. The results show that these physicians were mainly opposed particularly for three reasons:[8]

(1) Chemically equivalent drug products which they do not ordinarily prescribe generically are not bioequivalent and therapeutically equivalent;

(2) Drug products to be taken by patients should be solely the prerogative of physicians; and

(3) Pharmacology research will be stifled if profits of research-oriented manufacturers who market the more costly brand name drug products are lessened because of substitution.

Full results may be found in Appendix F.

Although Survey 3 indicates there is no consensus in the attitudes of physicians regarding a generic drug substitution law, when the number of physicians who are "in favor for certain drug products" is added to the number who are "in favor", a majority results.

Survey 4 - Pharmacists Survey

In November of 1978, a survey of pharmacists was undertaken. Questions similar to those posed of physicians were asked. Three hundred sixty-three questionnaires were sent to all pharmacists who had Hawaii addresses as their residences and who were registered with the state board of pharmacy. One hundred seventy-five responses were received equaling 48.2 per cent. The complete questionnaire and results may be seen in Appendix G.

Among other purposes, Survey 4 attempted to discern:

(1) The attitudes of pharmacists regarding a generic drug substitution law; and

(2) The reasons for opposition to a generic drug substitution law.

Pharmacists were questioned concerning a discretionary generic drug substitution.

Table VII

PHARMACISTS' ATTITUDES REGARDING
A GENERIC DRUG SUBSTITUTION LAW BY PLACE OF WORK
AND TIME OF RECEIPT OF PHARMACY DEGREE

Key: A = "In favor"
B = "In favor for certain drug products"
C = "Not in favor"
D = No opinion, multiple answers, or did not answer question

	In June 1973 or After				Prior to June 1973				
Place of Work	A	B	C	D	A	B	C	D	Total
Retail	9	5	4	0	21	23	31	1	95[a]
Hospital	2	3	3	0	18	8	7	1	43[b]
Retail/Hospital	2	2	1	0	2	0	1	0	8
Other	3	0	0	0	7	8	10	0	29[c]
Total	16	10	8	0	48	39	49	2	175[d]

a. Includes 1 respondent who worked in a retail pharmacy but did not indicate when the respondent's pharmacy degree was received.

b. Includes 1 respondent who worked in a hospital pharmacy but did not indicate when the respondent's pharmacy degree was received.

c. Includes 1 respondent who did not indicate where the respondent worked or when the respondent's pharmacy degree was received.

d. Includes 3 respondents who did not indicate when they received their degrees.

The table shows that:

(1) 36.6 per cent were in favor;

(2) 28.0 per cent were in favor for certain drug products;

(3) 32.6 per cent were not in favor; and

(4) 2.8 per cent had no opinion, had multiple answers, or did not make their positions known.

Of particular interest are the attitudes of pharmacists who work in retail pharmacies. A generic drug substitution law would have direct impact on these pharmacists. Most hospitals already operate under a formulary system where a committee of health professionals in the hospital establish a formulary of drug products which may be substituted if the prescribing physician agrees. Of the 95 pharmacists who worked in retail pharmacies:

(1) 31.6 per cent were in favor;

(2) 29.5 per cent were in favor for certain drug products;

(3) 36.8 per cent were not in favor; and

(4) 2.1 per cent could not be determined.

A hypothesis that pharmacists who received their pharmacy degrees more recently would be more liberal towards a generic drug substitution law appears true with:

(1) 47.1 per cent in favor;

(2) 29.4 per cent in favor for certain drug products; and

(3) 24.5 per cent not in favor.

Pharmacists who were "not in favor" of a generic drug substitution law were asked why they opposed it. The results show that these pharmacists mainly were opposed for two reasons:

(1) Liability suits against pharmacists may occur if pharmacists substitute; and

(2) Chemically equivalent drug products which are not ordinarily prescribed generically are not bioequivalent and therapeutically equivalent.

Full results may be found in Appendix G.

The pharmacist survey results are similar to the physicians survey. As with physicians, there appears to be no overriding consensus among pharmacists towards generic drug substitution.

Chapter 5

CONCLUSION

The previous chapters examined two basic issues of generic drug substitution, therapeutic equivalency, and costsavings. Additionally, chapter 4 attempted to determine whether certain factors necessary to achieve cost-savings, if a generic drug substitution law is enacted, are present in Hawaii. These factors are:

(1) A portion of the commonly prescribed drug products in Hawaii must be substitutable, that is, they must not be single-source or have bioequivalence problems;

(2) There must be a difference in retail prices between commonly prescribed, substitutable brand name drug products and their chemical equivalents;

(3) There must be physician support of a generic drug substitution law; and

(4) There must be pharmacist support of a generic drug substitution law.

After examination of these issues, it appears that a generic drug substitution law is feasible in Hawaii. Recommendations as to specific provisions are discussed in part II. Although the findings of the previous chapters do not indicate overwhelming support for a generic drug substitution law from the professionals involved, enough of the foregoing factors are present to warrant adoption of such a law.

Therapeutic Equivalency

There is no doubt that the issue of therapeutic equivalency of chemical equivalents is of prime importance in considering generic drug substitution. It is not a clear-cut issue. The surveys of physicians and pharmacists also show that therapeutic equivalency is of great concern to them.

It would be virtually impossible to show that all chemical equivalents are therapeutically equivalent or vice versa. The Bureau feels, however, that the therapeutic equivalency issue is not a problem for many drug products based on:

(1) The findings of the Drug Bioequivalence Study Panel of the Office of Technology Assessment that a list of interchangeable drug products is possible;

(2) The endorsement of the FDA for generic drug substitution. This organization is entitled to be relied on because of its responsibility in the area of drug products; and

(3) The absence of liability suits against pharmacists for substitution of drug products or for the filling of generically written prescriptions. To the Bureau's knowledge, there have been no liability suits brought against pharmacists for substituting or filling a generically written prescription anywhere in the United States.[1]

Cost-Savings and Factors in Hawaii

Cost-savings as a result of a generic drug substitution law have been demonstrated. The cost-savings found, however, do not approach the potential.

The Bureau believes that cost-savings in Hawaii under a generic drug substitution law are possible. An examination of factors in Hawaii shows that:

(1) Thirty-seven of the ninety brand name drug products among the one hundred most commonly prescribed in 1977 are substitutable in at least one of six states with generic drug substitution laws.

(2) For three of the nine drug products subjected to a price survey, the mean price differences between the commonly prescribed brand name and an available chemical equivalent was less than $1. For two of the nine drug products surveyed, the mean price differences were more than $1. For three of the nine surveyed, pharmacies did not generally carry chemical equivalents possibly because they had no incentive to do so under the present system. For these

three, it is conceivable that pharmacies may carry equivalents if generic drug substitution is enacted.

(3) Thirty-eight per cent of the physicians responding to an attitudinal survey were in favor of a generic drug substitution law and 33 per cent were not in favor. Approximately 26 per cent were in favor for certain drug products.

(4) Approximately 36 per cent of the pharmacists responding to a similar attitudinal survey were in favor of a generic drug substitution law and 32.6 per cent were not in favor. Twenty-eight per cent were in favor for certain drug products.

While the foregoing points may not demonstrate the absolute promise of success of a generic drug substitution law, the necessary elements for cost-savings to be realized appear to be present.

There are two other reasons, not previously mentioned, for enactment of a generic drug substitution law. It has been stated that 70 per cent of the top two hundred drug products prescribed nationwide will lose their patent protection by 1983.[2] Chemical equivalents, which may be less expensive, may then be manufactured for these products.

The Federal Drug Administration may also release a publication listing chemical equivalents of brand name drug products. This publication, the release of which the Pharmaceutical Manufacturers Association is attempting to prevent by litigation,[3] will be of valuable assistance in determining what drug products are substitutable.

During the course of this study, two issues have been raised:

(1) Why pick on "drugs and drug sundries" when they account for only 7.7 per cent of the nation's total health care expenditure?; and

(2) Why is a generic drug substitution law necessary?

The 7.7 per cent amounted to $12.5 billion,[4] and if this amount in drug expenditures can be reduced without loss in quality, the consumer will benefit.

A generic drug substitution law is necessary if the allegation is true that physicians prescribe the more expensive brand name drug products because they are aggressively marketed or easier written and not because of differences in therapeutic effects. Under each of the generic drug substitution laws the Bureau examined, the physician retains the right to prohibit substitution. The argument then that generic drug substitution interferes with the physician's prerogative of prescribing medicine is not persuasive. Physicians under these laws may still prohibit substitution. A generic drug substitution law only makes easier the element of choice in the dispensing of prescription drug products; physicians may choose to allow substitution, pharmacists may choose to substitute; and consumers may choose to lessen their drug bills if desired.

It is also argued that a generic drug substitution law is not necessary since physicians already may prescribe generically. However, a review of this report indicates that generic names are more complex than brand names. A generic drug substitution law would allow physicians to use brand names as though they were generic names and authorizing the dispensing of any chemical equivalent would be made easier.

Chapter 6

GENERIC DRUG SUBSTITUTION LAWS OF OTHER STATES

It has been stated that approximately forty states have enacted generic drug substitution laws.[1] The Bureau has obtained the laws of thirty-two states and the pertinent regulation of one.[2] Appendix H provides tables of certain aspects of these laws and the regulation, focusing on conditions of substitution. The following discuss the major aspects found in the various laws.

"Mandatory" or "Nonmandatory"

"Mandatory" generic drug substitution laws are those in which the pharmacist is required to substitute when all conditions are met. In these states, pharmacists cannot withhold substitution on their own prerogative. "Nonmandatory" generic drug substitution laws are those in which pharmacists are allowed to subsitute even though all conditions for substitution are met. Of the thirty-three states examined, eight have "mandatory" laws and twenty-five have "nonmandatory" laws.[3]

Physicians' Prerogative

All generic drug substitution laws examined allow physicians to prohibit substitution, except Minnesota's which allows pharmacists to substitute where physicians prohibit substitution if the substitute drug product is manufactured by the same manufacturer as the prescribed drug product.

Consumer Consent

Fourteen states have explicit provisions which require consumers to consent to substitution.[4] In Michigan, pharmacists are required to substitute

when consumers request it. Otherwise, it appears that consumer consent is not necessary.

General Criteria

Twenty states require the establishment of formularies[5] discussed later. Of the thirteen states which do not require formularies, nine have provisions which state that only a drug product which is chemically and therapeutically equivalent to the prescribed drug product may be substituted.[6] Two states, Maine and South Dakota, appear to have only the condition of chemical equivalency with no mention of therapeutic equivalency while two other states utilize the term "generically equivalent" when defining conditions of substitutability.[7]

Formulary

Thirteen of the twenty states with formularies require the establishment of "positive" formularies or list drug products which may be substituted. States with positive formularies are Arizona, Illinois, Kentucky, Massachusetts, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, and Wisconsin. The remaining seven states require the establishment of "negative" formularies or list drug products which are prohibited from being substituted. States with negative formularies are Arkansas, California, Delaware, Florida, Maryland, Utah,[8] and West Virginia.

The bodies responsible for establishing the formularies may be classified as follows:

(1) In eight states, departments or officers of the state government;

(2) In three states, the boards of pharmacy;

(3) In one state, the board of pharmacy and board of medical examiners meeting jointly;

(4) In seven states, specially created committees comprised of nongovernmental health professionals, government officials, and consumers;

(5) In Ohio, it appears that private companies establish individual formularies.

In almost all of the states, the criteria for allowing drug products to be substituted are based on bioequivalency, therapeutic equivalency, or both, in addition to chemical equivalency.

Cost Criteria

In almost all of the laws examined, pharmacists are required to dispense drug products which are less expensive than the prescribed drug products when substituting.[9] In addition, many states mandate the amount of savings which must be passed on to consumers. Usually, the savings which must be passed on is the difference between the wholesale cost of the prescribed and substituted drug products.[10] Other states mandate the amount of savings by prohibiting pharmacists from charging a different professional fee when substituting or charging more than the "regular and customary" price for the substitute drug product.

Pharmacists' Liability

Twelve states address the question of liability when pharmacists substitute by absolving pharmacists when they substitute[11] or by providing that the liability of pharmacists is the same or no greater than when pharmacists fill prescriptions written by generic name.[12] Oregon provides that substitution shall not constitute evidence of negligence if the substitution was made within the reasonable and prudent practice of the pharmacy or if the substitute drug product was on a generally recognized formulary or government list.

Physicians' Liability

Twelve states address the question of prescriber liability when pharmacists substitute by absolving prescribers of liability when substitution is made[13] or by providing that the failure of physicians to prohibit substitution does not constitute evidence of negligence.[14] Two states have both provisions.[15]

Other Provisions

Other provisions of the generic substitution laws and the states where applicable include:

(1) Prohibiting an employer from requiring a pharmacist-employee to substitute a drug product against that pharmacist-employee's professional judgment.[16]

(2) Prohibiting an employer from restricting a pharmacist-employee when substituting.[17]

(3) Requiring a sign be posted in each pharmacy stating that substitution is possible.[18]

(4) Requiring the placement of the name of the manufacturer or distributor of the dispensed drug product on the container when a substitution is made.[19]

(5) Requiring the name of the manufacturer or distributor of the dispensed drug product to be noted on the prescription form when a substitution is made.[20]

(6) Requiring the prescriber to be notified of each substitution made when the prescriber requests that information.[21]

(7) Requiring that refills may only be filled with the original drug product dispensed.[22]

Chapter 7

RECOMMENDATIONS

This chapter recommends provisions for a generic drug substitution law in Hawaii. First, however, preliminary material regarding the recommendations of the Federal Trade Commission and attitudes of Hawaii's physicians and pharmacists is presented.

Federal Trade Commission (FTC) Recommendations

The FTC is on the verge of completing a study on the generic drug substitution issue.

On June 23, 1978 before a conference on generic substitution, Michael Pertschuk, Chairman of the FTC, recommended three provisions for inclusion in a generic drug substitution law based on FTC research:[1]

(1) That physicians retain the right to prohibit substitution, but that the prohibition be communicated by writing by hand the words "Medically Necessary" on the prescription form. This recommendation is made because it would require a more conscious action by physicians then simply checking a pre-printed box;

(2) The adoption of a positive formulary. The Federal Drug Administration is developing a formulary for national use which is due for release soon; and

(3) No mandatory pass on of all cost-savings when pharmacists substitute. Such provisions are disincentives for pharmacists because they do not profit when substituting. The FTC feels that a generic drug substitution law should interfere as little as possible with pharmacists' "management prerogatives".

In addition, Chairman Pertschuk recommends that pharmacists be assured on the matter of liability although he did not recommend any specific provision to be included in the law. He did state that there have been no lawsuits filed

against pharmacists for legally substituting or filling a prescription written by generic name.

Hawaii's Physicians

In the same survey of physicians discussed in chapter 4, physicians who were in favor of a generic drug substitution law were asked what provisions should be embodied in the law. Three hundred seventy-four physicians were in favor of a generic drug substitution law or in favor for certain drug products. The following represents the answers of these physicians:

(1)	71 (19.0%)	Mandatory substitution unless prohibited by physician;
(2)	190 (50.8%)	Nonmandatory substitution;
(3)	231 (61.8%)	Retain physician's prerogative to prohibit substitution;
(4)	222 (59.4%)	Formulary of substitutable or nonsubstitutable drug products;
(5)	26 (7.0%)	No formulary necessary;
(6)	111 (29.7%)	Patient's consent required for substitution;
(7)	81 (21.7%)	Informing of physician by pharmacist when substitution made;
(8)	198 (52.9%)	Absolving of physician from liability when pharmacist substitutes;
(9)	99 (26.5%)	Absolving of pharmacist from liability when substituting; and
(10)	87 (23.3%)	Declaration that pharmacist substitute cheaper drug product.

As can be seen, provisions (1) and (2) relating to the mandatory/nonmandatory nature of the law and provisions (4) and (5) relating to the formulary are mutually exclusive. It is clear that physicians responding to the survey prefer a nonmandatory generic drug substitution law and the establishment of a formulary.

More than one-half of the physicians answering this question also favored provisions retaining the right to prohibit substitution and protecting physicians from liability when pharmacists substitute.

Hawaii's Pharmacists

In the survey discussed in chapter 4, pharmacists who were in favor of a generic drug substitution law were also asked what provisions should be embodied in the law. One hundred thirteen pharmacists were in favor of a generic drug substitution law or in favor for certain drug products. The following are the provisions these pharmacists favored:

(1)	4 (3.5%)	Mandatory substitution unless prohibited by physician;
(2)	98 (86.7%)	Nonmandatory substitution;
(3)	72 (63.7%)	Retain physician's prerogative to prohibit substitution;
(4)	57 (50.4%)	Formulary of substitutable or nonsubstitutable drug products;
(5)	42 (37.2%)	No formulary necessary;
(6)	36 (31.9%)	Patient's consent required for substitution;
(7)	16 (14.2%)	Informing of physician by pharmacist when substitution made;
(8)	30 (26.6%)	Absolving of physician from liability when pharmacist substitutes;
(9)	59 (52.2%)	Absolving of pharmacist from liability when substituting; and
(10)	14 (12.4%)	Declaration that pharmacist substitute cheaper drug product.

As with physicians, it appears that pharmacists favor nonmandatory substitution, establishment of a formulary, and retention of the physician's prerogative to prohibit substitution. In addition, more than one-half of the pharmacists favored protection from liability when substituting.

Recommendations

The Bureau feels that a generic drug substitution law is feasible. The recommended form is one which will provide for free market competition to some degree yet maintain the main element of antisubstitution, the prerogative of the prescriber.

With this in mind, the Bureau makes the following recommendations.

(1) Nonmandatory Law

The Bureau recommends that the generic drug substitution law be nonmandatory. It is recognized that realization of the maximum savings would require a mandatory law. The Bureau feels, however, that pharmacists as with physicians should have the prerogative to refuse to substitute. It has been mentioned that, under antisubstitution, pharmacists are merely "pill counters" who do not exercise their professional knowledge. A mandatory substitution law would merely replace one type of regulation with another and pharmacists would still remain "pill counters".

The physicians and pharmacists of Hawaii who favor generic drug substitution also appear to favor a nonmandatory provision.

(2) Retention of Physician's Prerogative to Prohibit Substitution

It is recommended that physicians retain the prerogative to prohibit substitution. All states with generic drug substitution laws which were examined have retained this right. Retention of this privilege appears necessary for the free practice of medicine by physicians. Those who favor substitution may allow it while those who do not may continue to have their prescriptions dispensed as written.

The Bureau has no recommendation as to the method physicians would communicate their desires to pharmacists.

(3) Consumer Consent Necessary

The Bureau recommends that consumers be allowed to refuse substitution. It should be their right since they are the users and purchasers of the product. Moreover, from a practical standpoint, it appears unlikely that pharmacists will substitute over the objection of consumers under a nonmandatory law.

The Bureau does not recommend a provision similar to Michigan's law which requires pharmacists to substitute when consumers request it. As discussed previously, pharmacists should not be forced to substitute against their professional judgment.

(4) Positive Formulary Should Be Established[2]

The Bureau recommends that a positive formulary of chemically and therapeutically equivalent drug products which are interchangeable be established. Drug products not on the formulary should not be used to substitute or be substituted for. The formulary should be established by or, at the least, with the advice of experts in medicine and pharmacology. The FTC recommends, and it appears that Hawaii's pharmacists and physicians who favor generic drug substitution desire a formulary.

The Bureau has no strong recommendations as to what should be the establishing body; although it appears that the department of health would have primary responsibility under existing state government structure.

The formulary should classify drug products which are interchangeable by generic drug type. That is, the drug products under the same classification should:

(1) Be chemically equivalent. That is, they should have the same active chemical ingredient or ingredients;

(2) Be therapeutically equivalent. That is, they should have essentially the same toxicity and efficacy when administered to the same person in the same dosage regimen; and

(3) Be of the same strength and dosage form.

Bioequivalency is not included as a criteria because, as the Drug Bioequivalence Panel indicated, bioinequivalency may not necessarily mean drug products are nonsubstitutable. This does not mean, however, that bioequivalency should be totally ignored. As the panel indicated, the toxic and effective ranges for some drug products are relatively narrow. For these drug products, bioequivalency should be considered.

The establishing body should also consider factors such as the:

(1) Insurance coverage of manufacturers;

(2) Manufacturer's liability coverage of pharmacists who dispense their drug products;

(3) Financial stability of manufacturers;

(4) Recall capabilities of manufacturers;

(5) Compliance of manufacturers with FDA regulations; and

(6) Product information capabilities of manufacturers.

The drug products of manufacturers who are found to be wanting in any of the above should not be included in the formulary. The Bureau has collected no material on these criteria and makes no recommendation concerning adequacy.

In addition, drug products which are under patent should not be included on the formulary.

The Bureau also recommends that the establishing body consider the problems involved with coated tablets and flavored drug products. It is maintained that, especially for children, flavored drug products should not be substitutable since the flavor is essential.

The Bureau also recommends that the establishing body consider whether refills may be filled with a brand different from the originally dispensed drug product.

The generic drug substitution law should not go into effect until after the formulary is established.

(5) Cost Criteria Should Be General

The Bureau does not recommend a provision mandating that a specific amount of savings be passed on to consumers when pharmacists substitute. The Bureau agrees with the FTC that such a provision serves as a disincentive for substitution. The Bureau also feels that such a provision would be difficult and costly to regulate.

Instead, the Bureau recommends a simple provision stating that the substitute drug product should have a lower retail price than the prescribed drug product. There is no reason, as yet, to believe that pharmacists would take advantage of the law.

(6) Containers Should Be Labeled When Substitution Made

It is recommended that the container in which consumers receive the purchased drug product be labeled with the name of the manufacturer of the drug product if a substitution is made and a subsequent refill is authorized. This would allow a pharmacist who did not dispense the original prescription to determine whether to dispense the originally dispensed drug product or not.

(7) Consumer Education Should Be Pursued

The Bureau feels strongly that consumer education should occur in this area. Consumers must realize that drug products are the same as other consumer commodities in that prices for the same product vary with different manufacturers and a degree of choice is possible. When consumers are sufficiently educated, the competitive market system would probably have significant impact on the prices of drug products. This consumer awareness should serve as a greater regulatory mechanism than direct government monitoring. Thus, consumer education should be viewed as an investment with potentially long-term benefits and it would also influence the professionals involved.

(8) Appropriation Should Be Less Than the Saving for Hawaii Estimated by the FTC

At this time, the Bureau has no projection of the amount of money which may be saved by generic drug substitution in Hawaii, nor the cost of establishing a formulary, instituting a consumer education program, or otherwise administering the law. The FTC has stated that its study will include estimations of the amount of savings which may be realized in each state.[3] The study is due prior to the end of the Regular Session of 1979. The appropriation for the administration of the law should not exceed the estimated savings to achieve at least an initially favorable cost-benefit ratio.

(9) Amendment of Present Statutes

Section 328-6(15), Hawaii Revised Statutes, which codifies the present antisubstitution provision, should be amended to allow substitution with the qualification that it be done in accordance with the generic drug substitution law. It should not be repealed because that paragraph also prohibits the dispensing of a different drug in place of the drug prescribed.

(10) Pharmacist and Physician Liability

Appendix I discusses the question of physician and pharmacist liability in detail. That discussion states that a limitation on pharmacist and physician liability may be necessary.

Five situations are discussed in which possible injury to a consumer receiving a substitute drug product may occur. The following summarizes the findings.

Under situation (1), the substitute drug product is defective because of an impurity and is therefore not chemically and therapeutically equivalent to the prescribed drug, and the consumer is injured because of that defect. Under this situation, the manufacturer, distributor, and pharmacist may be liable. Apparently, the prescribing physician is not liable if only acting as a prescriber.

Under situation (2), the substitute drug product is mislabeled and fails to give adequate directions for use or warn of side effects thus causing injury. In this situation, the manufacturer, distributor, physician, and pharmacist may be liable.

Under situation (3), the substitute drug product is sanctioned as therapeutically equivalent but really is not, and causes injury. In this situation, the manufacturer, distributor, and pharmacist may be held liable. If the substitute drug product is sanctioned as therapeutically equivalent by a state body, the state through its employees may also be held liable.

Under situation (4), the injury is caused by a mistake of the pharmacist by, for example, substituting the wrong drug product. In this situation, the pharmacist is liable.

Under situation (5), the physician prescribes the wrong drug product and the injury is caused by that action instead of the substitution. In this situation, the manufacturer and distributor are not liable, although the pharmacist may have some liability.

The discussion also notes that where the pharmacist is liable, the plaintiff will probably take action against the pharmacist because of ready accessibility rather than against the manufacturer or distributor who is based in another state. The pharmacist could then seek indemnity against the manufacturer.

Of the situations discussed, situation (3) should be addressed by the legislature. The legislature may limit liability by absolving the pharmacist totally if the substitution was made in accordance with the substitution law. If the pharmacist is absolved totally, the injured consumer still has recourse against the manufacturer or distributor. This provision, however, involves a trade off between the encouragement of substitution by a pharmacist by limiting the liability and inconveniencing an injured consumer by forcing action against a manufacturer or distributor located in another state.

Or, the legislature may choose to enact a provision limiting pharmacist liability by providing that it be the same as when filling a prescription written for a drug product by its generic name as suggested by the FTC.

In regards to physician liability, the Bureau feels that a physician should be absolved from liability when a substitution is made where the original prescription is correct. This provision, it appears, merely restates the present situation.

(11) State Liability

Appendix I points out that the State is immune from tort liability due to its sovereign immunity but has waived immunity for the negligent acts of its employees. It further states that liability is allowed by statute and can be excluded by statute.

Presumably, the State, if including a drug product on the formulary which is not therapeutically equivalent to other chemical equivalents, may be liable if there were no reasonably valid basis for including a drug product in the formulary. If a consumer is injured because of taking that drug product, it appears that the consumer may seek action against the State. If the consumer is successful, it appears that the State could seek indemnity against the manufacturer or distributor of the drug product if the manufacturer's or distributor's information was relied upon by the State and the information was incorrect.

Appendix I also suggests that the State be made immune from liability by statute.

FOOTNOTES

Chapter 1

1. Milton Silverman and Philip R. Lee, *Pills, Profits, and Politics* (Los Angeles: University of California Press, 1974), pp. 35 and 36.

2. *Ibid.*

3. 21 *Code of Federal Regulations* part 299.

4. U.S., Congress, Senate, Subcommittee on Monopoly of the Committee on Small Business, *Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, Ninetieth Congress, First Session, on Present Status of Competition in the Pharmaceutical Industry, Part 2*, 90th Cong., 1st Sess., 1967, p. 754.

5. Pharmaceutical Manufacturers Association, *Brands, Generics, Prices and Quality* (Washington, D.C.: 1971), p. 9.

6. United States Pharmacopeial Convention, Inc., *United States Pharmacopeia* (Nineteenth Rev., Rockville, Md.: 1974), p. 367.

7. *Ibid.*

8. *Hawaii Rev. Stat.*, sec. 328-6(15).

9. 35 U.S.C.A. sec. 101 (1954).

10. 35 U.S.C.A. sec. 154 (1954).

11. U.S., Department of Health, Education, and Welfare, Task Force on Prescription Drugs, *The Drug Makers and the Drug Distributors* (Washington, D.C.: U.S. Government Printing Office, 1968), p. 38.

12. Silverman and Lee, p. 36.

13. Medical Economics Company, *Physician's Desk Reference* (30 Ed.; New Jersey: 1976), p. 1018.

14. Harry F. Dowling, *Medicines for Man; The Development, Regulation and Use of Prescription Drugs* (New York: Alfred A. Knopf, Inc., 1970), p. 122; Richard Burack, M.D., F.A.P.C., *The New Handbook on Prescription Drugs* (New York: Ballantine Books, 1976), p. 3; Silverman and Lee, p. 54.

15. U.S., Congress, House, Subcommittee on Consumer Protection and Finance of the Committee on Interstate and Foreign Commerce, *Hearings Before the Subcommittee on Consumer Protection and Finance of the Committee on Interstate and Foreign Commerce, House of Representatives, Ninety-Fourth Congress, Second Session, on H.R. 882, H.R. 884, and All Identical Bills, Bills to Amend the Federal Food, Drug, and Cosmetic Act so as to Require that in the Labeling and Advertising of Drugs Sold by Prescription the "Established Name" of Such Drugs Must Appear Each Time Their Proprietary Name is Used, to Permit the Advertising of Drug Prices and to Require Retailers of Prescription Drugs to Post Prices of Certain Commonly Prescribed Drugs, and For Other Purposes*, 94th Cong., 2d. Sess., 1976, p. 226.

16. "The Mysteries of Prescription Pricing in Retail Pharmacies," *Medical Care*, March 1977, pp. 248 and 250.

Chapter 2

1. Eli Lilly and Co., *Implications of Drug Substitution Laws: Analysis and Assessment* (Indianapolis: 1978), p. 6; U.S., Congress, Senate, Subcommittee on Monpoly of the Select Committee on Small Business, *Present Status of Competition in the Pharmaceutical Industry, Part 4*, 90th Cong., 1st Sess., 1967, p. 1374.

2. *Ibid.*, p. 1375.

3. Milton Silverman and Philip R. Lee, *Pills, Profits, and Politics* (Los Angeles: University of California Press, 1974), p. 26.

4. U.S., Congress, Senate, Subcommittee on Health of the Committee on Labor and Public Welfare, *Hearings Before the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate, Ninety-Third Congress, Second Session, on Examination of the Office of Technology Assessment Report of the Drug Bioequivalence Study Panel*, 93rd Cong., 2d. Sess., 1974, pp. 142 and 143.

5. U.S., Department of Health, Education, and Welfare, Task Force on Prescription Drugs, *The Drug Prescribers* (Washington, D.C.: U.S. Government Printing Office, 1968), p. 24.

6. *Ibid.*, pp. 44 and 45.

7. *Ibid.*, p. 44.

8. United States Pharmacopeial Convention, Inc., *The Pharmacopeia of the United States of America* (Nineteenth Rev.; Rockville, Md.: 1974), p. xiii.

9. Task Force on Prescription Drugs, p. 44.

10. *Ibid.*, pp. 44 and 45.

11. American Pharmaceutical Association, *The National Formulary* (Fourteenth Ed.; Washington, D.C.: 1975), p. xx.

12. *Ibid.*

13. *Ibid.*, pp. xvii and xviii.

14. American Pharmaceutical Association, *A White Paper On ... The Pharmacist's Role in Product Selection* (Washington, D.C.: 1971), p. 9.

15. U.S., Office of Technology Assessment, Drug Bioequivalence Study Panel, *Drug Bioequivalence* (Washington, D.C.: U.S. Government Printing Office, 1974), p. 76.

16. American Pharmaceutical Association, *White Paper*, p. 9.

17. *Ibid.*

18. *Ibid.*

19. *Ibid.*, p. 10.

20. 21 *Code of Federal Reglations* sec. 320.1(a); hereinafter referred to as *CFR*.

21. American Pharmaceutical Association, *White Paper*, p. 10.

22. 21 *CFR* sec. 207.20.

23. 21 *CFR* sec. 207.21.

24. *Ibid.*

25. 21 U.S.C.A. sec. 360(h) (1972).

26. Task Force on Prescription Drugs, p. 32.

27. U.S., Congress, Senate, Subcommittee on Monopoly of the Select Committee on Small Business, *Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, Ninety-Second Congress, First Session, on Present Status of Competition in the Pharmaceutical Industry, Part 20*, 92nd Cong., 1st Sess., 1971, p. 7980.

28. 21 *CFR* sec. 211.16.

29. 21 *CFR* sec. 211.29.

30. 21 *CFR* sec. 211.30.

31. 21 *CFR* sec. 211.40.

32. 21 *CFR* sec. 211.46.

33. 21 *CFR* sec. 211.55.

34. 21 *CFR* sec. 211.58.

35. 21 U.S.C.A. sec. 355 (1972).

36. 21 U.S.C.A. sec. 321(p) (1972).

37. U.S., Congress, Senate, Subcommittee on Monopoly of the Select Committee on Small Business, *Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, Ninetieth Congress, First Session, on the Present Status of Competition in the Pharmaceutical Industry, Part 2*, 90th Cong., 1st Sess., 1967, p. 746.

38. Task Force on Prescription Drugs, p. 35.

39. Silverman and Lee, p. 119.

40. Task Force on Prescription Drugs, p. 35.

41. 21 *CFR* sec. 314.1(f).

42. Letter from Bernard E. Cabana, Ph.D., Division of Biopharmaceutics/Drug Monographs, Food and Drug Administration, Department of Health, Education, and Welfare to Martin Golden, January 26, 1977.

43. 21 *CFR* sec. 320.21.

44. 21 U.S.C.A. secs. 356(a) and 357(a) (1972).

45. U.S., Congress, Senate, Subcommittee on Monopoly of the Select Committee on Small Business, *Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, Ninetieth Congress, First and Second Sessions, on Present Status of Competition in the Pharmaceutical Industry, Part 6*, 90th Cong., 1st and 2d. Sess., 1967-68, p. 2159.

46. Task Force on Prescription Drugs, p. 34.

47. *Ibid.*, p. x.

48. Silverman and Lee, p. 151.

49. Task Force on Prescription Drugs, p. 26.

50. *Ibid.*, pp. 27 and 28.

51. U.S., Department of Health, Education, and Welfare, Task Force on Prescription Drugs, *Final Report* (Washington, D.C.: U.S. Government Printing Office, 1969), p. 31.

52. Drug Bioequivalence Study Panel, p. 5.

53. *Ibid.*

54. *Ibid.*, p. 11.

55. *Ibid.*, p. 21.

56. *Ibid.*, pp. 22 and 23.

57. *Ibid.*, p. 22.

58. *Ibid.*, p. 25.

59. *Ibid.*, p. 33.

60. *Ibid.*, p. 33.

61. *Ibid.*, p. 58.

62. U.S., Subcommittee on Health, p. 158.

63. *Ibid.*, p. 82.

64. *Ibid.*, p. 169.

65. *Ibid.*, p. 82.

66. *Ibid.*, p. 83.

Chapter 3

1. The *Red Book* is published by Drug Topics magazine and the *American Druggist Blue Book* is published by American Druggist magazine. Both provide wholesale prices of drug products.

2. Milton Silverman and Philip R. Lee, *Pills, Profits, and Politics* (Los Angeles: University of California Press, 1974), pp. 172 and 173.

3. U.S., Department of Health, Education, and Welfare, Task Force on Prescription Drugs, *The Drug Users* (Washington, D.C.: U.S. Government Printing Office, 1968), pp. 36 and 37.

4. *Ibid.*, p. 35.

5. "Prescription Writing by Generic Name and Drug Cost," *Journal of Chronic Diseases*, pp.

6. *Ibid.*

7. "Consumer Price Differentials Between Generic and Brand Name Prescriptions," *American Journal of Public Health*, October 1974, pp. 977-982.

8. "Savings from Generic Prescriptions," *Annals of Internal Medicine*, May 1975, pp. 601 to 607.

9. Reprint of "Effectiveness of Drug Product Selection Legislation in Delaware," *Contemporary Pharmacy Practice*, Vol. 1, No. 1, Summer 1978, pp. 4 to 8.

10. *Ibid.*, p. 7.

11. *Ibid.*

12. Theodore Goldberg, "Cost Implications of Drug Product Selection Legislation," paper presented at the Invitational Dissemination Workshop on Drug Product Selection Legislation, Seattle, Washington, September 21-22, 1978.

13. *Ibid.*, p. 20.

Chapter 4

1. Of the thirty-seven which are substitutable:

   (1) Four are substitutable in all six states: Erythrocin, Benadryl, Achromycin V, and Pen-Vee K;

   (2) Six are substitutable in five states: V-Cillin K, Darvon Compound-65, V-Cillin K Suspension, Hydrodiuril, Librium, and Benadryl Elixir;

   (3) Two are substitutable in four states: Tylenol Compound No. 3 and Antivert;

   (4) Five are substitutable in three states: Lomotil, Phenergan Expectorant, Dimetane Elixir and Expectorant, Kenalog Cream, and Erythrocin Suspension;

   (5) Ten are substitutable in two states: Actifed Syrup, Pediamycin Liquid, Vibramycin, Sudafed, Benylin Syrup, Kwell Lotion and Shampoo, Cortisporin Otic, Tegopen, Neosporin Ointment, and Ortho Novum-21; and

   (6) Ten are substitutable in one state: Dimetapp Elixir, Actifed, Premarin, Phenergan Expectorant with Codeine, Tenuate Dospan, Dimetapp Extentabs, Tylenol, Empirin Compound No. 3, Actifed C Syrup, and Fastin.

2. The six drug products which are listed on the Florida and/or Delaware negative formularies but which are substitutable in at least one of the states examined are: Erythrocin, Erythrocin Suspension, Ilosone, Ilosone Suspension, Pediamycin Liquid, and Kwell. All of the six except Kwell are various forms of Erythromycin.

3. Of the forty-one responding, nine were "mainland-based chains", fifteen were "part of a company with more than one retail pharmacy in the State", and seventeen were "sole proprietorships or the only retail pharmacy in the State run by the company of ownership".

4. Polycillin (ampicillin) is not discussed because it is prescribed almost exclusively by generic name. A generic substitution law may not have a significant impact on this drug product.

5. See generic drug substitution questionnaire, question number 1, Appendix E.

6. Dentists were not surveyed.

7. See Survey 2, question number 1, Appendix F.

8. See Survey 2, question number 2, Appendix F.

Chapter 5

1. Letter from Noreen Walsh of the Office of Legislative Oversight and Analysis of the Assembly of the State of New York to Calvin Azama, September 6, 1978; and letter from Peter D. Holmes, Staff Attorney and Project Director, Bureau of Consumer Protection, Federal Trade Commission to Calvin Azama, November 15, 1978.

2. *The Wall Street Journal*, December 7, 1978, p. 1.

3. *Ibid.*

4. U.S., Department of Health, Education and Welfare, Social Security Administration, *Social Security Bulletin*, vol. 41, no. 7, July 1978, p. 3.

Chapter 6

1. *The Wall Street Journal*, December 7, 1978, p. 1.

2. These states are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

3. Michigan's nonmandatory law, however, has a provision where pharmacists are required to substitute if consumers request it.

4. Arkansas, Connecticut, Florida, Georgia, Idaho, Illinois, Kentucky, Missouri, Montana, Pennsylvania, Rhode Island, Utah, Vermont, and West Virginia.

5. Arizona, Arkansas, California, Delaware, Florida, Illinois, Kentucky, Maryland, Massachusetts, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Virginia, West Virginia, and Wisconsin.

6. Colorado, Connecticut, Georgia, Idaho, Kansas, Minnesota, Montana, Oregon, and Washington.

7. Missouri provides that a chemically equivalent and generically equivalent drug product may be substituted for a prescribed drug product. Michigan provides that only a generically equivalent drug product may be substituted for a prescribed drug product. Neither state defines the term in their legislation.

8. Utah appears to allow its board of pharmacy to establish a formulary. A reading of the law, however, indicates that the formulary is required.

9. South Dakota does not appear to have any provision regarding cost-saving. Maine, Oregon, Vermont, and Wisconsin allow the cost of substitute drug products to be equal to or lower than the prescribed drug products.

10. States with such a provision are California, Delaware, Michigan, Minnesota, Ohio, Pennsylvania, Virginia, Washington, and West Virginia.

11. Illinois, Pennsylvania, Rhode Island, and West Virginia.

12. Arizona, California, Colorado, Florida, Missouri, Montana, and Utah.

13. California, Florida, Montana, Pennsylvania, Rhode Island, and Washington.

14. Arizona, Illinois, Oregon, and Utah.

15. Ohio and West Virginia.

16. Arizona.

17. West Virginia.

18. Connecticut, Florida, Idaho, Kentucky, Montana, Oregon, Pennsylvania, Vermont, Washington, and West Virginia.

19. Delaware, Idaho, and New Jersey.

20. Georgia and Idaho.

21. New Jersey.

22. Wisconsin.

Chapter 7

1. Michael Pertschuk, Chairman, Federal Trade Commission, "De-regulating the Prescription Drug Market" (Comments before the National Conference on Generic Drugs, June 23, 1978).

2. It should be noted that this section was written prior to the release of the FDA drug formulary. This section has been construed to mean that the State establish a formulary independent of the FDA formulary. This is not the case. The State may choose to incorporate the FDA formulary by reference if desired.

3. Letter from Peter D. Holmes, Staff Attorney and Project Director, Bureau of Consumer Protection, Federal Trade Commission to Calvin Azama, November 15, 1978.

APPENDICES

(To be made one and seven copies)

THE SENATE

NINTH LEGISLATURE, 1978

STATE OF HAWAII

Appendix A

S.R. NO. 272

SENATE RESOLUTION

REQUESTING A STUDY OF THE ADVISABILITY AND FEASIBILITY OF EXPANDING THE USE OF GENERIC DRUGS IN HAWAII.

WHEREAS, the availability of high quality prescription drugs at minimum cost is in the best interest of consumers, particularly for those with limited funds; and

WHEREAS, the costs of health care continue to rise, adding to the difficulties encountered by many consumers on fixed incomes who must purchase prescription drugs; and

WHEREAS, such drugs are essential to the continued life and well-being of those for whom the medicines are prescribed, and those persons have no choice but to purchase the prescribed drugs, or suffer the consequences; and

WHEREAS, there are many cases where a specific drug is produced by several different manufacturers and is marketed under a chemical or generic name; and

WHEREAS, such drugs, known as "generic drugs", are generally less costly than their chemical counterparts marketed under a "brand-name" by large pharmaceutical distributors; and

WHEREAS, a possible solution to the dilemma of those forced to purchase prescription drugs for continued life and well-being is the use of generic drugs in lieu of a "brand-name" drug specified by the prescribing physician; and

WHEREAS, considerable interest has been expressed by consumer groups for the establishment of a generic drug substitution program which would permit the filling of prescriptions specifying a "brand-name" drug with the generic drug, resulting in significant cost savings in most cases; and

WHEREAS, there is concern within the pharmaceutical industry that generic drugs, while chemically equivalent to certain brand-name drugs, may not be biologically and/or therapeutically equivalent, and therefore generic drugs could produced undesirable side-effects in the body when used in place of the prescribed brand-name drug; and

S.R. NO. 272

WHEREAS, studies made by the U.S. Office of Technology Assessment have pointed to difficulties in establishing the biological and therapeutic equivalency of generic drugs to brand-name drugs and the inherent problems of adverse side-effects in the body; and

WHEREAS, in light of certain conflicting information, there is a need to more completely assess the issue of generic drug substitution before enacting legislation to permit the consumer to exercise such option; now, therefore,

BE IT RESOLVED by the Senate of the Ninth Legislature of the State of Hawaii, Regular Session of 1978, that the Office of the Legislative Reference Bureau is requested to do a study of the relationship of generic drugs to brand-name drugs to determine the feasibility and advisability of adopting a policy of generic drug substitution; including data on cost savings to consumers if such a policy is implemented on a consumer-option basis and the implications that such a program would have on malpractice liability in the event of undesired side-effects of generic substitution; and

BE IT FURTHER RESOLVED that the Office of the Legislative Reference Bureau submit a report of its findings to the Legislature not later than thirty days prior to the convening of the next Regular Session of 1979; and

BE IT FURTHER RESOLVED that a certified copy of this Resolution be transmitted to the Director of the Legislative Reference Bureau.

OFFERED BY: Joe Kuroda

Mary George

Patsy K. Young

Jean King

Pat Saiki

3/7/78

Appendix B

SURVEY 1

PHARMACIES AND DATES
FOR WHICH PRESCRIPTIONS DISPENSED SURVEYED

Pharmacies	Dates (1977)
Apothecary Shop	Dec. 3 - 9
Beretania Prescription Pharmacy	July 16 - 22
Chun Hoon Pharmacy	Dec. 10 - 16
City Pharmacy	Mar. 19 - 25
Civic Professional Pharmacy	Aug. 13 - 19
College Pharmacy	Jan. 29 - Feb. 4
Kalihi Pharmacy	Jan. 1 - 7
Karwacki Professional Pharmacy	Dec. 3 - 9
King-Kalakaua Pharmacy	Apr. 23 - 29
King Pharmacy	Apr. 30 - May 6
Longs Drug - Ala Moana	June 2 - 8
Longs Drug - Downtown	July 23 - 29
Longs Drug - Kailua	May 21 - 27
Longs Drug - Pali Highway	Apr. 2 - 8
Longs Drug - Pearl City	Feb. 19 - 25
Longs Drug - Pearlridge	Sept. 3 - 9
McCully Drugs	Dec. 24 - 30
Medical Arts Pharmacy	Nov. 19 - 25
Okimoto Drugs	May 7 - 13
Parkview-Gem - Ala Moana	July 30 - Aug. 5
Pay Less - Dillingham	Dec. 17 - 23
Pay Less - Kailua	Mar. 26 - Apr. 1
Pay Less - Kaneohe	Oct. 15 - 21
Pay Less - Waimalu	Aug. 27 - Sept. 2
Pay'N Save - Mililani	Sept. 10 - 16
Pay'N Save - Salt Lake	Mar. 12 - 18
Pay'N Save - Temple Valley	June 4 - 10
Pay'N Save - Waianae	Nov. 26 - Dec. 2
Sav-Mor Drug - Moanalua	May 28 - June 3
Tanseido Drug	Sept. 24 - 30
Thrifty Drugs - Koko Marina	Nov. 12 - 18
Thrifty Drugs - Kaimuki	Jan. 15 - 21
Value Drug - Aiea	June 18 - 24
Wahiawa Pharmacy	Feb. 5 - 11
Waianae Drug	Aug. 6 - 12
Waipahu Drug	Jan. 22 - 28
Waipahu Professional Drug	Oct. 22 - 28
Walrich Drug - Kaneohe	Mar. 5 - 11
Walrich Drug - Kailua	June 8 - 14
Wilder Avenue Drugs	Apr. 16 - 22

Appendix C

1977 PRESCRIPTION SURVEY

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
A, Vitamin (GENERIC)			4		
Aarane (Syntex)		4			
Abdol (PD)		2			
Abdol w/Vit. C (PD)		2			
Achromycin V (Lederle)	250 mg.	93			
	500 mg.	14			
Achromycin V Susp. (Lederle)	?	5			
	125 mg.	2			
Achrostatin V (Lederle)	250 mg.	8			
Aci Jel (Ortho)		6			
Actifed (BW)		227			
Actifed Syr. (BW)		190			
Actifed C Tab. (BW)		3			
Actifed C Syr. (BW)		56			
Actol (Beecham)		2			
Actol Expect. (Beecham)		2			
Adapin (Pennwalt)	25 mg.	2			
Adeflor Chews (Upjohn)		5			
Adeflor Drops (Upjohn)		8			
Aeorlate (Fleming)		3			
Aeorlate Elix. (Fleming)		3			
Aeorlone Comp. Liq. (Lilly)		2			
Aeorosporin Otic Sol. (BW)		3			
Afrin Nasal Spray (Schering)		35			
Afrin Nose Drops (Schering)		7			
Albalon Opth. Sol. (Allergan)		4			
Albalon Opth. Drops (Allergan)		7			
Aldactazide (Searle)		157			
Aldactone (Searle)		25			
Aldochlor (MSD)		4			
Aldomet (MSD)	125 mg.	4			
	250 mg.	142			
	500 mg.	27			
Aldoril (MSD)	15 mg.	4			
	25 mg.	16			
All Bee C (Robins)		11			
Allopurinal (GENERIC)	?		2[b]		
	100 mg.		9[b]		
	300 mg.		7[b]		
Alpen (Lederle)	250 mg.	2			
Alpha Keri Soap, Lot., Oil (Westwood)		8			
Alupent (BI)		3			
Alupent Inhaler (BI)		2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Ambenyl Expect. (PD)		15			
w/Ephedrine		2			
Amesec (Lilly)		7			
Amino Cerv Cream (Milex)		6			
Aminophylline (GENERIC)	100 mg.		6		
Aminophylline Supp. (GENERIC)	125 mg.		3		
Amnestrogen (Squibb)	1.25 mg.	2			
Amoxicillin (GENERIC)	125 mg.		3		
	250 mg.		14		
	500 mg.		3		
Amoxicillin Susp. (GENERIC)	?		7		
	125 mg.		40		
	250 mg		18		
Amoxicillin Drops (GENERIC)	?		2		
	50 mg.		6		
Amoxil (Beecham)	125 mg.	3			
	250 mg.	31			
	500 mg.	4			
Amoxil Susp. (Beecham)	125 mg.	6			
	250 mg.	6			
Amoxil Drops (Beecham)	50 mg.	2			
Amphojel Liq. (Wyeth)		6			
Ampicillin (GENERIC)	250 mg.	176			
	500 mg.	81			
Ampicillin Susp. (GENERIC)	?		23		
	125 mg.		72		
	200 mg.		2		
	250 mg.		109		
Ampicillin Drops (GENERIC)	100 mg.		10		
Amytal (Lilly)	60 mg.	2			
Anacin (Whitehall Labs)		2			
Ananase (Rorer)	50,000 u.	2			
	100 mg.	6			
Anspor (SKF)	250 mg.	3			
Antabuse (Ayerst)	250 mg.	3			
	500 mg.	2			
Antiminth Liq. (Roerig)		2			
Antivert (Roerig)	12.5 mg.	49			
	25 mg.	16			
Anturane (Geigy)	100 mg.	7			
	200 mg.	7			
Anusol HC Cream (W-C)		6			
Anusol HC Supp. (W-C)		28			
Apresazide (Ciba)	?	2			
Apresoline (Ciba)	10 mg.	6			
	25 mg.	42			
	50 mg.	20			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Aquacare Lot. (G.S. Herbert)		2			
Aristocort Tab. (Lederle)	2 mg.	2			
	4 mg.	6			
Aristocort Cream (Lederle)		37			
Aristocort Oint. (Lederle)		6			
Aristocort A Cream (Lederle)		22			
Aristocort A Oint. (Lederle)		3			
Aristocort HP Cream (Lederle)		3			
Arlidin (USV)	6 mg.	10			
Artane (Lederle)	2 mg.	11			
	5 mg.	4			
Artane Sequels (Lederle)	5 mg.	2			
Arthopan (Purdue Frederick)		5			
ASA (Lilly)	?	3			
	5 gr.	5			
ASA Comp. No. 3 (Lilly)		17			
ASA Enseals (Lilly)	5 gr.	5			
	10 gr.	7			
ASA Supp. (Lilly)		2			
Asbron G (Dorsey)		12			
Asbron G Elix. (Dorsey)		5			
Ascorbic Acid (GENERIC)	500 mg.		2		
Ascriptin (Rorer)		10			
Ascriptin A/D (Rorer)		5			
Atabrine (Winthrop)		2			
Atarax (Roerig)	10 mg.	64			
	25 mg.	48			
	50 mg.	2			
Atarax Syr. (Roerig)		20			
Ativan (Wyeth)		4			
Atromid-S (Ayerst)		54			
Atropine Eye Drops (GENERIC)			2		
Auralgan Otic (Ayerst)		20			
AVC Cream (M-N)		37			
AVC Cream w/Dienestrol (M-N)		10			
AVC Supp. (M-N)		10			
Aventyl (Lilly)	10 mg.	2			
	25 mg.	2			
Azo-Gantanol (Roche)		14			
Azo-Gantrisin (Roche)		37			
Azulfidine (Pharmacia)		2			
B_{12}, Vitamin				2	
Bacitracin Oint. (GENERIC)			3		
Bacitracin Opth. Oint. (GENERIC)			5		
Bactrim (Roche)		4			
Bactrim DS (Roche)		21			
Banalag Liniment (Cole)		5			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Banalag Liniment (Cole)		5			
Barseb HC (Barnes-Hind)		6			
Becotin (Dista)		2			
Bellergal (Dorsey)		7			
Bellergal Spacetabs (Dorsey)		16			
Benadryl (PD)	25 mg.	86			
	50 mg.	39			
Benadryl Elix. (PD)		65			
Benadryl/Ephedrine Liq. (PD)		4			
Benadryl/Neosynephrine Liq. (PD)		6			
Bendectin (M-N)		60			
Benemid (MSD)		26			
Bengay Lin. (Leeming/Pacquin)		2			
Benisone Gel (W-C)		11			
Bentyl (M-N)	?	3			
	10 mg.	28			
	20 mg.	27			
Bentyl Syr. (M-N)		8			
Bentyl w/Phenobarbital (M-N)	10 mg.	4			
	20 mg.	3			
Benylin Syr. (PD)		78			
Benylin/Ephedrine (PD)		2			
Benzac (Owen)	5 mg.	3			
	10 mg.	2			
Benzagel (Dermik)		9			
Benzoyl Peroxide (GENERIC)			10		
Berocca (Roche)		7			
Betadine Douche (PF)		5			
Betadine Sol. (PF)		6			
Betadine Vag. Jelly (PF)		5			
Betapen VK (Bristol)	250 mg.	2			
Biphetamine "20" (Pennwalt)		7			
Bleph-10 Opth. (Allergan)		9			
Blephamide Opth. Drops (Allergan)		8			
Blephamide Opth. Sol. (Allergan)		16			
Bonine (Roerig)		3			
Brethine (Geigy)	2.5 mg.	3			
	5 mg.	18			
Brevicon-21 (Syntex)		9			
Brondecon (W-C)		25			
Brondecon Elix. (W-C)		22			
Bronkometer (Breon)		4			
Bronkosol (Breon)		3			
Buff & Puff (Riker)		4			
Butazolidan (Geigy)		5			
Butazolidan Alka (Geigy)		62			
Butibel (McNeil)		7			
Butigetic (McNeil)		2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Butisol Sodium (McNeil)	1/4 gr.	4			
	1/2 gr.	4			
Butisol Sod. Liq. (McNeil)		2			
C, Vitamin				9	
C, Vitamin w/Iron				3	
Cafergot (Sandoz)		12			
Cafergot PB (Sandoz)		5			
Caladryl (PD)		5			
Calamine Lot. (GENERIC)			4		
Calcium Gluconate (GENERIC)			8		
Calcium Lactate (GENERIC)	5 mg.		3		
Cantil (Lakeside)		5			
Cardilate (BW)	10 mg.	3			
Castor Oil (GENERIC)			5		
Catapress (BI)	0.1 mg.	12			
Cefol (Abbott)		6			
Celestone (Schering)		26			
Cepacol Lozenges (M-N)		10			
Cepacol Mouthwash (M-N)		2			
Cepacol Troches (M-N)		5			
Cepastat Lozenges		5			
Cerumenex Cream (PF)		2			
Cetapred Sol. (Alcon)		10			
Cevalin Vit. C (Lilly)	500 mg.	3			
Chloralhydrate (GENERIC)	500 mg.		7		
Chloralhydrate Syr. (GENERIC)			4		
Chloromycetin (PD)	250 mg.	2			
Chloromycetin Opth. (PD)		5			
Chloroptic Opth. (Allergan)		12			
Chloroseptic Gargyle (Eaton)		2			
Chloroseptic Inhaler (Eaton)		2			
Chloroseptic Spray (Eaton)		8			
Chloroseptic Susp. (Eaton)		2			
Chloroseptic Lozenges (Eaton)		2			
Chlorpheniramine Maleate (GENERIC)	4 mg.		6		
Chlor Trimeton (Schering)	?	6			
	4 mg.	13			
	8 mg.	5			
	12 mg.	10			
Chlor Trimeton Syr. (Schering)		4			
Chlor Trimeton Repetabs (Schering)	?	3			
	8 mg.	2			
	12 mg.	3			
Choledyl (W-C)	100 mg.	10			
	200 mg.	34			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Choledyl Elix. (W-C)		2			
Cimetidine (GENERIC)	300 mg.		2[b]		
Cleocin (Upjohn)	?	2			
	75 mg.	4			
	150 mg.	37			
Cleocin Drops (Upjohn)		2			
Cleocin Lot. (Upjohn)		34			
Cleocin Phosphate (Upjohn)		3			
Cleocin Sol. (Upjohn)		10			
Cleocin/Retin A (Upjohn)		19			
Cleocin in Lavacol (Upjohn)		2			
Clindamycin (GENERIC)	150 mg.		2[b]		
Clindamycin Phosphate in Isopropyl Alcohol (GENERIC)			14[b]		
Clindamycin Sol. (GENERIC)			8[b]		
Clistin (McNeil)	4 mg.	2			
	8 mg.	2			
Clistin D (McNeil)		15			
Clistin RA (McNeil)	?	7			
	8 mg.	50			
	12 mg.	3			
Clomid (M-N)		14			
Clonidine HCl (GENERIC)	0.1 mg.		2[b]		
	0.2 mg.		3[b]		
Cloxacillin (GENERIC)	250 mg.		7		
Codeine (GENERIC)	1 gr.		2		
Cogentin (MSD)	1 mg.	16			
	2 mg.	30			
Colace (MJ)	100 mg.	6			
Colace Syr. (MJ)		2			
Colbenemid (MSD)		28			
Colchicine (GENERIC)	1/100 gr.		5		
	1/120 gr.		2		
	0.5 mg.		4		
	0.6 mg.		9		
Colymycin Otic (W-C)		18			
Colymycin Otic w/Neomycin and Hydrocortisone (W-C)		7			
Colymycin S Otic (W-C)		2			
Colymycin S Otic w/Neomycin and Hydrocortisone (W-C)		2			
Combid Spansules (SKF)		34			
Combipress (BI)	0.1 mg.	4			
	0.2 mg.	4			
Compazine Spansule (SKF)	5 mg.	4			
	10 mg.	6			
	15 mg.	2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Compazine Supp. (SKF)	25 mg.	8			
Compocillin VK (Ross)	250 mg.	10			
Compocillin VK Liq. (Ross)	?	3			
	125 mg.	3			
	250 mg.	11			
Conar Syr. (Beecham)		12			
Conar A Tab. (Beecham)		2			
Conjugated Estrogens (GENERIC)	1.25 mg.		3		
	2.5 mg.		2		
Co-Pyronil (Dista)		34			
Co-Pyronil Ped. Caps (Dista)		18			
Co-Pyronil Susp. (Dista)		25			
Cordran Cream (Dista)		71			
Cordran Lot. (Dista)		24			
Cordran Oint. (Dista)		15			
Cordran Tape (Dista)		13			
Cordran N Cream (Dista)		10			
Cordran N Oint. (Dista)		2			
Cort Enema (Rowell)		2			
Cortisporin Otic (BW)		71			
Cortisporin Cream (BW)		3			
Cortisporin Oint. (BW)		7			
Cortisporin Opth. Oint. (BW)		13			
Cortisporin Opth. Drops (BW)		4			
Cortisporin Susp. (BW)		4			
Cosanyl Liq. (PD)		16			
Cotylenol (McNeil)		9			
Coumadin (Endo)	2 mg.	3			
	5 mg.	9			
Cytomel (SKF)	25 mg.	4			
D, Vitamin				2	
Dalmane (Roche)	15 mg.	39			
	30 mg.	117			
Danazol (Winthrop)	200 mg.	2			
Darvocet N (Lilly)		50			
Darvocet N 100 (Lilly)		223			
Darvon (Lilly)		10			
Darvon Comp. 65 (Lilly)		80			
Darvon/ASA (Lilly)		9			
Darvon N (Lilly)	100 mg.	4			
Darvon N/ASA (Lilly)		4			
Dayalets (Abbott)		2			
DBI-TD (Geigy)		11			
Debrox Ear Drops (Intern. Pharm.)		12			
Decadron (MSD)	0.25 mg.	2			
	0.5 mg.	3			
Decadron Elix. (MSD)		7			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Decadron Oint. (MSD)		3			
Decadron Opth. (MSD)		12			
Decadron Spray (MSD)		2			
Decardron Turbinaire (MSD)		4			
Decagesic (MSD)		9			
Decaspray (MSD)		2			
Declomycin HCl (Lederle)	75 mg.	3			
	150 mg.	2			
Deconamine (SMP)		13			
Demazin (Schering)		4			
Demazin Syr. (Schering)		2			
Demerol (Winthrop)	50 mg.	7			
Demulen-21 (Searle)		39			
Demulen-28 (Searle)		8			
Desonide Cream (GENERIC)			12[b]		
Desquam x 5 & 10 (Westwood)		65			
Dexamethasone (GENERIC)			4		
Diabinese (Pfizer)	100 mg.	25			
	250 mg.	83			
Dialose Plus (Stuart)		2			
Diamox (Lederle)	250 mg.	6			
	500 mg.	3			
Diamox Sequels (Lederle)		6			
Diazepam (GENERIC)	2 mg.		6[b]		
	5 mg.		4[b]		
Dibenzyline (SKF)	10 mg.	5			
Dicloxacillin (GENERIC)	250 mg.		2		
Didrex (Upjohn)	50 mg.	3			
Dienestrol Cream (GENERIC)			7		
Diethylstilbestrol (GENERIC)	1 mg.		3		
	5 mg.		4		
Digitoxin (GENERIC)	0.1 mg.		3		
Digoxin (GENERIC)	0.125 mg.		17		
	0.25 mg.		38		
Dihydrotachysterol (GENERIC)	0.2 mg.		3		
Dilantin (PD)	50 mg.	7			
	100 mg.	55			
Dilantin Susp. (PD)		3			
Dilantin Sodium (PD)	100 mg.	3			
Dimacol (Robins)		4			
Dimetane Elix. & Expect. (Robins)		72			
Dimetane Extentabs (Robins)	?	3			
	4 mg.	4			
	8 mg.	2			
Dimetane DC Expect. (Robins)		32			
Dimetapp Elix. (Robins)		234			
Dimetapp Extentabs (Robins)		71			
Diprosone Cream (Schering)		27			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Diprosone Oint. (Schering)		3			
Disphrol Chronotabs (Schering)		5			
Diupress (MSD)	250 mg.	4			
	500 mg.	3			
Diuril (MSD)	250 mg.	3			
	500 mg.	19			
Dolonil (W-C)		3			
Domeboro (Dome)		10			
Donnagel Susp. (Robins)		11			
Donnagel PG Susp. (Robins)		78			
Donnatal (Robins)		49			
Donnatal Extentabs (Robins)		5			
Donnatal Elix. (Robins)		27			
Donnazyme (Robins)		6			
Dorcol Ped. Syr. (Dorsey)		3			
Doriden (USV)		7			
Doxepin (GENERIC)	25 mg.		2		
Doxidan (Hoechst)		23			
Doxycycline (GENERIC)	50 mg.		26		
	100 mg.		2		
Dramamine (Searle)	50 mg.	6			
Drixoral (Schering)		77			
Drysol Liq. (Person & Covey)		3			
Dulcolax (BI)		14			
Dulcolax Supp. (BI)		8			
Duofilm Liq. (Stiefel)		4			
Duo Medihaler (Riker)		7			
Dyazide (SKF)		198			
Dymelor (Lilly)	250 mg.	23			
	500 mg.	15			
Dynapen (Bristol)	250 mg.	2			
Dyrenium (SKF)	50 mg.	5			
	100 mg.	15			
E, Vitamin (GENERIC)			2		
Econopred (Alcon)		4			
Ecotrin (SKF)		10			
EES (Abbott)	400 mg.	11			
EES Chews (Abbott)	200 mg.	2			
EES Liq. (Abbott)	?	4			
	200 mg.	7			
	400 mg.	6			
EES Drops (Abbott)	50 mg.	2			
Efudex Cream (Roche)		3			
Elase Oint. (PD)		2			
Elase-Chloromycetin (PD)		6			
Elavil (MSD)	10 mg.	9			
	25 mg.	14			
	50 mg.	13			
	75 mg.	5			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Eldoquin Oint. (Elder)		2			
Eldoquin-Forte Oint. (Elder)		3			
Elixophyllin Cap. (Cooper; Sherman)		9			
Elixophyllin Susp. (Cooper; Sherman)		17			
Elixophyllin-KI Susp. (Cooper; Sherman)		3			
Elixophyllin Ped. Susp. (Cooper; Sherman)		7			
Emetrol Syr. (Rorer)		6			
Empirin Comp. (BW)		3			
Empirin Comp. No. 2 (BW)		9			
Empirin Comp. No. 3 (BW)		58			
Empirin Comp. No. 4 (BW)		7			
Empracet Comp. No. 3 (BW)		42			
E-Mycin (Upjohn)	250 mg.	21			
Enarex (Roerig)	5 mg.	3			
Enduron (Abbott)	?	8			
	2.5 mg.	6			
	5 mg.	39			
Enduronyl (Abbott)		51			
Enduronyl Forte (Abbott)		6			
Enovid E-21 (Searle)		7			
Enterex (Baylor)		3			
Ephedrine (GENERIC)	250 mg.		3		
Ephedrine/Orthine		3			
Ephedrine Sulfate Susp. (GENERIC)			5		
Ephedrine/Robitussin Susp.		3			
Eppy N Opth. Sol. (Barnes-Hind)		9			
Eprolin (Lilly)	100 mg.	2			
Equagesic (Wyeth)		24			
Equanil (Wyeth)	400 mg.	6			
Ergotrate (Lilly)		5			
Erythrocin (Abbott)	250 mg.	145			
	500 mg.	8			
Erythrocin Chews (Abbott)	200 mg.	2			
Erythrocin Drops (Abbott)	100 mg.	9			
Erythrocin Ethyl Succinate Susp. (Abbott)	200 mg.	3			
Erythrocin Granules (Abbott)	200 mg.	19			
Erythrocin Susp. (Abbott)	?	5			
	200 mg.	44			
	400 mg.	13			
Erythromycin (GENERIC)	250 mg.		200		
	500 mg.		12		
Erythromycin Base (GENERIC)	250 mg.		4		
Erythromycin Granules (GENERIC)			2		
Erythromycin Stearate (GENERIC)	250 mg.		7		

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Erythromycin Susp. (GENERIC)	?		4		
	200 mg.		16		
	250 mg.		4		
	400 mg.		5		
Erythromycin Ethyl Succinate Drops (GENERIC)	200 mg.		6		
Erythromycin Ethyl Succinate Susp. (GENERIC)	200 mg.		2		
Esgic (Gilbert)		12			
Esidrix (Ciba)	25 mg.	12			
	50 mg.	12			
Esimil (Ciba)		11			
Eskalith (SKF)		5			
Estar Gel (Westwood)		3			
Estinyl (Schering)	0.02 mg.	3			
	0.05 mg.	4			
Estrace (MJ)	1 mg.	5			
Etrafon (Schering)	2-10	6			
	2-25	2			
	4-25	9			
Eurax Cream (Geigy)		17			
Euthroid (W-C)	1/2 gr.	4			
	1 gr.	22			
	2 gr.	14			
	3 gr.	7			
Exsel Lot. & Shamp. (G.S. Herbert)		2			
Fastin (Beecham)		53			
Femiron (J.B. Williams)		2			
Feosol (SKF)		16			
Feosol Spansules (SKF)		12			
Feosol Elix. (SKF)		2			
Fer-in-Sol Drops (MJ)		6			
Fer-in-Sol Syr. (MJ)		6			
Fero-Folic 500 (Abbott)		2			
Fero-Grad 500 (Abbott)		18			
Ferro-Sequels (Lederle)		7			
Ferro-Span (Imperial Labs)		2			
Ferrous Sulfate (GENERIC)	5 gr.		3		
	10 gr.		3		
$FeSO_4$	5 gr.		6		
Festal (Hoechst)		2			
Filibon FA (Lederle)		16			
Fiogesic (Sandoz)		6			
Fiorinal (Sandoz)		95			
Fiorinal w/Cod. No. 2 (Sandoz)		4			
Fiorinal w/Cod. No. 3 (Sandoz)		17			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
FL	500 mg.				2
Flagyl (Searle)	250 mg.	29			
Fleet Enema (Fleet)		6			
Flexeril (MSD)	10 mg.	3			
Fluoride (GENERIC)			5		
Fluoride Drops (GENERIC)			2		
Flura Drops (Kirkman)		35			
Flura-Loz (Kirkman)		2			
FML Eye Drops (Allergan)		18			
Folbesyn (Lederle)		3			
Folic Acid (GENERIC)			11		
Folvite (Lederle)	1.0 mg.	2			
Fostex Cake & Soap (Westwood)		2			
Fulvicin (Schering)	500 mg.	4			
Fulvicin U/F (Schering)	500 mg.	5			
Furantoin (N. Am. Pharm.)	50 mg.	2			
Gammene Lot. (Barnes-Hind)		12			
Gammene Shamp. (Barnes-Hind)		3			
Gamophene Soap (Arbrook)		3			
Gantanol (Roche)		35			
Gantrisin (Roche)		43			
Gantrisin Syr. (Roche)		16			
Gantrisin Ped. Syr. (Roche)		5			
Garamycin Cream (Schering)		5			
Garamycin Eye Drops (Schering)		9			
Garamycin Oint. (Schering)		18			
Gaviscon (Marion)		2			
Gelusil Liq. (W-C)		15			
Gelusil M (W-C)		2			
Gelusil M Liq. (W-C)		5			
Gentian Violet Sol. (GENERIC)			2		
Geriplex FS Kapseals (PD)		3			
Glyceryl Guaiacolate Expect. (GENERIC)			2		
Glyoxide Liq. (Intern. Pharm.)		2			
Griseofulvin (GENERIC)	500 mg.		2		
Gris-Peg (Dorsey)	125 mg.	12			
Gyne-Lotrimin (Delbay)		15			
Haldol (McNeil)	2 mg.	5			
	5 mg.	7			
	10 mg.	6			
Halog Cream (Squibb)		38			
Halotestin (Upjohn)	10 mg.	2			
Halotex Cream (Westwood)		5			
Harmonyl (Abbott)	0.25 mg.	6			
Hebcort Lot. (Barnes-Hind)		2			
Hebcort MC Lot. (Barnes-Hind)		3			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Herplex Liquefilm (Allergan)		2			
Hexadrol (Organon)	75 mg.	3			
Histadyl EC Liq. (Lilly)		3			
HMS Eye Drops (Allergan)		2			
Homatropine Eye Drops (GENERIC)			5		
Hormonin (Carnrick)		2			
Hybephen (Beecham)		4			
Hycomine Syr. (Endo)		2			
Hydergine (Sandoz)	1 mg.	7			
Hydralazine (GENERIC)	25 mg.	2			
Hydriodic Syr. (GENERIC)			3		
Hydrochlorothiazide (GENERIC)	25 mg.		9		
	50 mg.		28		
Hydrocortisone Cream (GENERIC)			13		
Hydrodiuril (MSD)	25 mg.	14			
	50 mg.	62			
Hydrogen Peroxide (GENERIC)			2		
Hydromox (Lederle)	50 mg.	9			
Hydropress (MSD)	25 mg.	6			
	50 mg.	5			
Hygroton (USV)	50 mg.	24			
	100 mg.	15			
Hytone Cream (Dermik)		10			
Iberet-500 (Abbott)		23			
Iberet Folic 500 (Abbott)		9			
Ilopan Choline (Warren-Teed)		2			
Ilosone (Dista)	125 mg.	6			
	250 mg.	86			
	500 mg.	31			
Ilosone Susp. (Dista)	?	8			
	125 mg.	71			
	250 mg.	34			
Ilosone Ped. Susp. (Dista)		2			
Ilosone Chews (Dista)		2			
Ilotycin Oint. (Dista)		12			
Ilotycin Opth. Oint. (Dista)		2			
Imipramine (GENERIC)	50 mg.		3		
Imodium (Ortho)		4			
Imuran (BW)	50 mg.	3			
Inderal (Ayerst)	?	2			
	10 mg.	63			
	20 mg.	3			
	40 mg.	58			
	80 mg.	4			
Indocin (MSD)	?	2			
	25 mg.	96			
	50 mg.	23			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
INH (Ciba)	300 mg.	3			
Insulin (GENERIC)	U-100		3		
Intal (Fisons)	20 mg.	5			
Ionamin (Pennwalt)	?	2			
	15 mg.	5			
	30 mg.	79			
Ipecac Syr. (GENERIC)			2		
Ismelin (Ciba)	10 mg.	21			
	25 mg.	6			
Isopto Carpine Sol. (Alcon)		13			
Isopto Cetamide Opth. Sol. (Alcon)		5			
Isopto Cetapred Sol. (Alcon)		8			
Isordil (Ives)	5 mg.	18			
	10 mg.	10			
Isordil Sublingual (Ives)	2.5 mg.	4			
	5 mg.	4			
Isordil Tembids (Ives)		5			
Isuprel Comp. Elix. (Winthrop)		9			
Isuprel Mistometer (Winthrop)		11			
K, Vitamin				2	
Kaon Tab. (Warren-Teed)		2			
Kaon Elix. (Warren-Teed)		4			
Kaopectate Liq. (Upjohn)		9			
Kay Ciel Elix. (Cooper)		4			
Keflex (Lilly)	?	2			
	250 mg.	103			
	500 mg.	21			
Keflex Susp. (Lilly)	125 mg.	16			
	250 mg.	9			
Keflex Ped. Drops (Lilly)		3			
Kenalog Cream (Squibb)		67			
Kenalog Lot. (Squibb)		9			
Kenalog Oint. (Squibb)		9			
Kenalog Orabase (Squibb)		26			
Kenalog Spray (Squibb)		12			
Keri Bath Oil & Lot. (Westwood)		3			
Klor (Abbott)		28			
Klorvess (Dorsey)		3			
K-Lyte (MJ)		22			
K-Lyte Powder (MJ)		2			
Kolyum Liq. (Pennwalt)		2			
Komed HC Lot. (Barnes-Hind)		7			
Kwell Lot. & Shamp. (Reed & Carnrick)		77			
Lactulose Syr. (M-N)		2			
Lanoxin (BW)	0.125 mg.	44			
	0.25 mg.	58			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Larotid (Roche)	250 mg.	44			
Larotid Susp. (Roche)	?	3			
	125 mg.	28			
	250 mg.	7			
Larotid Drops (Roche)		10			
Lasix (Hoechst)	20 mg.	91			
	40 mg.	65			
Ledercillin VK (Lederle)	250 mg.	10			
	500 mg.	2			
Ledercillin VK Susp. (Lederle)	250 mg.	19			
Lente Insulin (Squibb)		5			
Librax (Roche)		83			
Librium (Roche)	5 mg.	18			
	10 mg.	42			
	25 mg.	8			
Lidex Cream (Syntex)		62			
Lidex Oint. (Syntex)		27			
Lidosporin Otic (BW)		15			
Lithane (Roerig)		2			
Lithium Carbonate (GENERIC)			8		
Lo Dose Syringes		3			
Loestrin 1/20 (PD)		8			
Loestrin 1.5/30 (PD)		9			
Lomotil (Searle)		133			
Lomotil Liq. (Searle)		7			
Lo-Ovral (Wyeth)		56			
Lo-Ovral 28 (Wyeth)		6			
Lotrimin Cream (Delbay)		32			
Lotrimin Lot. (Delbay)		4			
Lotrimin Sol. (Delbay)		13			
Loxitane (Lederle)		8			
Luminol Sod. Amp. (Winthrop)		5			
	50 mg.	7			
	100 mg.	7			
Mandelamine (W-C)	1 mg.	5			
Mantadil Cream (BW)		16			
Marax (Roerig)		166			
Marax Syr. (Roerig)		75			
Marax DF Syr. (Roerig)		7			
Marezine (BW)	50 mg.	2			
Materna 1.60 (Lederle)		9			
Maxidex Opth. Sol. (Alcon)		2			
Maxitol Opth. Sol. (Pasadena Rsrch.)		8			
Mediatric Tab. (Ayerst)		6			
Maalox (Rorer)		4			
Maalox Susp. (Rorer)		6			
Maalox Plus Susp. (Rorer)		4			
Macrodantin (Eaton)	25 mg.	2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Medihaler-Iso (Riker)		3			
Medrol (Upjohn)	4 mg.	10			
Medrol Dosepak (Upjohn)		4			
Medrol Liq. (Upjohn)		2			
Mellaril (Sandoz)	10 mg.	9			
	15 mg.	4			
	25 mg.	12			
	50 mg.	11			
	100 mg.	15			
	150 mg.	2			
	200 mg.	4			
Menrium (Roche)	5-4	3			
Meprobamate (GENERIC)	400 mg.		9		
Mestinon (Roche)	60 mg.	2			
Metamucil Liq. (Searle)		9			
Metamucil Powder (Searle)		10			
Metaprel (Dorsey)	20 mg.	3			
Metaprel Medihaler (Dorsey)		11			
Metaprel Spray (Dorsey)		3			
Methionine (GENERIC)			2		
Methotrexate (GENERIC)	2.5 mg.		4[b]		
Metimyd Eye Drops (Schering)		5			
Metreton Opth. Sol. (Schering)		3			
Micatin Cream (J&J)		21			
Micebrin (Dista)		14			
Micro Pore Tape		3			
Midrin (Carnrick)		8			
Miltown (Wallace)	400 mg.	4			
Minipress (Pfizer)	1 mg.	17			
	2 mg.	6			
	5 mg.	4			
Minocin (Lederle)	50 mg.	13			
	100 mg.	3			
Modane (Warren-Teed)		10			
Modane Mild (Warren-Teed)		2			
Modicon-21 (Ortho)		17			
Modicon-28 (Ortho)		13			
Monistat Cream (Ortho)		55			
Monistat-7 Cream (Ortho)		8			
Motrin (Upjohn)	300 mg.	15			
	400 mg.	60			
Mucomyst Drops (MJ)		3			
Multiple Vitamins				3	
Multiple Vits. w/Fluoride Drops				2	
Myadec (PD)		3			
Mycolog Cream (Squibb)		107			
Mycolog Oint. (Squibb)		22			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Mycolog Vag. Cream (Squibb)		2			
Mycostatin Cream (Squibb)		5			
Mycostatin Drops (Squibb)		2			
Mycostatin Oint. (Squibb)		5			
Mycostatin Sol. (Squibb)		2			
Mycostatin Susp. (Squibb)		6			
Mycostatin Vag. Supp. (Squibb)		10			
Mycostatin Vag. Tab. (Squibb)		17			
Mylanta Tab. (Stuart)		2			
Mylanta Liq. (Stuart)		11			
Mylanta II Tab. (Stuart)		3			
Mylanta II Liq. (Stuart)		16			
Mylicon (Stuart)		9			
Mylicon-80 (Stuart)		10			
Mysoline (Ayerst)	250 mg.	9			
Mysteclin F (Squibb)	250 mg.	4			
$NaHCO_3$				2	
Naldecon (Bristol)		43			
Naldecon Syr. (Bristol)		6			
Naldecon Ped. Drops (Bristol)		19			
Naldecon Ped. Syr. (Bristol)		16			
Nalfon (Dista)	?	6			
	300 mg.	32			
	600 mg.	5			
Naphcon Eye Drops (Alcon)		3			
Naprosyn (Syntex)		17			
Naqua (Schering)	2 mg.	7			
	4 mg.	7			
Nardil (W-C)	15 mg.	3			
Natabec (PD)		5			
Natabec FA (PD)		5			
Naturetin (Squibb)	5 mg.	5			
	10 mg.	2			
Navane (Roerig)	5 mg.	11			
	10 mg.	7			
Neg Gram (Winthrop)	250 mg.	3			
Nembu Donna (Abbott)	1/4 gr.	3			
Nembutal (Abbott)	1/2 gr.	2			
	1-1/2 gr.	3			
Neocalglucon Syr. (Dorsey)		5			
Neocortef Opth. Oint. (Upjohn)		5			
Neodecadron Cream (MSD)		3			
Neodecadron Eye Drops (MSD)		8			
Neodecadron Oint. (MSD)		5			
Neodecadron Opth. (MSD)		21			
Neodecaspray (MSD)		3			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Neomycin Oint. (GENERIC)			2		
Neopolycin Oint. (Dow)		7			
Neosporin Cream (BW)		2			
Neosporin Oint. (BW)		56			
Neosporin Opth. Drops (BW)		7			
Neosporin Opth. Oint. (BW)		38			
Neosporin Opth. Sol. (BW)		13			
Neosporin G Cream (BW)		7			
Neosynalar Cream (Syntex)		13			
Neosynephrine Nasal Spray (Winthrop)		6			
Neosynephrine Nose Drops (Winthrop)		2			
Neutrogena Soap (Neutrogena)		2			
Niamcinamide (GENERIC)	500 mg.		2		
Nicobid (Armour)	250 mg.	4			
Nicotinic Acid (GENERIC)	50 mg.		3		
Nilstat (Lederle)		2			
Nilstat Susp. (Lederle)		5			
Nilstat Vag. Tabs (Lederle)		13			
Nitrofurantoin (GENERIC)	50 mg.		3		
Nitroglycerin (GENERIC)	2.5 gr.		2		
	1/100 gr.		2		
	1/150 gr.		22		
	1/200 gr.		4		
Nitrostat (PD)	1/150 gr.	2			
Noctec (Squibb)	250 mg.	2			
Noctec Syr. (Squibb)	500 mg.	12			
Noludar (Roche)	200 mg.	3			
	300 mg.	13			
Norflex (Riker)		14			
Norgesic (Riker)		44			
Norgesic Forte (Riker)		46			
Norinyl (Syntex)	?	2			
Norinyl (Syntex)	1/50-?	3			
Norinyl 1/50-21 (Syntex)		19			
Norinyl 1/50-28 (Syntex)		6			
Norinyl 1/80-21 (Syntex)		8			
Norinyl 1/80-28 (Syntex)		3			
Norisodrin Syr. (Abbott)		6			
Norlestrin (PD)		23			
Norlestrin Fe (PD)		16			
Norlutate (PD)	5 mg.	7			
Norlutin (PD)	5 mg.	2			
Norpramine (M-N)	25 mg.	2			
	50 mg.	8			
Novacebrin F Chews (Lilly)		6			
Novafed (Dow)		15			
Novafed Elix. (Dow)		4			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Novafed A (Dow)		11			
Novahistine Expect. (Dow)		52			
Novahistine DH Expect. (Dow)		101			
NPH Insulin (Lilly)		16			
Nupercainal (Ciba)		2			
Nystatin Vag. Tab. (GENERIC)			2		
Ogen (Abbott)	0.625 mg.	7			
	1.25 mg.	11			
	2.5 mg.	6			
Omnicillin (DDC)	250 mg.	2			
Omnipen (Wyeth)	250 mg.	15			
	500 mg.	6			
Omnipen Susp. (Wyeth)	125 mg.	14			
	250 mg.	22			
Omni-Tuss Liq. (Pennwalt)		8			
123 Oint. (Durel)		6			
Optimine (Schering)	1 mg.	13			
Orabase Oint. (Davies, Rose-Hoyt)		3			
Orinase (Upjohn)		26			
Orlex HC Otic Sol. (Baylor)		3			
Ornacol (SKF)		3			
Ornade Spansule (SKF)		81			
Ornex (SKF)		7			
Ortho All Flex Diaphragm (Ortho)		12			
Ortho Gynol Gel (Ortho)		2			
Ortho-Novum 2 (Ortho)		5			
Ortho-Novum 1/50-21 (Ortho)		52			
Ortho-Novum 1/50-28 (Ortho)		35			
Ortho-Novum 1/80-21 (Ortho)		26			
Ortho-Novum 1/80-28 (Ortho)		7			
Os Cal (Marion)		4			
Os Cal Mone (Marion)		2			
Otobiotic Ear Drops (Schering)		2			
Otrivin Nasal Spray (Geigy)		3			
Ovcon-35 (MJ)		3			
Ovcon-50 (MJ)		7			
Ovral (Wyeth)		7			
Ovral-21 (Wyeth)		40			
Ovral-28 (Wyeth)		5			
Ovulen-21 (Searle)		35			
Ovulen-28 (Searle)		5			
Oxacillin Liq. (GENERIC)			2		
Oxaine-M Liq. (Wyeth)		5			
Oxytetracycline (GENERIC)	250 mg.		2		
Papase (W-C)		11			
Parafon Forte (McNeil)		70			
Paragoric Liq. (GENERIC)			5		

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Paragoric Liq. (GENERIC)			5		
Parapectolin Liq. (Rorer)		14			
Pathibamate (Lederle)	200 mg.	9			
	400 mg.	4			
Pathilon (Lederle)		5			
Pavabid (Marion)		3			
PBZ (Ciba)	50 mg.	3			
PBZ Elix. (Ciba)		2			
PBZ/Ephedrine (Ciba)		2			
PBZ/Ephedrine Elix. (Ciba)		6			
P_4E_1 Drops (Carnrick)		2			
Pedialyte (Ross)		10			
Pediamycin Chews (Ross)		10			
Pediamycin Drops (Ross)		8			
Pediamycin Granules (Ross)		3			
Pediamycin Liq. (Ross	?	3			
	200 mg.	81			
	400 mg.	10			
Penbriten (Ayerst)	250 mg.	2			
Penicillamine (GENERIC)	250 mg.		3[b]		
Penicillin (GENERIC)	250 mg.		9		
	250,000 u.		6		
Penicillin Susp. (GENERIC)	125 mg.		4		
Penicillin G (GENERIC)	250 mg.		23		
	200,000 u.		4		
	250,000 u.		4		
	400,000 u.		4		
Penicillin G Susp. (GENERIC)			3		
Penicillin V (GENERIC)	250 mg.		16		
Penicillin V Susp. (GENERIC)	125 mg.		2		
Penicillin VK (GENERIC)	125 mg.		2		
	250 mg.		110		
Penicillin VK Susp. (GENERIC)	125 mg.		12		
	250 mg.		34		
Pen-Vee-K (Wyeth)	?	2			
	250 mg.	59			
	400,000 u.	4			
	800,000 u.	2			
Pen-Vee K Susp. (Wyeth)	125 mg.	2			
	250 mg.	30			
Percodan (Endo)		49			
Percodan Demi (Endo)		40			
Periactin (MSD)		30			
Periactin Syr. (MSD)		9			
Peri-Colace (MJ)		16			
Peri-Colace Liq. (MJ)		2			
Peritrate (W-C)	80 mg.	5			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Peritrate SA (W-C)		19			
Pernox Lot. (Westwood)		2			
Persagel Gel (Texas Pharm.)		8			
Persagel/Cleocin Gel		2			
Persantine (BI)	25 mg.	44			
Persistin Forte (Fisons)	90 mg.	2			
Phazyme (Reed & Carnrick)		6			
Phenaphen (Robins)		9			
Phenaphen Expect. (Robins)		2			
Phenaphen w/Cod. No. 2 (Robins)		19			
Phenaphen w/Cod. No. 3 (Robins)		23			
Phenaphen w/Cod. No. 4 (Robins)		6			
Phenergan Tab. (Wyeth)	12.5 mg.	4			
	25 mg.	9			
	50 mg.	4			
Phenergan D Tab. (Wyeth)		2			
Phenergan Supp. (Wyeth)	25 mg.	3			
Phenergan Expect. (Wyeth)		94			
Phenergan Expect. w/Cod. (Wyeth)		133			
Phenergan DM Expect. (Wyeth)		3			
Phenergan Fortis Syr. (Wyeth)		5			
Phenergan Ped. Expect. (Wyeth)		41			
Phenergan PL Expect. (Wyeth)		3			
Phenergan VC Expect. (Wyeth)		55			
Phenergan VC Expect. w/Cod. (Wyeth)		43			
Phenobarbital (GENERIC)	1/4 gr.		16		
	1/2 gr.		31		
	1 gr.		6		
Phenobarbital Elix. (GENERIC)			20		
Phen-O-Bel #2 (Coastal)		2			
Phenoxymethyl Pot. Pen. (GENERIC)	250 mg.		3		
Phenoxymethyl Pot. Pen. Susp. (GENERIC)	125 mg.		11		
Phisoderm (Winthrop)		3			
Phisohex (Cook-Waite)		38			
Pilocarpine Sol. (GENERIC)			14		
Placidyl (Abbott)	500 mg.	18			
	750 mg.	19			
Polaramine Maleate (Schering)	?	2			
	2 mg.	3			
	4 mg.	3			
	6 mg.	5			
Polaramine Repetabs (Schering)		2			
Polycillin (Bristol)	250 mg.	11			
	500 mg.	4			
Polycillin Susp. (Bristol)		3			
Polymox (Bristol)	250 mg.	21			
Polymox Susp. (Bristol)	125 mg.	12			
	250 mg.	6			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Polymox Drops (Bristol)		3			
Polysporin Oint. (BW)		3			
Poly Vi Flor Chews (MJ)		92			
Poly Vi Flor Chews w/Iron (MJ)		2			
Poly Vi Flor Drops (MJ)		53			
Poly Vi Flor w/Iron Drops (MJ)		2			
Poly Vi Sol Drops (MJ)		2			
Ponstel (PD)	250 mg.	3			
Potaba (Glennwook)		3			
Potassium Chloride Liq. (GENERIC)			3		
Potassium Iodide Enseals (Lilly)		4			
Povan (PD)		3			
Povan Susp. (PD)		7			
Pramet FA (Ross)		14			
Pramilet FA (Ross)		3			
Prazosin (GENERIC)	2 mg.		2[b]		
Pred Forte Opth. Susp. (Allergan)		3			
Pred Forte Drops (Allergan)		6			
Prednefrin Opth. Sol. (Allergan)		2			
Prednisone (GENERIC)	1 mg.		2		
	5 mg.		114		
	10 mg.		6		
Prednisolone (GENERIC)	5 mg.		18		
Preludin Endurette (BI)	75 mg.	4			
Premarin (Ayerst)	0.3 mg.	24			
	0.625 mg.	77			
	1.25 mg.	54			
	2.5 mg.	3			
Premarin Vag. Cream (Ayerst)		6			
Prestate (W-C)		2			
Principen Susp. (Squibb)	250 mg.	11			
Pro Banthine (Searle)	7.5 mg.	3			
	15 mg.	22			
Pro Banthine PA (Searle)		3			
Prolixin (Squibb)	1 mg.	2			
	5 mg.	5			
Prolixin Elix. (Squibb)		4			
Proloid (W-C)	1 gr.	11			
Pronestyl (Squibb)	250 mg.	8			
	500 mg.	3			
Propadrine HCl (MSD)	50 mg.	3			
Propanolol (GENERIC)	10 mg.		15[b]		
	40 mg.		15[b]		
Propythiouracil (GENERIC)	50 mg.		11		
Prostaphlin (Bristol)	250 mg.	4			
Prostaphlin Sol. (Bristol)	250 mg.	5			
Provera (Upjohn)	10 mg.	42			
Purpose Cream (J&J)		2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Pyribenzamine (Ciba)	50 mg.	4			
Pyridium (W-C)	100 mg.	13			
	200 mg.	33			
Pyridoxine (GENERIC)	50 mg.		7		
Quaalude (Rorer)	300 mg.	10			
Quadrinal (Knoll)		2			
Questran Powder (MJ)		9			
Quibron (MJ)		13			
Quibron Elix. (MJ)		36			
Quinaglute (Cooper)		13			
Quinamm (M-N)		15			
Quinidex Extentabs (Robins)		6			
Quinidine (GENERIC)	3 gr.		11		
Racet Cream (Lemmon)		5			
Raudixin (Squibb)	50 mg.	3			
	100 mg.	4			
Rauzide (Squibb)	50 mg.	3			
Regroton (USV)		42			
Rela (Schering)	350 mg.	5			
Renese (Pfizer)	?	2			
	1 mg.	15			
Renese R (Pfizer)		5			
Renoquid (PD)	250 mg.	5			
Reserpine (GENERIC)	0.1 mg.		3		
	0.25 mg.		26		
Retin A Cream (J&J)		11			
Retin A Gel (J&J)		33			
Riopan Susp. (Ayerst)		10			
Ritalin (Ciba)	5 mg.	3			
	10 mg.	3			
Robaxin (Robins)	500 mg.	7			
Robaxin 750 (Robins)		8			
Robaxisol (Robins)		14			
Robimycin (Robins)	250 mg.	3			
Robitet (Robins)	250 mg.	11			
Robitet Syr. (Robins)	250 mg.	2			
Robitussin Syr. (Robins)		49			
Robitussin AC Syr. (Robins)		14			
Robitussin CF Syr. (Robins)		10			
Robitussin DM Syr. (Robins)		18			
Robitussin PE Syr. (Robins)		18			
Robitussin PG Syr. (Robins)		2			
Rondec Tab. (Ross)		22			
Rondec Syr. (Ross)		13			
Rondec Drops (Ross)		17			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Rondec DM Tab. (Ross)		2			
Rondec DM Syr. (Ross)		74			
Rondec DM Drops (Ross)		43			
Roniacol (Roche)		5			
Salicyclic Acid (GENERIC)			4		
Saline Sol.				2	
Salutensin (Bristol)		36			
Sandomed					2
Sandril (Lilly)	0.25 mg.	2			
Sanorex (Sandoz)	1 mg.	9			
	2 mg.	12			
Sebulex Shamp. (Westwood)		2			
Seconal (Lilly)	1/2 gr.	2			
	1-1/2 gr.	8			
Selsun Shamp. (Abbott)		18			
Senokot Granules (PF)		3			
Senokot Tab. (PF)		2			
Septra (BW)		11			
Septra DS (BW)		25			
Ser Ap Es (Ciba)		52			
Serax (Wyeth)	15 mg.	6			
	30 mg.	2			
Serentil (BI)	25 mg.	4			
Serpasil (Ciba)	0.25 mg.	8			
Serpasil/Apresoline No. 2 (Ciba)		3			
Serpasil/Esidrix No. 1 (Ciba)		10			
Serpasil/Esidrix No. 2 (Ciba)		5			
Sinemet (MSD)		4			
Sinequan (Pfizer)	25 mg.	13			
	50 mg.	8			
	75 mg.	6			
	100 mg.	12			
Singlet (Dow)		10			
Sinubid (W-C)		16			
Sinutab (W-C)		14			
Sinutab II (W-C)		4			
SK-65 Comp. (SKF)		16			
Slo-Phyllin Gyrocaps (Dooner)		2			
Sloughton's Cleocin					10
Slow K (Ciba)		19			
Sodium Bicarbonate (GENERIC)			3		
Sodium Fluoride (GENERIC)			19		
Sodium Fluoride Drops (GENERIC)			2		
Sodium Sulamyd Drops (Schering)		17			
Sodium Sulamyd Oint. (Schering)		5			
Soma (Wallace)		15			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Sorbitrate (Stuart)	5 mg.	4			
	10 mg.	5			
Sorbitrate Chews (Stuart)	5 mg.	2			
Spec T Lozenges		2			
Sporostacin Cream (Ortho)		2			
SSKI (Upsher-Smith)		5			
Stelazine (SKF)	2 mg.	3			
	5 mg.	10			
	10 mg.	11			
Sterane (Pfipharmecs)	5 mg.	8			
Sterazolidin (Geigy)		10			
Stero-Darvon/ASA (Lilly)		15			
Stilbestrol (GENERIC)	5 mg.		2		
Stoxil Opth. Oint. (SKF)		6			
Stresscaps (Lederle)		5			
Stresstabs (Lederle)		32			
Stuart Formula (Stuart)		2			
Stuartnatal 1+1 (Stuart)		13			
Sudafed (BW)	?	6			
	30 mg.	11			
	60 mg.	67			
Sudafed Syr. (BW)		17			
Sulfacet HC Lot. (Dermik)		2			
Sulfacet R Lot. (Dermik)		6			
Sulphacetamide Eye Drops (GENERIC)			12		
Sulphacetamide Eye Oint. (GENERIC)			2		
Sultrin (Ortho)		9			
Sultrin Cream (Ortho)		22			
Sumycin (Squibb)	250 mg.	3			
	500 mg.	2			
Surbex (Abbott)		3			
Surfak (Hoechst)		6			
Symmetrel (Endo)	100 mg.	3			
Synalar Cream (Syntex)		27			
Synalar Oint. (Syntex)		6			
Synalar Sol. (Syntex)		2			
Synthroid (Flint)	0.05 mg.	2			
	0.1 mg.	12			
	0.15 mg.	2			
	0.2 mg.	19			
	0.3 mg.	5			
Syntrogel (Block)		3			
Tabron (PD)		3			
Tacaryl Chews (Westwood)	3.6 mg.	3			
Tagamet (SKF)	300 mg.	23			
Talwin (Winthrop)	50 mg.	36			
Talwin Compound (Winthrop)		4			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Tandearil (Geigy)	100 mg.	2			
Tapazole (Lilly)	10 mg.	2			
Taractan (Roche)	100 mg.	3			
Tavist (Sandoz)	2.68 mg.	2			
Tedral (W-C)		16			
Tedral Elix. (W-C)		10			
Tedral Anti-H (W-C)		2			
Tedral SA (W-C)		7			
Tegopen (Bristol)	250 mg.	61			
	500 mg.	9			
Tegopen Susp. (Bristol)	?	2			
	125 mg.	9			
	250 mg.	3			
Tegretol (Geigy)	200 mg.	9			
Teldrin (SKF)	8 mg.	10			
	12 mg.	10			
Temaril (SKF)	?	3			
	2.5 mg.	8			
Temaril Spansule (SKF)		6			
Temaril Syr. (SKF)		3			
Tempra Drops (MJ)		10			
Tenuate (M-N)	25 mg.	8			
Tenuate Dospan (M-N)	75 mg.	83			
Tepanil Ten-Tab (Riker)	75 mg.	10			
Terbutaline (GENERIC)	2.5 mg.		2		
Terpin Hydrate Elix. (GENERIC)			4		
Terpin Hydrate w/Cod. (GENERIC)			6		
Terpin Hydrate w/Cod. Elix. (GENERIC)			47		
Terra Cortil Oint. (Pfizer)		2			
Terramycin Opth. Oint. (Pfizer)		2			
Terramycin Susp. (Pfizer)		4			
Tessalon (Endo)	100 mg.	2			
Testape (Lilly)		9			
Tetracycline (GENERIC)	250 mg.		301		
	500 mg.		53		
Tetracycline Susp. (GENERIC)	125 mg.		7		
	200 mg.		2		
	250 mg.		2		
Tetracyn (Pfipharmecs)	250 mg.	2			
Tetrex (Bristol)	250 mg.	5			
Tetrex Bidcaps (Bristol)	500 mg.	17			
Theolair (Riker)	?	3			
	125 mg.	10			
	250 mg.	8			
Theragran (Squibb)		2			
Theragran-M (Squibb)		4			
Thiordazine (GENERIC)	150 mg.		2[b]		

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Thorazine (SKF)	25 mg.	6			
	50 mg.	6			
	100 mg.	8			
	200 mg.	9			
Thymol in $CHCl_3$ (GENERIC)			2		
Thyroid (GENERIC)	?		2		
	1/4 gr.		4		
	1/2 gr.		12		
	1 gr.		36		
	2 gr.		7		
	3 gr.		3		
Thyroid, Ext.	?			2	
	1 gr.			2	
Tigan (Beecham)	250 mg.	22			
Tigan Supp. (Beecham)	?	3			
	200 mg.	19			
Tigan Ped. Supp. (Beecham)	100 mg.	29			
Tinactin Cream (Schering)		14			
Tinver Lotion (Barnes-Hind)		9			
Titralac (Riker)		3			
Tofranil (Geigy)	10 mg.	2			
	25 mg.	9			
	50 mg.	3			
Tofranil PM (Geigy)	75 mg.	3			
	150 mg.	2			
Tolectin (McNeil)		18			
Tolinase (Upjohn)	100 mg.	11			
	250 mg.	18			
Topicort Cream (Hoechst)		36			
Topsyn Gel (Syntex)		8			
Tranxene (Abbott)	3.75 mg.	35			
	7.5 mg.	36			
	15 mg.	9			
	22.5 mg.	6			
Tranxene SD (Abbott)	22.5 mg.	2			
Tranxene SD Half-Strength (Abbott)	11.25 mg.	4			
Triamcinolone Cream (GENERIC)			11		
Triaminic (Dorsey)		12			
Triaminic Expect. & Syr. (Dorsey)		29			
Triaminic Expect. w/Cod. (Dorsey)		45			
Triaminic Juvelets (Dorsey)		3			
Triaminic Ped. Drops (Dorsey)		3			
Triaminicol Syr. (Dorsey)		9			
Triamterene (GENERIC)			3[b]		

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Triavil (MSD)	2-10	7			
	2-25	8			
	4-25	4			
Tricofuran Supp. (Eaton)		3			
Tridesilone Cream (Dome)		3			
Trilafon (Schering)	2 mg.	3			
	8 mg.	6			
	16 mg.	5			
Trimosan Vag. Cream (Milex)		8			
Triniscon (Dista)		7			
Triple Sulfa Tab. (GENERIC)			2		
Triple Sulfa Susp. (GENERIC)			2		
Tri Vi Flor Chews (MJ)		10			
Tri Vi Flor Drops (MJ)		42			
Tuinal (Lilly)	1-1/2 gr.	2			
Turbinaire Spray (MSD)		3			
Tussend (Dow)		6			
Tussend Expect. (Dow)		10			
Tussionex (Pennwalt)		10			
Tussionex Liq. (Pennwalt)		17			
Tuss Ornade Spansule (SKF)		32			
Tuss Ornade Liq. (SKF)		3			
Tylenol (McNeil)		65			
Tylenol w/Cod. No. 2 (McNeil)		20			
Tylenol w/Cod. No. 3 (McNeil)		315			
Tylenol w/Cod. No. 4 (McNeil)		47			
Tylenol Extra Strength (McNeil)		10			
Tylenol Elix. (McNeil)		33			
Tylenol Drops (McNeil)		2			
Tylox (McNeil)		10			
Tyzine Drops (Pfizer)		6			
Unicap (Upjohn)		5			
Urecholine (MSD)	10 mg.	2			
	25 mg.	4			
Urised (Webcon)		7			
Urispass (SKF)		8			
Utibid (W-C)		4			
Uticort Gel (PD)		4			
Vagitrol Cream (Syntex)		2			
Vagitrol Supp. (Syntex)		3			
Valisone Cream (Schering)		69			
Valisone Lot. (Syntex)		6			
Valisone Oint. (Schering)		13			
Valisone Spray (Schering)		2			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Valium (Roche)	2 mg.	117			
	5 mg.	458			
	10 mg.	181			
Valmid (Dista)	500 mg.	3			
Vanceril Inhaler (Schering)		9			
Vanobid Oint. (M-N)		2			
Vanoxide Oint. (Dermik)		5			
Varidase (Lederle)		12			
Vascon A Opth. Sol. (SMP)		14			
Vasocidin Opth. Oint. (SMP)		5			
Vasocidin Opth. Sol. (SMP)		16			
Vasodilan (MJ)	10 mg.	12			
	20 mg.	5			
Vasodilan Liq. (MJ)		2			
Vaso-Sulf Eye Drops (SMP)		11			
V Cillin K (Lilly)	125 mg.	6			
	250 mg.	174			
	500 mg.	22			
V Cillin K Susp. (Lilly)	125 mg.	20			
	250 mg.	57			
V Cillin K Ped. Syr. (Lilly)		2			
Vectrin (PD)	50 mg.	2			
Verequad Susp. (Knoll)		2			
Vermox (Ortho)		26			
Versapen K (Bristol)	225 mg.	7			
Verstran (W-C)	10 mg.	7			
Vibramycin (Pfizer)	50 mg.	15			
	100 mg.	68			
Vi Daylin Chews (Ross)		2			
Vi Daylin ADC Drops (Ross)		20			
Vi Daylin F Chews (Ross)		30			
Vi Daylin F Drops (Ross)		82			
Vioform HC Cream & Oint. (Ciba)		51			
Vi Penta F Chews (Roche)		25			
Vi Penta F Drops (Roche)		7			
Vi Penta F Testabs (Roche)		2			
Vira-A Opth. Oint. (PD)		11			
Vistaril (Pfizer)	25 mg.	24			
	50 mg.	16			
	100 mg.	2			
Vistaril Susp. (Pfizer)		16			
Vitron C (Fisons)		10			
Vivactil (MSD)	10 mg.	3			
Volsol HC Otic Sol. (Wallace)		7			
Wyanoid Oint. (Wyeth)		2			
Wyanoid HC Supp. (Wyeth)		5			

Name (Manufacturer)[a]	Strength	Number of Prescriptions			
		Brand Name	Generic Name	Nongeneric Multiple-Source	Unknown
Wygesic (Wyeth)		21			
Xylocaine Jelly (Astra)		7			
Xylocaine Viscuous (Astra)		3			
Zactirin (Wyeth)		12			
Zaroxolyn (Pennwalt)	2.5 mg.	5			
	5 mg.	6			
Zinc Sulfate (GENERIC)	200 mg.		2		
Zorane (Lederle)	1/50	6			
	1.5/30	8			
Zyloprim (BW)	100 mg.	76			
	300 mg.	81			
Total		18,875*	2,550*	61*	23*

Other drugs for which there was only one prescription during the time of the survey: Aarane Inhaler (Syntex); Acetaminophen (GENERIC), 5 gr.; Achromycin V Susp. (Lederle), 250 mg.; Acid Mantle Cream (Dorsey); Acnestrol Lotion (Dermik); Acnomel (SKF); Actifed Syr. w/Ambenyl (BW); Adenosine & Vit. B_{12} (Nongeneric Multiple Source), 2.5 mg.; Adrenalin Chloride Sol. (GENERIC); Airet GG (Baylor); Alpha Redisol (MSD); Aludrox Tab. (Wyeth); Aludrox Liq. (Wyeth); Aminophylline Supp. (GENERIC), 250 mg.; Amitriptylline (GENERIC), 25 mg., 50 mg. and 100 mg.; Amoxicillin Drops (GENERIC), 75 mg.; Amphojel (Wyeth); Ampicillin (GENERIC), ? and 125 mg.; Ampicillin Susp. (GENERIC), 500 mg.; Ampicillin + Probenecid (GENERIC); Amyl Nitrate (GENERIC); Anacin Arthritis Form (Whitehall); Ana-Kit (Hollister-Stier); Anamine (Mayrand), 50 mg.; Ananase (Rorer), 50 mg.; Anspor (SKF), 500 mg.; Antivert (Roerig), ?; Anugesic Oint. (W-C); Apresazide (Ciba), 25 mg. and 50 mg.; Apresoline (Ciba), ? and 100 mg.; Apresoline Esidrex (Ciba); Aristocort Tab. (Lederle), 1 mg.; Arlidin (USV), 12 mg.; Armour Thyroid (Armour), 1 gr. and 3 gr.; ASA (Lilly), 10 gr.; Ascodeen-30 (BW); Aspirin (GENERIC), 5 gr. and 10 gr. (EC); Atarax (Roerig), ? and 100 mg.; B_1, Vitamin (Nongeneric Multiple Source), 50 mg.; Beminal Forte w/Vit. C (Ayerst); Benadryl (PD), ?; Benadryl/Marax Liq. (PD); Benadryl/Terramycin Liq. (PD); Bendroflumethiazide (GENERIC), 5 mg.;[b] Benoquin Lot. (Elder); Bentyl w/Phenobarbital (M-N), ?; Bentyl w/Phenobarbital Elix. (M-N); Betadine Oint. (PF); Betadine Skin Cleanser (PF); Betamethasone Cream (GENERIC); Bicarbonate (Unknown); Biozyme Lot. (Armour); Bluboro (Derm-Arts); Bricaryl (Astra), 5 mg.; Bronkodyl (Breon), 200 mg.; Bufferin (Bristol Myers); Burow's Sol. (Halsey); Butabarbital (GENERIC), 1/2 gr.; Butisol Sodium (McNeil), 8 mg. and 1-1/2 gr.; Cafergot Supp. (Sandoz); Cafergot PB Supp. (Sandoz); Cantil w/Phenobarbital (Lakeside); Carbenicillin (GENERIC), 328 mg.; Cartrax (Roerig), 20 mg.; Cascara (Lilly); Catapress (BI), 0.2 mg.; Cetaphil Lot. (Texas Pharm.); Cheracol D Syr. (Upjohn); Chlordiazepoxide (GENERIC), 25 mg.; Chloromycetin (PD), 200 mg. and 500 mg.; Chloromycetin Otic (PD); Chloroseptic Mouthwash (Eaton); Chloroseptic Troches (Eaton); Chloroseptic Opth. Drops (Eaton); Chlorothiazide (GENERIC),

250 mg.; Chlorpheniramine Maleate (GENERIC), 8 mg.; Chlorpromazine (GENERIC), 200 mg.; Chlor Trimeton/Sudafed (Schering); Choledyl (W-C), ?; Cleocin/Sulfacet Lot. (Upjohn); Clistin (McNeil), ?; Clomiphene Citrate (GENERIC), 50 mg.[b]; Clomipramine (Geigy), 50 mg.; Clonopin (Roche), 2 mg and 5 mg.; Cloxacillin Liq. (GENERIC); Cloxacillin Drops (GENERIC); Codeine (GENERIC), 1/2 gr.; Cogentin (MSD), 0.5 mg.; Colace (MJ), 200 mg.; Colchicine Syr. (GENERIC); Combipress (BI), ?; Compazine Inj. (SKF); Compazine Supp. (SKF), 50 mg.; Compocillin VK (Ross), 500 mg.; Compocillin VK Liq. (Ross), 500 mg.; Co-Pyronil Susp. w/Brondecon (Dista); Coricidin Demilets (Schering); Coriforte (Schering); Coryban D (Roerig); CVP (USV); Cyclopar (PD), 250 mg.; Cylert (Abbott), 37.5 mg.; Cytomel (SKF), 5 mg.; D_2, Vitamin (Nongeneric Multiple Source); Dantrium (Eaton), 25 mg.; Darvon N (Lilly), 50 mg.; Datril (Bristol Myers); DBI (Geigy), 25 mg. and 50 mg.; Decadron (MSD), 0.75 mg.; Declomycin HCl (Lederle), 300 mg.; Declomycin Syr. (Lederle); Declostatin (Lederle); Deconamine Syr. (SMP); Delcid (M-N); Delfen Foam (Ortho); Delfen Cream (Ortho); Deltasone (Upjohn), 20 mg.; Demerol (Winthrop), 100 mg.; Dermatol (Nongeneric Multiple Source); Desipramine (GENERIC), 50 mg.; Desitin Cream (Leeming); Desoxyn Gradumets (Abbott), 10 mg.; Dexamyl (SKF), 0.5 mg.; Dexedrine (SKF), 5 mg.; Diamox (Lederle), 125 mg.; Dienestrol (GENERIC), ?, 25 mg. and 100 mg.; Diethylstilbestrol (GENERIC), 0.5 mg.; Digitoxin (GENERIC), 0.05 mg. and 0.2 mg.; Digolase (Boyle); Digoxin (GENERIC), ? and 0.5 mg.; Diprosone Lot. (Schering); Disolans (Lannett); Dolene 65 (Lederle); Donnagel PG Ped. Drops (Robins); Doxepin (GENERIC), 10 mg.; Dramamine Liq. (Searle); Duohaler (Riker); Dyrenium (SKF), ?; Edecrin (MSD), 50 mg. and 250 mg.; EES (Abbott), 250 mg.; EES Liq. (Abbott), 250 mg.; EES Drops (Abbott), 100 mg.; EES Granules (Abbott), 200 mg.; Elavil (MSD), 100 mg.; Enarex (Roerig), 10 mg.; Enovid (Searle), 5 mg. and 10 mg.; Ensure Liq. (Ross); Entozyme (Robins); Ephedrine Opth. Sol. (GENERIC); Ephedrine Sulfate (GENERIC); Ephedrine/Orthoxical Susp.; Epinal Drops (Alcon); Epragen (Lilly); Ergophene Oint. (Upjohn); Erythrocin Ethyl Succinate (Abbott), 200 mg. and 400 mg.; Erythrocin Ethyl Succinate Chews (Abbott), 300 mg.; Erythrocin Ethyl Succinate Susp. (Abbott), 400 mg.; Erythrocin Stearate (Abbott), 125 mg. and 250 mg.; Erythrocin Susp. (Abbott), 250 mg.; Erythromycin Chews (GENERIC), 200 mg.; Erythromycin Opth. Oint. (GENERIC); Erythromycin Susp. (GENERIC), 125 mg.; Erythromycin Ethyl Succinate (GENERIC), 200 mg. and 400 mg.; Estomul-M (Riker); Etrafon (Schering), 4-10; Euthroid (W-C), ?; Eye Patches (Nongeneric Multiple Source); Expectran DM Expect. (G.S. Herbert); Fenoprofen (Lilly), 500 mg.; Feosol Plus (SKF); Fer-in-Sol (MJ); Ferrous Gluconate (GENERIC); Ferrous Sulfate (GENERIC), ?; $FeSO_4$, ?, 4 gr. and 10 gr.; Filibon (Lederle); Flumethasone (GENERIC), 10 mg.;[b] Fluoride Gel (GENERIC); Flurazepam (GENERIC);[b] Flurobate Gel (Texas Pharm.); Formatrix (Ayerst); Fostex Cream (Westwood); Fulvicin (Schering), 125 mg.; Furacin Oint. (Eaton); Furantoin Susp. (N. Am. Pharm.); Gantanol DS (Roche); Gantrisin Opth. Oint. (Roche); Gantrisin Vag. Cream (Roche); Gelusil (W-C); Grifulvin V (McNeil), 25 mg. and 50 mg.; Grisactin (Ayerst), 250 mg. and 500 mg.; Griseofulvin (GENERIC), 250 mg.; Griseofulvin Liq. (GENERIC), 125 mg.; Gris-Peg (Dorsey), 250 mg.; Haloperidol (GENERIC), 5 mg.[b] and 10 mg.;[b] Halotestin (Upjohn), 5 mg.; Harmonyl (Abbott), 0.1 mg.; Heptuna Plus (Roerig); Hycodan (Endo); Hydralazine (GENERIC), 10 mg., 50 mg. and 100 mg.; Hydrochlorothiazide Liq. (GENERIC), 50 mg.; Hydrocortisone (GENERIC), 5 mg. and 20 mg.; Hydrocortisone Cream w/Alcohol (GENERIC); Hydrocortisone Lot. (GENERIC); Hydrodiuril (MSD), ?; Hydroquinine (GENERIC); Hydroxyzine (GENERIC), 10 mg.; Iberet-500 Liq. (Abbott); Iberol (Abbott); Ichthammol Oint. (GENERIC); Ilonomycin (Unknown); Ilosone Drops (Dista); Imavate (Robins), 50 mg.; Imipramine (GENERIC), 10 mg. and 25 mg.; Incremin Liq. (Lederle); Indomethacin (GENERIC), 25 mg.[b] and 50 mg.;[b] Ionax Swabs (Owen); Iosel Shamp. (Owen); Ircon FA (Key); Isoniazid (GENERIC), 300 mg.; Isoprophyl Alcohol (GENERIC); Isoptofrin Sol. (Alcon); Isordil (Ives), ?; Kaochlor (Warren-Teed); Keflin (Lilly), 250 mg.; Keflex (Lilly), 125 mg.; Kemadrin (BW); Kolantyl Gel (M-N);

Lactinex (Hynson, Westcott & Dunning); Lanamins (Lannett); Lanoxin (BW), 0.5 mg.; Lanoxin Elix. (BW), 0.05 mg.; Larobec (Roche); Larodopa (Roche), 250 mg.; Larotid (Roche), 125 mg. and 500 mg.; Larotid Ped. Susp. (Roche); Lasix Liq. (Hoechst); Lavoris + NaF (Vick); Laxinate Liq. (Mallard); LCN (Unknown), 250 mg.; Ledercillin VK (Lederle), 125 mg.; Levodopa (GENERIC), 250 mg. and 500 mg.; Levothyroxine (GENERIC), 0.1 mg.; Librax Syr. (Roche); Librium (Roche), ?; Liniment Menthyl Salicyclic (Unknown); Liotrix (GENERIC), 250 mg.; Lipoflavanoid (SMP); Liquefilm Forte #2 (Allergan); LiVitamin Chews (Beecham); Lotrimin Oint. (Delbay); L-Thyroxine (GENERIC), 0.3 mg.;[b] Lubriderm Lot. (Texas Pharm.); Lufa (USV); Maalox Plus (Rorer); Maltsupex (Wallace); Marax DF Syr. w/Benylin (Roerig); Maxafil Cream (Texas Pharm.); Meclizine (GENERIC), 12.5 mg. and 25 mg.; Medihaler (Riker); Medrol (Upjohn), 8 mg. and 32 mg.; Mellaril (Sandoz), ?; Mentholin Sol. (Apco); Metandren (Ciba), 5 mg.; Metaprel (Dorsey), 10 mg.; Metaprel Supp. (Dorsey); Metaproternol Syr. (GENERIC); Methergine (Sandoz), 0.2 mg.; Methyldopa (GENERIC), 500 mg.;[b] Methylene Blue (GENERIC), 65 mg.; Methyl Testosterone (GENERIC), 10 mg.; Metimyd Eye Oint. (Schering); Miltown (Wallace), 200 mg.; Mineral Oil (GENERIC); Minocycline (GENERIC), 50 mg. and 100 mg.; Moban (Endo), 10 mg.; Monistat (Ortho), 1/150 gr.; Mucomyst (MJ); Multicebrin (Lilly); Multiple Vits. w/Fluoride Chews (Nongeneric Multiple Source); Myambutol (Lederle), 400 mg.; Mycolog/Tinactin Cream (Squibb); Mycostatin Mouthwash (Squibb); Mycostatin Drops (Squibb); Mycostatin Powder (Squibb); Mycostatin/Aristocort Cream; Myleran (BW), 2 mg.; Mysoline (Ayerst), 50 mg.; NaCl Opth. Sol. (Nongeneric Multiple Source); Nacton (McNeil), 4 mg.; Naldetuss Syr. (Bristol); Naproxen (GENERIC), 250 mg.;[b] Natafort (PD); Natalins (MJ); Navane (Roerig), 2 mg. and 20 mg.; Neg Gram (Winthrop), 500 mg.; Nembu Donna (Abbott), 1/2 gr.; Neocortef Oint. (Upjohn); Neocortisporin Oint. (Unknown); Neodacadron Elix. (MSD); Neoloid Liq. (Lederle); Neomedrol Cream (Upjohn); Neomycin Tab. (GENERIC); Neosporin Gel (BW); Neosporin Powder (BW); Neosporin Susp. (BW); Neosporin Spray (BW); Neosynephrine Jel (Winthrop); Neptazone (Lederle), 50 mg.; Nilstat Cream (Lederle); Nilstat/Aristocort Cream (Lederle); Nitroglycerin (GENERIC), 0.4 mg., 0.6 mg. and 1/400 gr.; Nitrostat (PD), 0.4 mg. and 1/200 gr.; Norinyl (Syntex), 2 mg.; Norinyl (Syntex), 1/80-?; Norpace (Searle); Novacebrin F Chews (Lilly); Novahistine w/Cod. (Dow); Novahistine w/Cod. Expect. (Dow); Novrad (Lilly), 100 mg.; NTZ Nasal Spray (Winthrop); Ocean Spray (Fleming); Optilet M (Abbott); Orabase/Benzocaine; Oreticyl (Abbott), 50 mg.; Orisul (Ciba); Ornacol Liq. (SKF); Orthine (Winsole), 5 mg.; Ortho-Novum 10 (Ortho); Ortho-Novum (Ortho), 1/50-? and 1/80-?; Orthoxical (Upjohn); Oxaine-M (Wyeth); Oxsoralen (Elder), 10 mg.; Oxymetazoline Sol. (GENERIC); Oxymethalone (GENERIC), 50 mg.; PBZ-SR (Ciba), 100 mg.; P_1E_1 Drops (Carnrick); P_6E_1 Drops (Carnrick); Pediatric Susp. (Nongeneric Multiple Source); Penicillin (GENERIC), 125 mg. and 500 mg.; Penicillin G (GENERIC), 800,000 u.; Penicillin V (GENERIC), 400,000 u.; Penicillin V Susp. (GENERIC), 250 mg.; Penicillin V Ped. Susp. (GENERIC); Pen-Vee-K (Wyeth), 125 mg.; Penta-Tal (Kenyon), 10 mg.; Pentazocine (GENERIC), 50 mg.;[b] Pentids 800 (Squibb); Pentrax Shamp. (Texas Pharm.); Periactin Ped. Drops (MSD); Peri Michel Tape Roll; Perphenazine (GENERIC), 16 mg.; Personaphen Lot. (Person & Covey); Phenergan w/Cod. No. 2 (Wyeth); Phenergan Supp. (Wyeth), 12.5 mg.; Phenobarbital (GENERIC), 1-1/2 gr.; Phenol (GENERIC), 0.6 mg.; Phenoxymethyl Penicillin (GENERIC), 250 mg. and 500 mg.; Phenoxymethyl Pen. Susp. (GENERIC); Phenoxymethyl Pot. Pen. Susp. (GENERIC), 250 mg.; Phospholine Iodide Eye Drops (Ayerst); Placidyl (Abbott), 250 mg.; Plaquenil (Winthrop), 200 mg.; Plegine (Ayerst); Polycillin Chews (Bristol); Polycillin Ped. Drops (Bristol); Polycillin w/Iron Susp. (Bristol); Polymox (Bristol), 500 mg.; Polymox Susp. (Bristol), ?; Polysporin Opth. Oint. (BW); Pramocon (Ross); Prazosin (GENERIC), 1 mg.;[b] Pred Mild Sol. (Allergan); Prednisone (GENERIC), 20 mg.; Pre-Sun Sunscreen (Westwood); Primatene Mist (Whitehall); Pro

Banthine/Dartol (Searle), 15 mg.; Probarbital (GENERIC);[b] Probital (Searle); Prolixin (Squibb), 2.5 mg.; Prolixin Drops (Squibb); Proloid (W-C), ?, 1/2 gr., 3 gr. and 5 gr.; Pronestyl (Squibb), 375 mg.; Propanolol (GENERIC), 20 mg.;[b] Propoxyphene (GENERIC), 65 mg.; Prostaphlin (Bristol), 500 mg.; Prostigimin (Roche), 15 mg.; Provera (Upjohn), 2.5 mg.; Prozyde (Tracy), PV Carpine Sol. (Allergan); Pyocidin Otic Sol. (SMP); Pyraldine (Mallinckroft), 6 gr.; Pyribenzamine Expect. w/Cod. (Ciba), 250 mg.; Pyridium (W-C), ?; Quadrinal Susp. (Knoll); Quiebel (Nevin); Quinidine (GENERIC), 5 gr.; Quinine (GENERIC), 5 gr.; Quotane Oint. (SKF); Raused (Squibb), 0.25 mg.; Renese (Pfizer), 2 mg.; Retin A Swabs (J&J); Rhuligel (Lederle); Robicillin VK Susp. (Robins), 125 mg.; Robinul (Robins); Robinul Forte (Robins), 2 mg.; Rondec Chews (Ross); Sanorex (Sandoz), ?; Sansert (Sandoz); Scope + NaF Liq. (Proctor & Gamble); Sebizon Lot. (Schering); Sedadrops (M-N); Selsun Blue Shamp. (Abbott); Serax (Wyeth), ? and 10 mg.; Serpasil (Ciba), 0.1 mg.; Serpasil/Apresoline No. 1 (Ciba); Simethicone (GENERIC), 80 mg.; Sinequan (Pfizer), ? and 150 mg.; Sinubid w/Cod. (W-C); SK Estrogens (SKF), 1.25 mg.; Slo-Phyllin (Dooner), 100 mg., 125 mg. and 250 mg.; Sodium Chloride (GENERIC); Sorbitrate (Stuart), ?; Sorbitrate Sublingual (Stuart), 2.5 mg.; Sparine (Wyeth), 25 mg.; Spironolactone (GENERIC), 25 mg.;[b] Stelazine (SKF), ?; Sterile Gauze (Nongeneric Multiple Source); Stilbestrol (GENERIC), 25 mg.; Stratrol Opth. Sol. (Alcon); Stuartinic (Stuart); Stuart Pre-natal Vits. (Stuart); Sulframol Cream (Mylex); Sulfisoxazole (GENERIC), 0.5 mg.; Suprel Mistometer (Unknown); Synalar G Cream (Syntex); Syntamine (Intern. Chem.); Tacaryl (Westwood), 8 mg.; TAC Sol. (Vita Fore); TAD (Unknown), 250 mg.; Talwin Sol. (Winthrop); TAO (Roerig), 250 mg.; Tapazole (Lilly), 5 mg.; Tears Naturale (Alcon); Tegopen (Bristol), ?; Telfa Pads; Tempra Syr. (MJ); Tenuate (M-N), ?; Tepanil (Riker), 25 mg.; Terbutaline (GENERIC), 5 mg.; Terramycin Vag. Supp. (Pfizer); Terrastatin (Pfizer), 250 mg.; Tetracycline (GENERIC), 125 mg.; Thalfed (Beecham); Theonar (Key), 125 mg.; Theophylline (GENERIC), 200 mg.; Theragran-M Liq. (Squibb); Thiamine (GENERIC), 25 mg.; Thorazine (SKF), ? and 10 mg.; Thorazine Syr. (SKF); Thyroid (GENERIC), 4 gr.; Thyroid, Dessicated (Nongeneric Multiple Source), 1 gr. and 2 gr.; Thyroid, Ext. (Nongeneric Multiple Source), 1/2 gr.; Tinactin Sol. (Schering); Tolinase (Upjohn), ? and 500 mg.; Trancopol (Winthrop), 100 mg. and 200 mg.; Triavil (MSD), 4-10; Trilafon (Schering), 4 mg.; Trilafon Repetabs (Schering), 8 mg.; Trimosan Vag. Jel (Milex); Trisoralen (Elder), 5 mg.; Tronothane Cream (Abbott); Tucks Pads (Fuller); Tuinal (Lilly), 1/2 gr.; Tylenol w/Cod. Elix. (McNeil); Unicap M (Upjohn); Urecholine (MSD), 5 mg.; Urestrin (Upjohn), 1.0 mg.; Vallestril (Searle), 3 mg. and 20 mg.; Vanobid Vag. Tab. (M-N); V Cillin K Drops (Lilly); Vectrin (PD), 100 mg.; Velosef (Squibb), 250 mg.; Versapen Susp. (Bristol); Vibramycin (Pfizer), ?; Vi Daylin Drops (Ross); Vi Daylin F Drops w/Iron (Ross); Visine Drops (Leeming/Pacquin); Vistaril Sol. (Pfizer); Vistrax (Pfizer), 5 mg.; Whitfield's Oint. (Haberle); Winstrol (Winthrop), 2 mg.; Xylocaine Oint. (Astra); Xylocaine Supp. (Astra); Zestabs w/F (Block); Zetar Lot. (Dermik); Zinc Gluconate (GENERIC), 100 mg.; and Zinc Sulfate (GENERIC), 220 mg.

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*Totals include those drugs for which there was only one prescription during the term of the survey.

a. Initials are used to denote certain manufacturers:

BI = Boehringer Ingelheim
BW = Burroughs Wellcome
J&J = Johnson & Johnson
MJ = Mead Johnson

M-N = Merrell-National
MSD = Merck, Sharp & Dohme
PD = Parke, Davis
PF = Purdue Frederick
SKF = Smith, Kline & French
SMP = Smith, Miller, & Patch
W-C = Warner-Chilcott

b. These drug products, although prescribed generically, are available from only one source.

Appendix D

SURVEY 2

Table I

PRICE COMPARISONS BETWEEN ACHROMYCIN V AND TETRACYCLINE HCl
(250 mg., 20 Capsules)

Manufactured by Lederle Labs

Store No.	Type[a]	Price Achromycin V	Price Equivalent	Manufacturer	Difference
1	A	$1.75	--	--	--
2	A	1.75	--	--	--
3	A	1.75	--	--	--
4	A	1.75	--	--	--
5	A	1.75	--	--	--
6	A	1.75	--	--	--
7	A	1.75	--	--	--
8	A	1.75	--	--	--
9	A	1.75	$1.75	SKF[b]	$0.00
10	B	1.75	--	--	--
11	B	2.00	2.00	Wyeth	0.00
12	B	2.02	1.89	Wyeth	0.13
13	B	2.75	2.50	SKF	0.25
14	B	2.85	2.85	Robins	0.00
15	B	1.75	1.75	Robins	0.00
16	B	1.95	1.89	Wyeth	0.06
17	B	2.55	2.25	Wyeth	0.30
18	B	2.00	2.00	Parke, Davis	0.00
19	B	--	2.50	Squibb	--
20	B	1.75	1.75	Parke, Davis	0.00
21	B	1.95	1.75	Robins	0.20
22	B	4.75	3.75	Squibb	1.00
23	B	1.75	1.75	SKF	0.00
24	B	--	3.75	Parke, Davis	--
25	C	--	1.75	Squibb	--
26	C	1.75	1.75	SKF	0.00
27	C	1.75	1.75	Parke, Davis	0.00
28	C	1.85	--	--	--
29	C	--	2.00	Parke, Davis	--
30	C	2.50	--	--	--
31	C	1.40	1.00	SKF	0.40
32	C	1.75	1.75	Parke, Davis	0.00
33	C	2.25	1.75	Schein	0.50
34	C	1.75	1.75	Parke, Davis	0.00
35	C	--	2.00	Squibb	--
36	C	1.50	1.50	McKesson	0.00

Table 1 (continued)

Store No.	Type[a]	Price Achromycin V	Price Equivalent	Manufacturer	Difference
37	C	1.50	1.50	McKesson	0.00
38	C	2.00	1.50	SKF	0.50
39	C	1.75	1.75	Parke, Davis	0.00
40	C	1.50	1.25	Parke, Davis	0.50
41	--	1.75	0.06[c] per	Lederle	--
Mean		$1.97 (36)	$1.98 (29)		$0.16 (24)
Median		1.75	1.75		0.00
Mode		1.75	1.75		0.00
Range		4.75 to 1.40	3.75 to 1.00		1.00 to 0.00

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company of ownership.

b. Smith, Kline & French.

c. Was not used to determine mean, median, or mode.

Table 2

PRICE COMPARISONS BETWEEN POLYCILLIN AND AMPICILLIN
(250 mg., 20 Capsules)

Manufactured by Bristol Laboratories

Store No.	Type[a]	Price Polycillin	Price Equivalent	Manufacturer	Difference
1	A	$6.10	$2.35	Beecham	$3.75
2	A	6.10	2.35	Beecham	3.75
3	A	6.10	2.35	Wyeth	3.75
4	A	6.10	2.35	Wyeth	3.75
5	A	6.10	2.35	Beecham	3.75
6	A	5.30	2.40	Beecham	2.90
7	A	6.10	2.35	Wyeth	3.75
8	A	6.10	2.35	Wyeth	3.75
9	A	--	2.00	Wyeth	--
10	B	--	3.60	Wyeth	--
11	B	4.25	4.25	Wyeth	0.00
12	B	5.87	2.86	Wyeth	3.01
13	B	6.50	3.85	SKF[b]	2.65
14	B	7.00	5.00	Parke, Davis	2.00
15	B	6.40	2.60	Parke, Davis	3.80
16	B	5.17	2.86	Wyeth	2.31
17	B	--	4.25	Wyeth	--
18	B	7.00	4.00	SKF	3.00
19	B	--	2.95	SKF	--
20	B	5.40	2.00	Wyeth	3.40
21	B	4.00	3.20	Wyeth	0.80
22	B	4.75	3.75	Squibb	1.00
23	B	5.20	2.40	SKF	2.80
24	B	--	4.75	Squibb	--
25	C	--	3.15	Squibb	--
26	C	6.20	2.00	SKF	4.20
27	C	--	4.00	Squibb	--
28	C	6.40	4.00	Beecham	2.40
29	C	--	3.70	Parke, Davis	--
30	C	6.95	3.85	Wyeth	3.10
31	C	5.70	1.75	SKF	3.95
32	C	6.60	4.00	Parke, Davis	2.60
33	C	6.25	3.25	Robins	3.00
34	C	6.45	2.90	Squibb	3.55
35	C	--	2.00	Squibb	--
36	C	6.00	3.00	Squibb	3.00
37	C	5.60	2.40	SKF	3.20
38	C	6.00	3.00	SKF	3.00
39	C	--	1.75	Lederle	--
40	C	5.00	3.00	Squibb	2.00
41	--	5.40	0.15[c] per	Wyeth	--

Table 2 (continued)

Store No.	Type[a]	Price Polycillin	Price Equivalent	Manufacturer	Difference
Mean		$5.87 (31)	$3.02 (40)		$3.03 (29)
Median		6.10	2.925		3.01
Mode		6.10	2.35		3.75
Range		7.00 to 4.00	5.00 to 1.75		4.20 to 0.80

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company of ownership.

b. Smith, Kline & French.

c. Was not used to determine mean, median, or mode.

Table 3

PRICE COMPARISONS BETWEEN ERYTHROCIN STEARATE AND ERYTHROMYCIN STEARATE
(250 mg., 20 Tablets)

Manufactured by Abbott Laboratories

Store No.	Type[a]	Price Erythrocin	Price Equivalent	Manufacturer	Difference
1	A	$4.05	$2.70	"SR"	$1.35
2	A	4.50	3.60	Wyeth	0.90
3	A	4.50	3.60	Squibb	0.90
4	A	4.05	2.75[b]	(Abbott)	--
5	A	4.05	3.60	Wyeth	0.45
6	A	4.40	2.95	Lederle	1.45
7	A	4.05	3.35	Lederle	0.70
8	A	4.05	3.60	Wyeth	0.45
9	A	4.20	2.30	Lederle	0.90
10	B	4.00	--	--	--
11	B	4.00	3.95	SKF[c]	0.05
12	B	4.89	2.86	Wyeth	2.03
13	B	5.50	4.25	SKF	1.25
14	B	7.40	--	--	--
15	B	4.60	3.60	SKF	1.00
16	B	4.40	2.86	Wyeth	1.54
17	B	5.65	4.00	Wyeth	1.65
18	B	4.00	4.00	Parke, Davis	0.00
19	B	5.25	3.35	SKF	1.90
20	B	4.00	--	--	--
21	B	3.20	3.20	Wyeth	0.00
22	B	4.75	3.75[b]	(Abbott)	--
23	B	3.60	--	--	--
24	B	4.75	--	--	--
25	C	0.25[d] per	5.15[e]	(Abbott)	--
26	C	4.30	2.60	Lederle	1.70
27	C	4.20	--	--	--
28	C	3.35	--	--	--
29	C	4.95	3.95	Parke, Davis	1.00
30	C	4.00	3.85	Wyeth	0.15
31	C	3.30	2.15	Parke, Davis	1.15
32	C	6.00	4.20	Parke, Davis	1.80
33	C	4.00	3.25	Parke, Davis	0.75
34	C	4.45	3.60	Parke, Davis	0.85
35	C	--	5.20[e]	(Abbott)	--
36	C	3.00	--	--	--
37	C	4.00	--	--	--
38	C	4.50	3.00	SKF	1.50
39	C	3.70	--	--	--
40	C	4.00	--	--	--
41	--	3.65	0.18[d] per	(Abbott)	--

Table 3 (continued)

Store No.	Type[a]	Price Erythrocin	Price Equivalent	Manufacturer	Difference
Mean		$4.34 (39)	$3.38 (25)		$1.02 (25)
Median		4.05	3.60		1.00
Mode		4.00	3.60		0.90
Range		7.40 to 3.00	4.25 to 2.15		2.03 to 0.00

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company of ownership.

b. These pharmacies listed Abbott as the manufacturer of the chemical equivalent. Abbott is the manufacturer of Erythrocin. The price listed for the chemical equivalent, however, was lower although the manufacturer of both are the same. The price listed was not used to determine the mean, median, or mode.

c. Smith, Kline & French.

d. Was not used to determine the mean, median, or mode.

e. This pharmacy listed Abbott as the manufacturer of the chemical equivalent. Abbott is the manufacturer of Erythrocin. The price listed was not used to determine the mean, median, or mode.

Table 4

PRICE COMPARISONS BETWEEN V-CILLIN K AND PENICILLIN V POTASSIUM
(250 mg., 20 Tablets)

Manufactured by Eli Lilly and Co.

Store No.	Type[a]	Price V-Cillin K	Price Equivalent	Manufacturer	Difference
1	A	$3.05	$2.30	Lederle	$0.75
2	A	3.05	2.30	Lederle	0.75
3	A	3.05	2.30	Lederle	0.75
4	A	3.05	2.30	Lederle	0.75
5	A	3.05	2.30	Lederle	0.75
6	A	3.05	2.40	Lederle	0.65
7	A	3.05	2.30	Lederle	0.75
8	A	3.05	2.30	Lederle	0.75
9	A	3.30	2.30	Lederle	1.00
10	B	3.20	2.40	Wyeth	0.80
11	B	3.00	3.00	Lederle	0.00
12	B	3.63	3.42	Wyeth	0.21
13	B	4.05	2.75	SKF[b]	1.30
14	B	5.35	--	--	--
15	B	3.20	2.40	SKF	0.80
16	B	3.63	2.51	Wyeth	1.11
17	B	3.95	3.95	Wyeth	0.00
18	B	4.00	3.00	Parke, Davis	1.00
19	B	3.95	2.75	SKF	1.20
20	B	2.60	2.00	Lederle	0.60
21	B	2.60	1.75	Wyeth	0.85
22	B	4.75	3.75	Squibb	1.00
23	B	2.00	--	--	--
24	B	4.75	3.75[d]	Parke, Davis	1.00
25	C	0.15[c] per	3.15[d]	(Lilly)	--
26	C	3.00	1.90	SKF	1.10
27	C	3.80	2.60	Squibb	1.20
28	C	3.10	--	--	--
29	C	3.75	2.75	Parke, Davis	1.00
30	C	4.00	3.25	Robins	0.75
31	C	2.75	--	--	--
32	C	3.30	2.10	Parke, Davis	1.20
33	C	3.50	1.75	Schein	1.75
34	C	3.35	2.55	Squibb	0.80
35	C	--	3.65[d]	(Lilly)	--
36	C	3.00	--	--	--
37	C	3.00	2.40	Lederle	0.60
38	C	3.00	--	--	--
39	C	2.90	1.75	Squibb	1.15
40	C	2.60	1.80	Squibb	0.80
41	--	3.20	0.16[c] per	(Lilly)	--

Table 4 (continued)

Store No.	Type[a]	Price V-Cillin K	Price Equivalent	Manufacturer	Difference
Mean		$3.35 (39)	$2.53 (32)		$0.85 (32)
Median		3.10	2.40		0.80
Mode		3.05	2.30		0.75
Range		5.35 to 2.00	3.95 to 1.75		1.75 to 0.00

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. Smith, Kline & French.

c. Was not used to determine the mean, median, or mode.

d. This pharmacy listed Lilly as the manufacturer of the chemical equivalent. Lilly is also the manufacturer of V-Cillin K. The price was not used to determine the mean, median, or mode.

Table 5

PRICE COMPARISONS BETWEEN TYLENOL COMPOUND NO. 3 AND ACETAMINOPHEN + CODEINE PHOSPHATE (12 Tablets)

Manufactured by McNeil Laboratories, Inc.

Store No.	Type[a]	Price Tylenol #3	Price Equivalent	Manufacturer	Difference
1	A	$2.30	--	--	--
2	A	2.30	$2.20	BW[b]	$0.10
3	A	2.45	2.25	BW	0.20
4	A	2.45	2.20	BW	0.25
5	A	2.30	2.25	BW	0.05
6	A	2.30	--	--	--
7	A	2.30	--	--	--
8	A	2.30	--	--	--
9	A	2.55	--	--	--
10	B	2.20	1.75	BW	0.45
11	B	2.50	--	--	--
12	B	2.55	2.50	BW	0.05
13	B	2.95	--	--	--
14	B	3.50	--	--	--
15	B	2.30	1.80	Robins	0.50
16	B	2.79	--	--	--
17	B	3.10	--	--	--
18	B	2.00	2.00	BW	0.00
19	B	2.95	--	--	--
20	B	1.80	--	--	--
21	B	1.95	--	--	--
22	B	2.40	--	--	--
23	B	1.95	--	--	--
24	B	3.00	--	--	--
25	C	2.10	--	--	--
26	C	1.95	1.75	BW	0.20
27	C	2.60	--	--	--
28	C	2.10	--	--	--
29	C	2.35	--	--	--
30	C	3.10	2.80	BW	0.30
31	C	1.65	--	--	--
32	C	2.00	1.75	BW	0.25
33	C	2.25	--	--	--
34	C	2.25	--	--	--
35	C	--	2.50[c]	(McNeil)	--
36	C	1.75	1.50[d]	(McNeil)	--
37	C	2.50	--	--	--
38	C	2.50	--	--	--
39	C	1.75	1.75	BW	0.00
40	C	1.95	--	--	--
41	--	2.00	0.17[e] per	(McNeil)	--

Table 5 (continued)

Store No.	Type[a]	Price Tylenol #3	Price Equivalent	Manufacturer	Difference
Mean		$2.35 (40)	$2.08 (12)		$0.20 (12)
Median		2.30	2.10		0.20
Mode		2.30	1.75		--
Range		3.50 to 1.65	2.80 to 1.75		0.50 to 0.00

a. "A" = A mainland-based chain.
"B" = Part of company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. Burroughs Wellcome.

c. This pharmacy listed McNeil as the manufacturer of the chemical equivalent. McNeil is also the manufacturer of Tylenol Compound No. 3. The price listed was not used to determine the mean, median, or mode.

d. This pharmacy listed McNeil as the manufacturer of the chemical equivalent. McNeil is also the manufacturer of Tylenol Compound No. 3. The price listed for the chemical equivalent, however, was lower although the manufacturer of both are the same. The price listed was not used to determine the mean, median, or mode.

e. Was not used to determine the mean, median, or mode.

Table 6

PRICE COMPARISONS BETWEEN LOMOTIL AND DIPHENOXYLATE HCl + ATROPINE SULFATE (20 Tablets)

Manufactured by Searle Laboratories

Store No.	Type[a]	Price Lomotil	Price Equivalent	Manufacturer	Difference
1	A	$3.90	--	--	--
2	A	3.90	--	--	--
3	A	3.90	--	--	--
4	A	3.90	--	--	--
5	A	3.90	--	--	--
6	A	3.60	--	--	--
7	A	3.90	--	--	--
8	A	3.90	--	--	--
9	A	4.35	--	--	--
10	B	4.40	--	--	--
11	B	4.20	--	--	--
12	B	4.94	--	--	--
13	B	5.10	--	--	--
14	B	5.65	--	--	--
15	B	4.20	--	--	--
16	B	4.23	--	--	--
17	B	4.95	--	--	--
18	B	5.50	--	--	--
19	B	4.65	$2.75	Westwood	$1.90
20	B	4.20	--	--	--
21	B	4.40	--	--	--
22	B	5.00	--	--	--
23	B	3.40	--	--	--
24	B	5.75	--	--	--
25	C	4.15	--	--	--
26	C	3.90	--	--	--
27	C	4.60	--	--	--
28	C	4.20	--	--	--
29	C	4.80	3.05	Rexall	1.75
30	C	5.55	--	--	--
31	C	3.50	--	--	--
32	C	5.00	--	--	--
33	C	4.50	--	--	--
34	C	3.95	--	--	--
35	C	--	5.20[b]	(Searle)	--
36	C	4.00	--	--	--
37	C	4.50	--	--	--
38	C	4.00	--	--	--
39	C	3.70	--	--	--
40	C	3.60	--	--	--
41	--	4.00	0.19[c] per	(Searle)	--

Table 6 (continued)

Store No.	Type[a]	Price Lomotil	Price Equivalent	Manufacturer	Difference
Mean		$4.34 (40)	$2.90 (2)		$1.83 (2)
Median		4.20	--		--
Mode		3.90	--		--
Range		5.75 to 3.40	--		--

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. This pharmacy listed Searle as the manufacturer of the chemical equivalent. Searle is also the manufacturer of Lomotil. The price listed was not used to determine the mean, median, or mode.

c. Was not used to determine the mean, median, or mode.

Table 7

BENADRYL AND DIPHENHYDRAMINE HCl
(25 mg., 30 Capsules)

Manufactured by Parke, Davis & Co.

Store No.	Type[a]	Price Benadryl	Price Equivalent	Manufacturer	Difference
1	A	$2.05	--	--	--
2	A	2.05	--	--	--
3	A	2.05	--	--	--
4	A	2.05	--	--	--
5	A	2.05	--	--	--
6	A	1.90	--	--	--
7	A	2.05	--	--	--
8	A	2.05	--	--	--
9	A	1.95	--	--	--
10	B	2.10	--	--	--
11	B	2.00	--	--	--
12	B	2.38	--	--	--
13	B	2.50	--	--	--
14	B	3.25	--	--	--
15	B	2.10	--	--	--
16	B	2.28	--	--	--
17	B	3.10	--	--	--
18	B	2.30	--	--	--
19	B	2.80	--	--	--
20	B	1.80	--	--	--
21	B	1.75	--	--	--
22	B	3.00	$2.50	Schein	$0.50
23	B	1.75	--	--	--
24	B	3.00	--	--	--
25	C	1.95	--	--	--
26	C	1.75	--	--	--
27	C	2.80	2.20[b]	(Parke, Davis)	0.60
28	C	1.85	--	--	--
29	C	2.25	--	--	--
30	C	2.80	--	--	--
31	C	1.35	--	--	--
32	C	1.80	--	--	--
33	C	1.75	--	--	--
34	C	1.75	--	--	--
35	C	--	--	--	--
36	C	1.50	--	--	--
37	C	2.00	--	--	--
38	C	2.00	1.50	Schein	0.50
39	C	1.75	--	--	--
40	C	1.90	--	--	--
41	--	1.75	0.05[c] per	(Parke, Davis)	--

Table 7 (continued)

Store No.	Type[a]	Price Benadryl	Price Equivalent	Manufacturer	Difference
Mean		$2.13 (40)	$2.00 (2)		$0.50 (2)
Median		2.05	--		--
Mode		1.75, 2.05	--		--
Range		3.25 to 1.35	--		--

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. This pharmacy listed Parke, Davis as the manufacturer of the chemical equivalent. Parke Davis is the manufacturer of Benadryl. The price listed for the chemical equivalent, however, was lower although the manufacturer of both are the same. The price listed was not used to determine the mean, median, or mode.

c. This pharmacy listed Parke, Davis as the manufacturer of the chemical equivalent. Parke, Davis is the manufacturer of Benadryl. The price listed was not used to determine the mean, median, or mode.

Table 8

PRICE COMPARISONS BETWEEN HYDRODIURIL AND HYDROCHLOROTHIAZIDE
(50 mg., 100 Tablets)

Manufactured by Merck, Sharp & Dohme

Store No.	Type[a]	Price Hydrodiuril	Price Equivalent	Manufacturer	Difference
1	A	$ 7.70	$ 3.75	TP[b]	$3.95
2	A	7.70	3.75	TP	3.95
3	A	7.70	3.75	TP	3.95
4	A	7.70	3.75	TP	3.95
5	A	7.70	3.75	TP	3.95
6	A	7.70	3.75	Abbott	3.95
7	A	7.70	3.75	TP	3.95
8	A	7.70	3.75	TP	3.95
9	A	7.70	4.90	Zenith	2.80
10	B	11.00	--	--	--
11	B	8.50	--	--	--
12	B	7.57	4.42	Parke, Davis	3.15
13	B	8.40	4.25	Westwood	4.15
14	B	11.85	--	--	--
15	B	7.30	5.95	Rexall	1.35
16	B	7.57	5.28	Parke, Davis	2.29
17	B	9.55	4.35	Parke, Davis	5.20
18	B	16.50	--	--	--
19	B	8.65	4.25	Westwood	4.40
20	B	7.50	4.80	Parke, Davis	2.70
21	B	8.70	5.35	Parke, Davis	3.35
22	B	8.00	5.50	Schein	2.50
23	B	7.50	6.00	Abbott	1.50
24	B	8.00	5.00	Schein	3.00
25	C	8.65	--	--	--
26	C	8.95	2.20	Schein	6.75
27	C	--	6.00	Lederle	--
28	C	10.75	--	--	--
29	C	8.55	5.70	Rexall	2.85
30	C	11.25	6.25	Lederle	5.00
31	C	9.65	2.55	Parke, Davis	7.10
32	C	12.00	5.55	Parke, Davis	6.45
33	C	10.70	--	--	--
34	C	9.65	5.10	Parke, Davis	4.55
35	C	--	12.80[c]	(MSD)	--
36	C	10.00	--	--	--
37	C	8.25	4.50	Parke, Davis	3.75
38	C	8.00	3.75	Schein	4.25
39	C	7.75	5.00	Abbott	2.75
40	C	7.50	3.50	Stanlabs	4.00
41	--	8.55	--	--	--

Table 8 (continued)

Store No.	Type[a]	Price Hydrodiuril	Price Equivalent	Manufacturer	Difference
Mean		$ 8.87 (39)	$ 4.52 (31)		$3.85 (30)
Median		8.25	4.42		3.95
Mode		7.70	3.75		3.95
Range		16.50 to 7.30	6.25 to 2.20		7.10 to 1.35

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. Towne, Paulsen.

c. This pharmacy listed Merck, Sharp & Dohme as the manufacturer of the chemical equivalent. Merck, Sharp & Dohme is the manufacturer of Hydrodiuril. The price listed was not used to determine the mean, median, or mode.

Table 9

PRICE COMPARISONS BETWEEN ACTIFED AND TRIPROLIDINE + PSEUDOEPHEDRINE
(20 Tablets)

Manufactured by Burroughs Wellcome & Co.

Store No.	Type[a]	Price Actifed	Price Equivalent	Manufacturer	Difference
1	A	$2.00	--	--	--
2	A	2.00	--	--	--
3	A	2.00	--	--	--
4	A	2.00	--	--	--
5	A	2.00	--	--	--
6	A	1.95	--	--	--
7	A	2.00	--	--	--
8	A	2.00	--	--	--
9	A	2.30	--	--	--
10	B	1.75	--	--	--
11	B	2.00	--	--	--
12	B	1.95	5.89[b]	(BW)[c]	--
13	B	2.70	--	--	--
14	B	2.85	--	--	--
15	B	1.80	--	--	--
16	B	1.95	--	--	--
17	B	2.55	--	--	--
18	B	2.50	--	--	--
19	B	2.70	--	--	--
20	B	1.85	--	--	--
21	B	1.75	--	--	--
22	B	3.00	--	--	--
23	B	1.75	--	--	--
24	B	3.00	--	--	--
25	C	1.75	--	--	--
26	C	1.75	--	--	--
27	C	2.50	--	--	--
28	C	1.85	--	--	--
29	C	2.15	--	--	--
30	C	2.35	--	--	--
31	C	1.30	--	--	--
32	C	1.75	--	--	--
33	C	2.25	--	--	--
34	C	1.75	--	--	--
35	C	--	2.00[b]	(BW)	--
36	C	1.50	7.00[b]	(BW)	--
37	C	1.75	--	--	--
38	C	1.50	--	--	--
39	C	1.75	--	--	--
40	C	1.50	--	--	--
41	--	1.75	--	--	--

Table 9 (continued)

Store No.	Type[a]	Price Actifed	Price Equivalent	Manufacturer	Difference
Mean		$2.04 (40)	--		--
Median		1.975	--		--
Mode		1.75	--		--
Range		3.00 to 1.30	--		--

a. "A" = A mainland-based chain.
"B" = Part of a company with more than one retail pharmacy in the State.
"C" = A sole proprietorship or the only retail pharmacy in the State run by the company.

b. These pharmacies listed Burroughs Wellcome as the Manufacturer of the chemical equivalent. Burroughs Wellcome is the manufacturer of Actifed. The price listed was not used to determine the mean, median, or mode.

c. Burroughs Wellcome.

Appendix E

SURVEY 2

PHARMACY SURVEY
QUESTIONS AND RESULTS FOR QUESTION 1

GENERIC DRUG SUBSTITUTION QUESTIONNAIRE

This store is (check one):

___(a) A mainland-based chain
___(b) Part of a company with more than one retail pharmacy in the State
___(c) A sole proprietorship or the only retail pharmacy in the State run by the company of ownership

1. When you or another pharmacist at your store receives a prescription written for a drug by its generic name (e.g., Tetracycline 250 mg.), what is your store's policy in filling the prescription? (Check all blanks applicable.)

22 (a) Fill it with the lowest priced brand name chemically equivalent drug in stock which the store has confidence in.

11 (b) Fill it with the lowest priced nonbrand name chemically equivalent drug in stock which the store has confidence in.

5 (c) Fill it with a brand name chemically equivalent drug which the store has confidence in, but which is not the lowest cost brand name chemically equivalent drug in stock.

4 (d) Fill it with a nonbrand name chemically equivalent drug which the store has confidence in but which is not the lowest cost chemically equivalent drug in stock.

19 (e) Fill it with a brand name or nonbrand name chemically equivalent drug which the manufacturer backs the pharmacist with good liability coverage.

0 (f) Fill it with the originator (the original patent holder) of the prescribed drug.

___(g) Other _____

_____

Appendix F

SURVEY 3

PHYSICIANS' SURVEY
QUESTIONS AND RESULTS

(1) What is your feeling towards a "generic drug substitution" law which would allow, unless specifically prohibited, a pharmacist to substitute a chemically- and therapeutically-equivalent but cheaper drug product of the same dosage form and strength for one which you prescribe? (Check one.)

(a)____ In favor
(b)____ In favor for certain drug products
(c)____ Not in favor
(d)____ No opinion

(2) If you are not in favor of such a law, why do you oppose it? (Check any blank applicable.)

(a)____ Chemically-equivalent drug products which I do not ordinarily prescribe generically are not bioequivalent and therapeutically-equivalent.
(b)____ Drug product to be taken by the patient should be solely my prerogative.
(c)____ Malpractice suits may arise if I allow a pharmacist to substitute.
(d)____ Such a law will not result in cost-savings to the consumer.
(e)____ Such a law will result in cost-savings, but the resultant danger or inconvenience in taking "inferior" generics will negate the benefits.
(f)____ Pharmacist may not substitute equivalents or pass on cost-savings to consumers.
(g)____ Patient will experience unnecessary confusion.
(h)____ Pharmacology research will be stifled if profits of research-oriented manufacturers who market the more costly brand-name drug products are lessened because of substitution.

(3) If you are in favor of a "generic drug substitution" law, what do you think shoud be embodied in the law? (Check any blank applicable.)

(a)____ Mandatory substitution by pharmacist unless specifically prohibited by physician.
(b)____ Nonmandatory substitution. That is, the pharmacist would be allowed to substitute unless specifically prohibited by physician.
(c)____ Physician's prerogative to prohibit substitution.

(d)____ Formulary of "substitutable" or "nonsubstitutable" drug products established by experts in medicine and pharmacology.
(e)____ No formulary necessary. Rather, the pharmacist would rely on professional judgment when substituting.
(f)____ Patient's consent required for pharmacist to substitute.
(g)____ Informing of physician by pharmacist for each substitution.
(h)____ Declaration that physician shall not be held liable for malpractice if a pharmacist substitutes.
(i)____ Declaration that pharmacist shall not be held liable when substituting.
(j)____ Declaration that pharmacist substitute a cheaper drug product than that prescribed.

(4) If you currently prescribe generically for some drug products, why do you do so? (Check any blank applicable.)

(a.)____ Confident that drug products of all manufacturers are therapeutically equivalent.
(b)____ Confident that pharmacist will only dispense proven drug products.
(c)____ Do not prescribe generically.

____ a, b, c
____ a, b
____ b, c

Results

Table 1 (Question number 1)

What is your feeling towards a "generic drug substitution" law which would allow, unless specifically prohibited, a pharmacist to substitute a chemically- and therapeutically-equivalent but cheaper drug product of the same dosage form and strength for one which you prescribe?

221 (38.0%) -- In favor
153 (26.3%) -- In favor for certain drug products
192 (33.0%) -- Not in favor
16 (2.7%) -- No opinion or multiple answers

582 (100.0%) -- Total

Table 2 (Question number 2)

If you are not in favor of such a law, why do you oppose it?

Physician's Answer	a	b	c	d	e	f	g	h
In favor	3	0	0	1	0	6	2	1
In favor for certain drug products	41	10	12	10	28	33	20	22
Not in favor	128	115	86	45	94	93	80	103
No opinion or multiple answers	7	5	4	1	4	4	5	3
TOTAL	179	130	102	57	126	136	107	129

Table 3 (Question number 3)

If you are in favor of a "generic drug substitution" law, what do you think should be embodied in the law?

Physician's Answer	a	b	c	d	e	f	g	h	i	j
In favor	56	121	143	127	21	61	42	112	66	54
In favor for certain drug products	15	69	88	95	5	50	39	86	33	33
Not in favor	2	4	13	10	2	8	9	10	1	5
No opinion or multiple answers	0	4	5	4	1	4	5	6	1	2
TOTAL	73	198	249	236	29	123	95	214	101	94

Table 4 (Question number 4)

If you currently prescribe generically for some drug products, why do you do so?

Physician's Answer	a	b	c	a,b,c	a,b	b,c
In favor	73	71	9	1	21	0
In favor for certain drug products	37	65	11	0	7	0
Not in favor	29	25	55	1	6	2
No opinion or multiple answers	2	3	5	0	2	0
TOTAL	141	164	80	2	36	2

Appendix G

Survey 4

PHARMACISTS SURVEY
QUESTIONS AND RESULTS

GENERIC DRUG SUBSTITUTION QUESTIONNAIRE

1. Do you presently work in a:

___Retail pharmacy
___Hospital pharmacy
___Other_____

2. When did you obtain your degree in pharmacy?

___In June 1973 or after
___Prior to June 1973

3. What is your feeling towards a "generic drug substitution" law which would allow, unless specifically prohibited, a pharmacist to substitute a chemically and therapeutically equivalent but cheaper drug product of the same dosage form and strength for one which a physician prescribes?

___In favor
___In favor for certain drug products
___Not in favor
___No opinion

4. If you are not in favor of such a law, why do you oppose it? (Check all blanks applicable.)

(a) ___Chemically equivalent drug products which are not ordinarily prescribed generically are not bioequivalent and therapeutically equivalent.

(b) ___Drug product to be taken by the customer should be solely the physician's prerogative.

(c) ___Liability suits against the pharmacist may arise if the pharmacist substitutes.

(d) ___Malpractice suits may arise if the pharmacist substitutes.

(e) ___Such a law will not result in cost-savings to the consumer.

(f) ___Such a law will result in cost-savings, but the resultant danger or inconvenience in taking "inferior" generics will negate the benefits.

(g) ___Customer will experience unnecessary confusion.

(h) ___Pharmacology research will be stifled if profits of research-oriented manufacturers who market the more costly brand-name drug products are lessened because of substitution.

5. If you are in favor of a "generic drug substitution" law, what do you think should be embodied in the law? (Check all blanks applicable.)

(a) ___ Mandatory substitution by pharmacist unless specifically prohibited by physician.

(b) ___ Nonmandatory substitution. That is, the pharmacist would be allowed to substitute unless specifically prohibited by physician.

(c) ___ Physician's prerogative to prohibit substitution.

(d) ___ Formulary of "substitutable" or "nonsubstitutable" drug products established by experts in medicine and pharmacology.

(e) ___ No formulary necessary. Rather, the pharmacist would rely on professional judgment when substituting.

(f) ___ Customer's consent required for pharmacist to substitute.

(g) ___ Informing of physician by pharmacist for each substitution.

(h) ___ Declaration that physician shall not be held liable for malpractice if a pharmacist substitutes.

(i) ___ Declaration that pharmacist shall not be held liable when substituting.

(j) ___ Declaration that pharmacist substitute a cheaper drug product than that prescribed.

Results

Table 1 (Question number 1)

Do you presently work in a:

95	(54.3%)	-- Retail pharmacy
43	(24.6%)	-- Hospital pharmacy
29	(16.6%)	-- Other
8	(4.5%)	-- Retail and Hospital
175	(100.0%)	-- Total

Table 2 (Question number 2)

When did you obtain your degree in pharmacy?

34	(19.4%)	-- In June 1973 or after
138	(78.9%)	-- Prior to June 1973
3	(1.7%)	-- No answer or multiple answers
175	(100.0%)	-- Total

Table 3 (Question number 3)

What is your feeling towards a "generic drug substitution" law which would allow, unless specifically prohibited, a pharmacist to substitute a chemically and therapeutically equivalent but cheaper drug product of the same dosage form and strength for one which a physician prescribes?

64	(36.6%)	-- In favor
49	(28.0%)	-- In favor for certain drug products
57	(32.6%)	-- Not in favor
5	(2.8%)	-- No opinion or multiple answers
175	(100.0%)	-- Total

Table 4 (Question number 4)

If you are not in favor of such a law, why do you oppose it?

Pharmacist's Answer	a	b	c	d	e	f	g	h
In favor	0	0	0	0	0	0	0	0
In favor for certain drug products	13	1	9	10	2	8	3	10
Not in favor	42	39	46	37	18	34	28	36
No opinion or multiple answers	4	1	4	4	1	2	0	2
TOTAL	59	41	59	51	21	44	31	48

Table 5 (Question number 5)

If you are in favor of a "generic drug substitution" law, what do you think should be embodied in the law?

Pharmacist's Answer	a	b	c	d	e	f	g	h	i	j
In favor	3	59	42	28	27	20	5	19	34	9
In favor for certain drug products	1	39	30	29	15	16	11	11	25	5
Not in favor	0	0	2	1	0	1	0	0	1	0
No opinion or multiple answers	0	0	2	0	1	0	0	1	2	0
TOTAL	4	98	76	58	43	37	16	31	62	14

Appendix H

GENERIC DRUG SUBSTITUTION LAWS

Table 1

WHETHER SUBSTITUTION IS MANDATORY OR NONMANDATORY,
WHETHER PRESCRIBER MAY PROHIBIT SUBSTITUTION,
AND WHETHER CONSUMER MUST CONSENT TO SUBSTITUTION

State	Mandatory/ Nonmandatory	Prescriber May Prohibit	Consumer Consent Necessary
Arizona	Nonmandatory	1	--
Arkansas	Nonmandatory	Yes	Yes
California	Nonmandatory	Yes	--
Colorado	Nonmandatory	Yes	--
Connecticut	Nonmandatory	Yes	Yes
Delaware	Nonmandatory	Yes	--
Florida	Mandatory	Yes	Yes
Georgia	Nonmandatory	Yes	Yes
Idaho	Nonmandatory	Yes	Yes
Illinois	Nonmandatory	Yes	Yes
Kansas	Nonmandatory	Yes	--
Kentucky	Mandatory	Yes	Yes
Maine	Nonmandatory	Yes	--
Maryland	Nonmandatory	Yes	--
Massachusetts	Mandatory	Yes	--
Michigan	Nonmandatory[2]	Yes[4]	3
Minnesota	Nonmandatory	Yes	--
Missouri	Nonmandatory	Yes	Yes
Montana	Nonmandatory	Yes	Yes
New Jersey	Mandatory	Yes	--
New York	Mandatory	Yes	--
Ohio	Nonmandatory	Yes	--
Oregon	Nonmandatory	Yes	--
Pennsylvania	Mandatory	Yes	Yes[5]
Rhode Island	Nonmandatory	Yes	Yes
South Dakota	Nonmandatory	Yes	--
Tennessee	Nonmandatory	Yes	--
Utah	Nonmandatory	Yes	Yes
Vermont	Mandatory	Yes	Yes
Virginia	Nonmandatory	Yes	--

Table 1 (continued)

State	Mandatory/ Nonmandatory	Prescriber May Prohibit	Consumer Consent Necessary
Washington	Nonmandatory	Yes	--
West Virginia	Nonmandatory	Yes	Yes
Wisconsin	Mandatory	Yes	--

1. Arizona's law provides that prescription blanks have two signature lines, with the words "Dispense as Written" below one and "Substitution Permissible" below the other. While the intention of the provision is obvious, the remainder of the statute does not explicitly tie-in the physicians prerogative with the conditions of substitution.

2. Michigan's law requires pharmacists to substitute when consumers request.

3. Consumers may require pharmacists to substitute. Otherwise, consumer consent is not necessary if pharmacists wish to substitute.

4. Allows pharmacists, even when receiving prescriptions where physicians prohibit substitution, to substitute if the drug product dispensed is manufactured by the same manufacturer as the prescribed drug product.

5. Consumers may prohibit by making desires known in writing.

Table 2

GENERAL CRITERIA WHEN SUBSTITUTION IS ALLOWED
EXCLUDING COST-SAVINGS CONDITIONS

State	General Criteria
ARIZONA	(1) Pharmacist may substitute if drug product on formulary. (2) Pharmacist may substitute when manufacturer shows that: (A) Its drug products have expiration dates on original packages; (B) It maintains recall and return capabilities and statement is on file with the Board of Pharmacy; and (C) It has liability statement on file with the Board of Pharmacy.
ARKANSAS	(1) Pharmacist may substitute if drug product not on formulary. (2) Pharmacist may substitute "generically equivalent" drug product.
CALIFORNIA	(1) Pharmacist may substitute if drug product not on formulary. (2) Pharmacist may substitute drug product with the same active ingredients, of the same strength, quantity and dosage form, and of the same generic drug type.
COLORADO	Pharmacist may substitute if drug product is same generic drug type and, in the pharmacist's professional judgment, is therapeutically equivalent.
CONNECTICUT	Pharmacist may substitute same generic drug product with same strength, quantity, dose, and dosage form and which, in the pharmacist's professional opinion, is therapeutically equivalent.
DELAWARE	Pharmacist may substitute if drug product is not on formulary.

State	General Criteria
FLORIDA	(1) Pharmacist shall substitute unless drug product is on formulary.[1] (2) Pharmacist shall substitute a drug product listed on the pharmacy formulary.[1] (3) Pharmacist shall substitute generic equivalent that is distributed by a business entity doing business and is subject to service and legal process in the United States.
GEORGIA	Pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form and which, in the pharmacist's professional opinion, is "pharmaceutically equivalent".[2]
IDAHO	Pharmacist may substitute therapeutically equivalent generic drug product when bioequivalence is shown.
ILLINOIS	Pharmacist may substitute when drug product is on formulary.
KANSAS	(1) Pharmacist may substitute when drug product has not been determined by the FDA to be bioinequivalent. (2) Pharmacist may substitute a drug product of the same dosage form, strength, and generic name.
KENTUCKY	Pharmacist shall dispense lowest priced therapeutically equivalent drug product on formulary.
MAINE	Pharmacist may dispense generic or chemically equivalent drug product if it is listed in the current edition of the NF or USP.
MARYLAND	(1) Pharmacist may substitute if drug product is not on formulary. (2) Pharmacist may substitute generically equivalent drug product of the same dosage form and strength.
MASSACHUSETTS	Pharmacist shall substitute drug product on formulary.
MICHIGAN	Pharmacist may or shall, as the case may be, dispense a generically equivalent drug product.[3]

State	General Criteria
MINNESOTA	(1) Pharmacist may substitute drug product with same generic name and, in the pharmacist's professional judgment, is therapeutically equivalent and interchangeable. (2) Pharmacist may also substitute when prescriber prohibits, if the substitute drug product is manufactured by the same manufacturer of the prescribed drug product.
MISSOURI	Pharmacist may substitute a generically equivalent drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug type as determined by the USAN and accepted by the FDA.
MONTANA	Pharmacist may substitute a drug product with the same generic name, same strength, quantity, dose, and dosage form and which, in the pharmacist's professional opinion, is therapeutically equivalent, bioequivalent, and bioavailable.
NEW JERSEY	Pharmacist shall substitute drug product on formulary.
NEW YORK	(1) Pharmacist shall substitute drug product on formulary. (2) Pharmacist shall substitute drug product with same active ingredients, dosage form, and strength.
OHIO	(1) Pharmacist may substitute drug product which is on formulary. (2) Pharmacist may substitute drug product which is generically equivalent.
OREGON	Pharmacist may substitute drug product with the same generic name in the same strength, quantity, dose and dosage form and which, in the pharmacist's professional opinion, is therapeutically equivalent.
PENNSYLVANIA	Pharmacist shall substitute drug product on formulary.
RHODE ISLAND	(1) Pharmacist may substitute drug product on formulary. (2) Pharmacist may substitute drug product with the same active chemical ingredients of the same strength, quantity, and dosage form.

State	General Criteria
SOUTH DAKOTA	(1) Pharmacist may substitute drug product with the same active chemical ingredients of the same strength, quantity, and dosage and of the same generic drug type. (2) Pharmacist may substitute drug product which manufacturer: (A) Marks capsules and tablets with identification code or monogram; (B) Labels products with their expiration date; (C) Provides reasonable services to accept return goods that have reached their expiration date; (D) Maintains reasonable resources for product information; (E) Maintains recall capabilities for unsafe or defective drug products.
TENNESSEE	(1) Pharmacist may substitute drug product on formulary. (2) Pharmacist may substitute drug product which has the same generic name. (3) Pharmacist may substitute drug product manufactured in the United States, Puerto Rico, or the Virgin Islands.
UTAH	(1) Pharmacist may substitute drug product not on formulary. (2) Pharmacist may substitute: (A) Drug product of same generic type; (B) Drug product which is therapeutically equivalent and interchangeable; (C) Drug product which is not on FDA's bioequivalence problem list;[4] (D) Drug product which complies with FDA's bioavailability and bioequivalence requirements; and (E) Drug product which is permitted to move in interstate commerce.
VERMONT	Pharmacist shall substitute drug product on formulary.

State	General Criteria
VIRGINIA	Pharmacist may substitute drug product on formulary.
WASHINGTON	(1) Pharmacist may substitute therapeutically equivalent generic drug product. (2) Pharmacist may substitute if manufacturer: (A) Maintains quality control standards equal to those of the FDA; (B) Complies with regulations promulgated by the FDA; (C) Marks products with identification code or monogram; (D) Labels products with expiration date; (E) Provides reasonable services to accept returned goods that have reached their expiration date; (F) Maintains 24-hour resources for product information; and (G) Maintains recall capabilities for unsafe or defective drug products.
WEST VIRGINIA	(1) Pharmacist may substitute when drug product is not on formulary. (2) Pharmacist may substitute drug product which manufacturer: (A) Labels products with the name of the original manufacturer and control number; (B) Maintains quality control standards equal to or greater than those of the FDA; (C) Marks products with identification code or monogram; and (D) Labels products with expiration dates.
WISCONSIN	Pharmacist shall substitute drug product on formulary.

1. Florida requires the State to promulgate a negative formulary. It also requires each pharmacy to promulgate a positive pharmacy.

2. "Pharmaceutically equivalent" means those drug products which have the same active chemical ingredients. Usually, these drug products are termed to be "chemically equivalent". "Substitute", however, means to dispense pharmaceutically equivalent and therapeutically equivalent drug products in place of the drug prescribed.

3. Michigan allows pharmacists to substitute except when consumers request it. In these instances, pharmacists are required to substitute.

4. The FDA publishes a list of drug products for which bioequivalence is important. This list is provided in 21 CFR 302.22(c).

Table 3

INFORMATION ON FORMULARIES WHERE REQUIRED BY LAW

State	Formulary	Establishing Body	Criteria for Inclusion in Formulary
ARIZONA	Positive	Board of Pharmacy	Drug products which demonstrate clinically biological or therapeutic equivalence and, when substituted, do not pose a threat to the health and safety of patients.
ARKANSAS	Negative	State Health Officer	Drug products which are not equivalent in quality and effectiveness.
CALIFORNIA	Negative	Director of Health	Drug products which demonstrate clinically significant biological or therapeutic inequivalence.
DELAWARE	Negative	Delaware Drug Advisory Board[1]	(1) Drug products by generic class which are not equivalent in effectiveness. (2) Drug products which are required to meet FDA bioequivalence requirements until requirements are met.
FLORIDA	Negative	Board of Pharmacy and Board of Medical Examiners	Drug products which demonstrate clinically significant biological and therapeutic inequivalence.
ILLINOIS	Positive	Department of Public Health	None.
KENTUCKY	Positive	Kentucky Drug Formulary Council[2]	Drug products which are therapeutically equivalent to specified brand name drug products.
MARYLAND	Negative	Department of Mental Health and Hygiene	Drug products for which there is evidence of actual or potential bioequivalency of therapeutic significance.
MASSACHUSETTS	Positive	Drug Formulary Commission[3]	(1) Drug products which are equivalent based on published data. (2) Drug products on FDA list of interchangeable drug products included by reference when available. (3) Drug products which are not on patent.

State	Formulary	Establishing Body	Criteria for Inclusion in Formulary
NEW JERSEY	Positive	Drug Utilization Review Council[4]	Drug products which are interchangeable. Distinctions also made when (1) evidence of bioequivalence is considered critical and when it is not, and (2) levels of toxicity are considered critical and when they are not.
NEW YORK	Positive	Commissioner of Health	Drug products which have been certified or approved by the FDA and for which approved NDAs and ANDAs are held. The FDA has: (1) Not proposed or promulgated regulations to establish bioequivalency requirements for the drug products; (2) Proposed regulations to establish bioequivalency requirements for such drug products and subsequently has determined that they are not necessary; and (3) Promulgated regulations to establish bioequivalency requirements for such drug products and has approved supplemental applications that provide evidence that the drug products meet the bioequivalency requirements.
OHIO	Positive	"Terminal Distributor"[5]	Drug products which may be substituted.
PENNSYLVANIA	Positive	Secretary of Health	Drug products which are generically equivalent.[6]
RHODE ISLAND	Positive	Formulary Commission[7]	Drug products which are therapeutically equivalent and interchangeable with specific brand name drug products.
TENNESSEE	Positive	Department of Public Health	Drug products which are clinically equivalent.
UTAH[8]	Negative	Board of Pharmacy	Empowered to adopt a list of non-equivalent drug products as published by the FDA.

State	Formulary	Establishing Body	Criteria for Inclusion in Formulary
VERMONT	Positive	Formulary Committee[9]	Drug products which are chemically and therapeutically equivalent.
VIRGINIA	Positive	Virginia Voluntary Formulary Board[10]	Drug products which are therapeutically and chemically interchangeable.
WEST VIRGINIA	Negative	Board of Pharmacy	Drug products which demonstrate significant biological or therapeutic inequivalence and which, when substituted, would pose a threat to the health and safety of patients.
WISCONSIN	Positive	Department of Health and Social Services	Drug products approved under Medicare and Medicaid and satisfied that they are equivalent.

---

1. Consists of: (1) one physician; (2) one osteopath; (3) one pharmacist; (4) one dentist; (5) director of the division of public health; and (6) director of the division of consumer affairs.

2. Consists of: (1) chairman of the Department of Pharmacology of the University of Louisville School of Medicine; (2) chairman of the Department of Pharmacology of the University of Kentucky College of Medicine; (3) Dean of the University of Kentucky College of Pharmacy; (4) two physicians; (5) one pharmacist; (6) one consumer; (7) one appointee at the discretion of the Governor; and (8) one member of the General Assembly.

3. Consists of: (1) one clinical pharmacist; (2) one pharmaceutical chemist; (3) one clinical pharmacologist; (4) one retail pharmacist; (5) one person with experience in pharmaceutical manufacturing; (6) two practicing physicians; and (7) two repre-representatives of the public, one of whom represents the elderly.

4. Consists of: (1) commissioner of health; (2) director of the division of consumer affairs; (3) two pharmacists; (4) two physicians; (5) three experts in pharmacology; and (6) two members of the general public.

5. We do not have the definition of "terminal distributor" available. When the law is read in context, however, a "terminal distributor" appears to be a private wholesaler.

6. "Generically equivalent drugs" means drug products having the same generic name, dosage form and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration or the Pennyslvania Department of Health.

7. Consists of: (1) one hospital pharmacist; (2) one pharmacologist; (3) two senior citizens; (4) three pharmacists; (5) director of health; (6) director of social and rehabilitative services; (7) Chairman of the Senate Committee on Health, Education and Welfare; and (8) Chairman of the House Committee on Health, Education and Welfare.

8. The Board of Pharmacy is authorized and not required to establish a formulary. When the law is read, however, it appears that a formulary is mandated.

9. Consists of: (1) one faculty member of the Department of Pharmacology of the College of Medicine at the University of Vermont; (2) one faculty member of another department of the College of Medicine at the University of Vermont; (3) one member of the Board of Pharmacy; (4) one physician; (5) one pharmacist; and (6) one public member.

10. Consists of nine voting and three nonvoting members: (1) four physicians (voting); (2) two pharmacists (voting); (3) one biopharmaceutist (voting); (4) one dentist (voting); (5) Chairman of Clinical Pharmacology, Medical College of Virginia (voting); (6) adiminstrator of consumer affairs (nonvoting); (7) attorney general (nonvoting); and (8) one member of the public (nonvoting).

Table 4

CRITERIA ON COST SAVINGS WHEN SUBSTITUTION MADE

State	Cost Savings Criteria
ARIZONA	Pharmacist shall notify consumer of cost difference when substituting.
ARKANSAS	(1) Pharmacist shall substitute a drug product with the same or lower cost. (2) Pharmacist may substitute a higher-priced drug product with consumer's consent. (3) Pharmacist shall charge only the amount "normally and regularly" charged for the drug product.
CALIFORNIA	(1) Pharmacist shall pass on difference in acquisition costs of prescribed and substitute drug products. (2) Pharmacist shall not charge a different or higher professional fee for substitute drug product.
COLORADO	(1) Pharmacist shall substitute drug product which costs less. (2) Pharmacist shall pass on "all difference" in cost. (3) Pharmacist shall not charge a different professional fee for substitute drug product.
CONNECTICUT	Pharmacist shall substitute only when there is a savings in cost to the consumer and shall pass on the savings.
DELAWARE	Pharmacist shall pass on full difference in acquisition costs between prescribed and substitute drug products.
FLORIDA	Pharmacist shall substitute a less expensive drug product and pass on full amount of savings.
GEORGIA	Pharmacist shall substitute lowest retail price drug product.

State	Cost Savings Criteria
IDAHO	Pharmacist shall substitute only when it results in cost-savings and shall pass on savings to consumer.
ILLINOIS	Pharmacist shall substitute drug product which has less unit cost than prescribed drug product.
KANSAS	Pharmacist shall not charge more than the regular and customary retail price for the dispensed drug product.
KENTUCKY	Pharmacist shall substitute lowest priced equivalent in stock.
MAINE	Pharmacist shall substitute drug product which price does not exceed prescribed drug product's price.
MARYLAND	Pharmacist shall substitute a lower cost drug product.
MASSACHUSETTS	Pharmacist shall substitute a less expensive drug product.
MICHIGAN	Pharmacist shall substitute a lower cost drug product and pass on the difference in wholesale costs between prescribed and substitute drug product.
MINNESOTA	Pharmacist shall substitute drug product with lower retail price and pass on difference between acquisition costs of prescribed and substitute drug products.
MISSOURI	Pharmacist shall substitute less expensive drug product.
MONTANA	(1) Pharmacist shall substitute less expensive drug product and pass on the "full amount of the savings realized". (2) Pharmacist shall not charge a different professional fee for dispensing a substitute drug product than for dispensing the prescribed drug product.
NEW JERSEY	Pharmacist shall substitute when savings to the consumer results and shall pass on the savings in full by charging no more than the regular and customary retail price for the substitute drug product.

State	Cost Savings Criteria
NEW YORK	Pharmacist shall substitute a less expensive drug product.
OHIO	(1) Pharmacist shall substitute a drug product which regular and customary retail price is less than the prescribed drug product. (2) Pharmacist shall pass on difference between cost of prescribed and substitute drug products.
OREGON	(1) Pharmacist shall substitute only when there will be a savings or no increase in cost to the consumer. (2) Pharmacist shall, consistent with reasonable professional judgment, substitute the lowest retail cost, effective drug product in stock.
PENNSYLVANIA	(1) Pharmacist shall pass on difference in acquisition cost between prescribed and substitute drug product exclusive of professional fee. (2) Pharmacist shall not charge a higher or different professional fee for the substitute drug product.
SOUTH DAKOTA	---
TENNESSEE	(1) Pharmacist shall substitute a lower-priced drug product. (2) Pharmacist shall pass on difference between prescribed and substitute drug product.
UTAH	(1) Pharmacist shall pass on difference between prescribed and substitute drug product. (2) Pharmacist shall not charge a different professional fee for substitute drug product.
VERMONT	(1) Pharmacist shall substitute the lowest-priced drug product in stock. (2) Pharmacist shall charge no more than the usual and customary retail price of the substitute or prescribed drug product.

State	Cost Savings Criteria
VIRGINIA	Pharmacist shall substitute drug product with lower retail price than the prescribed drug product and pass on difference between acquisition costs of prescribed and substitute drug products.
WASHINGTON	Pharmacist shall pass on difference between acquisition costs of the prescribed and substitute drug products.
WEST VIRGINIA	Pharmacist shall pass on difference between retail prices of prescribed and substitute drug products; this savings shall not be less than the difference between acquisition costs of the prescribed and substitute drug products.
WISCONSIN	Pharmacists shall substitute if the average wholesale cost of the substitute is not greater than the prescribed drug product.

Table 5

PROVISIONS RELATING TO PHARMACIST AND PRESCRIBER LIABILITY

State	Pharmacist	Prescriber
ARIZONA	No greater than when filling a generic prescription.	Failure to specify no substitution is not evidence of negligence.
ARKANSAS	--	--
CALIFORNIA	Same as when filling generic prescription.	Absolves prescriber.
COLORADO	Same as when filling generic prescription.	--
CONNECTICUT	--	--
DELAWARE	--	--
FLORIDA	Same as when filling generic prescription.	Absolves prescriber except when original prescription was wrong.
GEORGIA	--	--
IDAHO	--	--
ILLINOIS	Absolves pharmacist if substitute drug product is on formulary.	Failure to specify no substitution is not evidence of negligence.
KANSAS	--	--
KENTUCKY	--	--
MAINE	--	--
MARYLAND	--	--
MASSACHUSETTS	--	--
MICHIGAN	--	--
MINNESOTA	--	--
MISSOURI	Same as when filling generic prescription.	--
MONTANA	Same as when filling generic prescription.	Absolves prescriber except when original prescription was wrong.
NEW HAMPSHIRE	--	--

State	Pharmacist	Prescriber
NEW JERSEY	--	--
NEW YORK	--	--
OHIO	--	(1) Absolves prescriber when substitution made incorrectly by pharmacist. (2) Absolves prescriber except when original prescription was wrong. (3) Failure of prescriber to prohibit substitution is not evidence of negligence unless prescriber had evidence that patient needed prescribed drug product.
OREGON	Substitution shall not constitute evidence of negligence if substitution made within reasonable and prudent practice of pharmacy or if substitute drug product was accepted in a generally recognized formulary or government list.	Failure of prescriber to prohibit substitution is not evidence of negligence unless prescriber had evidence that patient needed the prescribed drug product.
PENNSYLVANIA	Absolves pharmacist except when drug product incorrectly substituted.	Absolves prescriber of liability except when original drug product was incorrectly prescribed.
RHODE ISLAND	Absolves pharmacist.	Absolves prescriber.
TENNESSEE	--	--
UTAH	Same as when filling generic prescription except pharmacist charged with notice and knowledge of FDA bioequivalence problems list.	Failure of prescriber to prohibit substitution does not constitute evidence of negligence.
WASHINGTON	--	Absolves prescriber.
WEST VIRGINIA	Absolves pharmacist unless substitution made incorrectly.	Absolves prescriber unless original prescription was incorrect. Failure to prohibit substitution shall not constitute evidence of negligence unless physician had cause to believe prescribed drug product was necessary.
WISCONSIN	--	--

Appendix I

LEGAL ASPECTS: LIABILITY IN PRODUCTION AND MARKETING OF DRUGS

by Lester Ishado

A. Introduction

A person involved in the production and marketing of drugs which are defective or misbranded may be subject to criminal liability for violation of the federal and state food, drug, and cosmetic acts and may also be subject to civil suit by a person who is injured by the drug. The federal and state drug acts provide criminal penalties, and not private civil remedies, for violations.[1] However, a given set of facts may give rise to both criminal and civil liabilities. The Federal Food, Drug, and Cosmetic Act and the Hawaii Food, Drug, and Cosmetic Act are very similar in scope with the principal difference being that the federal act requires that the drugs pass through interstate commerce. Both acts probably apply to the production and marketing of drugs within the State since most drugs used in Hawaii are shipped from outside the State, i.e., in interstate commerce, subject to the federal act. The Hawaii Act also recognizes that substitution of generic drugs may occur, similar provision for which is not found in the federal drug act.[2]

Civil liability to a person injured by the drug arises under the common law (non-statutory) theories of negligence, deceit and misrepresentation, battery, and strict liability and for breach of warranty under the Uniform Commercial Code.

B. Criminal Liability under the Food, Drug, and Cosmetic Acts

The principal prohibitions of the federal and state drug acts concern the introduction, delivery, or receipt (and sale, under state act) of any adulterated or misbranded drug and the adulteration or misbranding of any drug.[3]

1. Adulteration

Adulteration of a drug may occur when it contains a filthy substance or other harmful material; where the methods, facilities, and controls used in manufacturing the drug do not conform to good manufacturing practices to assure that the drug is safe and has the identity, strength, purity, and quality which it purports to have; when a substance has been added to it reducing its strength, quality, or purity; or when the drug, if listed on an official compendium such as the United States Pharmacopoeia, differs in strength from, or is lower in, quality and purity than prescribed by the compendium standards; or, if not listed on an official compendium, differs in strength from, or is lower in, quality and purity than that which it purports to represent.[4]

In applying the federal drug act, the federal courts have held that intent to defraud or even an awareness of a violation is not necessary for conviction

under the federal drug act, but it should be noted that good faith exceptions to liability are made.[5] The state drug act might also be interpreted by state courts not to require an intent to violate the act since the state and federal acts are so similar, but there does not appear to be any Hawaii cases on this issue.

2. Misbranding

A drug is deemed misbranded under the federal and state drug acts when its label or container is false or misleading; it is an imitation of another drug or sold under the name of another drug; it is dangerous to health when used in the manner prescribed on the label; or when information relating to its side effects, effectiveness, and ingredients or adequate warnings and directions for use have been omitted.[6] It should be noted that when the drug acts prohibit imitation, counterfeiting, and other acts designed to make one drug appear to be another drug, the acts do not prohibit generic drug substitution but are intended to prevent any deception that the drug furnished is actually the same drug and brand requested.

Both federal and state drug acts also provide that dispensing without following a prescription certain habit-forming drugs, drugs which are not safe without supervision, and drugs for which supervision is required by federal law results in these drugs being misbranded.[7] This provision might be construed to mean that a prescription is limited to the brand name drug, that any dispensing of a generic drug unless specifically authorized on the prescription is dispensing that generic drug without a prescription, and thus that the generic drug is misbranded. It appears unlikely, however, that the courts would construe the prescription requirements in this manner, and since some generic drug substitution is presently allowed, perhaps the courts will simply construe a prescription to include generic substitution where allowed by law.

3. Hawaii Provision

The state drug act under section 328-6(15), Hawaii Revised Statutes, prohibits the dispensing or causing to be dispensed of a different drug or brand of drug in place of the drug or brand ordered or prescribed without the express permission of the person ordering or prescribing. The wording of this provision is unclear as to whether the term "ordering" prohibits substitution without permission of non-prescription as well as of prescription drugs. The Hawaii Department of Health has apparently construed this provision to apply only to prescription drugs, and as to such drugs, the express permission of the prescribing physician is required, and the patient has no right to demand or allow substitution.[8]

C. Civil Liability

A person may be liable in a civil action for injuries suffered by the consumer of a drug under the tort concepts of negligence, deceit and misrepresentation, battery, or under the contractual theory of breach of warranty as provided in the Uniform Commercial Code. It should be noted that a single act may make the defendant liable under several (alternative) theories of liability, and these theories may overlap.

1. Negligence

In an action based on negligence, the plaintiff must show that the defendant owed a duty to use due care to the plaintiff, the defendant breached this duty, and the breach was the proximate cause of the injury to the plaintiff.[9] Acts by third parties in addition to that of the plaintiff may affect the cause of action based upon negligence. For instance, the intervening negligence of another person may make that person jointly and severally liable as a joint tortfeasor, an unforeseen act may cut off the chain of causation between defendant's negligent act and plaintiff's injury, or the plaintiff's contributory negligence may bar recovery or reduce the amount of liability.[10]

Physicians, pharmacists, and manufacturers and distributors of drugs owe the consumer a duty of due care in the performance of their profession, i.e., the same standard of due care as practiced by those in that profession under the same or similar circumstances.[11]

The production and marketing of a drug which causes injury to a consumer generally involves: the manufacturer, distributor, physician, and pharmacist. The physician's liability when dispensing a drug is generally the same as a pharmacist in dispensing the drug and will be discussed under the pharmacist's liability. It should be noted that the plaintiff may have a cause of action (though only one recovery) against several people, and a defendant from whom recovery is obtained may then seek to be indemnified by another defendant who may be ultimately liable. For example, a plaintiff in a breach of implied warranty of fitness for a defective drug may sue either the pharmacist or the manufacturer, but if the pharmacist is held liable, the pharmacist may then seek indemnity from the manufacturer. The plaintiff's decision in deciding which person (or both) to sue may depend on the defendant's ability to pay a judgment and accessibility.

The manufacturer is under a duty to use due care in the manufacturing, testing, and marketing of the drug and is liable for a breach of this duty.[12] Courts have found the manufacturer to be liable for negligence in testing the drug, in failing to give proper warnings about side effects, and in producing a defective drug.[13]

The distributor is probably not liable under the negligence theory since the distributor usually acts as a conduit in marketing the drug, unless the distributor is under a duty to inspect the drug and fails to discover an obvious defect or markets the drug under its own label and is negligent in doing so.

The physician is under a duty to use due care in the treatment of the patient, including prescribing the correct drug, and is liable for a breach of this duty.[14] Thus, a physician might be found to be negligent in administering the wrong drug or in failing to inform the patient about the possible side effects of the drug.[15]

The pharmacist is under a duty of due care in selecting and preparing prescription drugs. Thus, the pharmacist may be liable in filling an obviously fatal prescription at least without consulting the physician about a possible error in prescribing,[16] in mistakenly substituting the wrong (different) drug for the one prescribed,[17] or in failing to warn about the mixing of certain

chemicals where the pharmacist was aware that the chemical would be mixed and as such was dangerous.[18] The Hawaii Supreme Court has held that the pharmacist was negligent in mistakenly substituting the wrong drug and in filling a prescription using the wrong amounts of ingredients.[19]

The State is generally immune from a civil action, except to the extent authorized under chapter 662 of the Hawaii Revised Statutes wherein its sovereign immunity is waived as to actions for the torts of state employees.[20] Thus, it is possible that the State might be held liable where through the negligence of a state agency, for example, a drug which is not therapeutically equivalent to the drug prescribed is permitted to be substituted under a generic drug substitution list furnished by the State, and the negligence causes injury to the plaintiff. This might be avoided by claiming sovereign immunity.

Compliance or non-compliance with a statutory duty relating to drugs may have some effect upon a civil action, even though the statute itself does not authorize a civil recovery. Violation of the federal (and probably the state) Food, Drug, and Cosmetic Act has been held to establish negligence.[21] Adherence to the standards established by the drug acts, on the other hand, may not be enough to establish the use of due care in actions based upon negligence. Some courts have held in cases involving strict liability that compliance with federal requirements relating to adequacy of warnings is not enough where the manufacturer knew of additional dangers not contemplated by the federal standards, but on the other hand, it has also been held that a drug properly tested, marketed under federal regulations, with labels approved by the Food and Drug Administration is as a matter of law reasonably safe.[22] There is a possibility that Hawaii's courts might find that compliance with state requirements, e.g., a generic drug list, is a defense to civil liability, and it should be made clear statutorily whether compliance should be given this effect.

2. Misrepresentation and Fraud and Deceit

A person may be liable in a civil action based upon fraud and deceit for making a false statement of fact, e.g., that a drug has no side effects, where that person knows that the statement is false or for making a statement recklessly without attempting to determine its truthfulness, with intent to deceive and to induce the other person to rely upon the statement, and the other person relies upon the statement resulting in injury.[23] The person injured (the plaintiff) does not have to be the person who actually purchased the drug, and liability under fraud and deceit applies to situations where the defendant conceals material facts as well as makes misstatements.[24]

Section 402B of the Restatement of Torts 2d provides that a person engaged in the business of selling chattels (personal property) who makes to the public a misrepresentation of a material fact concerning the character or quality of a product is liable for physical harm caused by justifiable reliance upon that misrepresentation.[25] This rule applies to drug manufacturers and distributors and pharmacists and imposes liability even though the misrepresentation was made innocently without fraud or negligence and without a relationship of privity (buyer-seller) between the plaintiff and defendant.[26]

The difficulty in fraud and deceit and misrepresentation actions is that the misrepresentation must relate to a statement of fact rather than mere opinion

or puffing (bragging) about the value of the product. For example, a statement that this drug is better than any other drug might be considered to be mere opinion (puffing) about the drug, whereas it has been held that a statement that this drug is without side effects is a statement of fact.[27]

3. Battery

Battery is an intentional tort whereby the defendant intentionally inflicts an offensive or harmful contact with the plaintiff, e.g., in administering a drug which injures the plaintiff. Thus, a physician may be liable for administering a drug which has side effects which injure the plaintiff as long as the physician intentionally administered the drug, whether or not the physician intended to injure the patient. Consent is a defense in this situation where the patient consents to the treatment, but consent, to be valid, must be informed consent, and the physician may be liable where the physician failed to inform the patient of the possible side effects of the drug.[28]

4. Strict Liability

The trend in products liability appears to be moving from liability based upon negligence, fraud, deceit, misrepresentation, and battery to strict liability and breach of warranties wherein the defendant may be held liable even though the defendant used due care in manufacturing or in marketing the drug as long as the drug was defective or a warranty was breached.

A person may be held liable under the tort theory of strict liability where that person sells a drug in a defective condition unreasonably dangerous to the person or property of the ultimate consumer, and the person is a seller engaged in the business of selling such a drug, where the drug is expected to and does reach the consumer without substantial change in the condition in which it was sold.[29] Liability is imposed even though the seller was not negligent in manufacturing or marketing the drug, and the plaintiff did not purchase the drug from the defendant.[30] Strict liability is similar to liability for breach of warranties because liability in both cases is applied regardless of negligence. Strict liability, as a theory in tort, however, is not subject to the traditional defenses such as lack of notice of breach and disclaimers in a contractual breach of warranty case.[31] It has been said that social policy requires strict liability to be imposed upon the retailer, e.g., a pharmacist, even though the manufacturer is ultimately liable since it would be difficult for the consumer to sue the manufacturer who is often out-of-state, and the retailer is in a better position to sue the manufacturer.[32]

Under the Restatement of Torts 2d a person engaged in selling the defective drug may be held liable under strict liability, and this includes the manufacturer, distributor, and pharmacist but apparently does not include a physician. The rationale is that a physician is engaged in selling medical services, not the drug. This may be true where the physician merely prescribes the drug,[33] but it is unclear whether the physician who actually dispenses the drug is rendering services of which the sale of drugs is incidental or is selling drugs and should be held liable like the pharmacist.

In order to recover in an action based upon strict liability, the plaintiff must prove that the drug was defective and that this defect caused plaintiff's

injury.[34] A defect might occur because of drug impurity,[35] or even if pure, where the drug is unavoidably unsafe and has potential side effects, and the seller knows or should know of them and fails to give proper warnings.[36] A sale of a drug which is unavoidably unsafe does not result in strict liability where the drug is properly prepared, i.e., no defect therein, and marketed, and adequate warnings about potential side effects are given.[37]

A seller of drugs has a duty to warn only of potential side effects which are known or should be known to the seller at the time of sale, and strict liability is not imposed for failure to warn of side effects which are discovered after the sale.[38] Generally, the manufacturer meets the duty to warn by giving proper warnings to the physicians who may use the drug. Several courts have held that the manufacturer must insure that each patient is adequately warned and warning the physicians is not sufficient where there is no individualized medical judgment to use the drug for a particular person, e.g., in a mass immunization clinic.[39] Thus, some courts appear to emphasize the physician's exercise of judgment to use the drug in determining whether warnings given to the physicians alone are sufficient. Since generic drug substitution may to some extent negate physician judgment, it is unclear whether generic drug warnings to physicians alone are sufficient to avoid strict liability, especially where the physician has no voice in the generic substitution.

5. Breach of Warranties

A civil action based upon breach of warranty is very similar to one based upon strict liability, even though the first action is in tort while the second action is on a contract theory, and at least one court has stated that the theories are the same, except for a difference in terminology.[40]

Under the Uniform Commercial Code, adopted in this State, a seller may be liable for an express warranty, an implied warranty of merchantability, or an implied warranty of fitness for a particular purpose.[41] It is unclear whether the Code applies to a physician. Where the physician merely prescribes a drug, there is no sale of goods, and thus the Code does not apply. The physician could argue that the Code does not apply even where drugs are furnished since the physician is essentially furnishing a sale of services as to which the furnishing of drugs is merely incidental.[42]

A seller of drugs may be liable for an express warranty which is created by any affirmation of fact or promise to the buyer which relates to the drug, any description of the drug or any sample or model of the drug where the affirmation or promise, description, or sample is made part of the basis of the bargain, and where the seller warrants that the drug shall conform to the affirmation or promise, description, or sample.[43] The affirmation required must be one of fact, rather than a mere opinion or statement of the value of the drug, and in this sense is similar to the tort action based upon fraud and deceit and misrepresentation. Thus, a druggist has been held to have given an express warranty where the druggist intentionally substituted another drug for the drug requested stating that they were the same thing.[44] The affirmation or promise, description, and sample must become part of the basis of the bargain, or the bargaining process, and to this extent the buyer must be aware of the express warranty and rely upon it in making the purchase.

A seller of drugs may also be liable for an implied warranty of merchantability which generally goes to the overall quality of the drugs. A breach of implied warranty of merchantability may be found where the drug is not fit for the ordinary purpose for which it is used, e.g., it is defective, or where the drug does not conform to the promises or affirmations of fact made on the container or label, e.g., mislabeling.[45] An implied warranty of merchantability applies only if the seller is a person who regularly deals in the drugs sold or who otherwise holds oneself out as having knowledge or skill peculiar to the drugs involved.[46]

A seller of drugs may be liable for a breach of implied warranty of fitness for a particular purpose where at the time of contracting the seller has reason to know of the particular purpose for which the drugs are required and that the buyer is relying on the seller's skill or judgment to select or furnish drugs suitable for that purpose.[47] Liability under a breach of implied warranty of fitness for a particular purpose is imposed upon the pharmacist as well as the manufacturer even though the defect causing the breach existed before the drug reached the pharmacist, i.e., at the manufacturing stage, and even though the pharmacist could not have discovered the defect.[48]

Where a breach of implied fitness for a particular purpose is involved, the courts have found a breach where the drug had side effects (case also based on strict liability).[49] It has been held that the warranty is directed toward a contemplated class of people to be used in a certain manner as directed, and this class of contemplated users does not include persons with an allergic reaction to the drug unless a substantial number of users suffer the same reaction.[50]

Some courts have also held that there is no breach of implied warranty of fitness for a particular purpose by a pharmacist where the drug was sold in its original package, at least where the product was a proprietary drug, apparently on the rationale that the pharmacist is unable to examine the drug for defects, and the consumer is not relying upon the pharmacist's skill in selecting or furnishing a drug.[51] Other courts have modified this sealed package doctrine by giving the consumer direct recourse against the manufacturer stating that the warranty given on a drug sold in an original package runs to the ultimate consumer[52] or by rejecting the doctrine, finding that the customer does in fact rely upon the reputation of the retailer in making the purchase and that public policy requires the customer to have recourse against the retailer who is more easily reachable than the manufacturer who is probably in another state.[53]

The original package defense does not appear to present an issue in Hawaii under the Uniform Commercial Code since the Code does not recognize any exceptions in making the pharmacist or the seller at the retail level liable for a breach of warranty even though the drug is sold in its original container as received from the manufacturer.[54]

An implied warranty of fitness requires the seller to have reason to know that the buyer is relying on the seller's skill to furnish suitable drugs fit for the purpose for which the drug is sought.[55] A Florida court has held that a pharmacist was not liable for breach of implied warranty of fitness where the drug had some ill side effects on the rationale that since the drug was patented, prescribed by the physician, and no substitute was available, the patient was relying upon the physician's skill in selecting a drug and not on the

pharmacist's skill, and thus there was no implied warranty given by the pharmacist.[56] It appears that a contrary conclusion under this rationale might be reached under a broadened generic substitution drug law, i.e., that the consumer is relying upon the pharmacist's skill in selecting a drug, and therefore there exists an implied warranty of fitness.

It does appear that the consumer is relying upon the pharmacist to fill the prescription accurately, and where the pharmacist fails to do so, there are probably grounds to sue for breach of implied warranty of fitness. In the Florida case above, the prescription was accurately filled, but unfortunately, the drug had detrimental side effects. It should be noted that the pharmacist probably would be liable under strict liability if the drug had been sold without adequate warning of the side effects.

While earlier cases basing liability for breach of warranty required privity (a contract relationship to be shown between the injured party and the wrongdoer), there is no privity requirement in Hawaii under the Uniform Commercial Code which follows the modern legal trend.[57] Thus, the patient-consumer could sue the manufacturer directly for a breach of warranty. The protection, however, extends to any person who may reasonably be expected to consume the drug so that as to prescription drugs, it possibly is limited to the patient and does not cover other people, such as members of the patient's family, who are not expected to take a drug prescribed for another person.

An action based upon a breach of warranty under the Code in Hawaii is further limited in that the buyer is required to give reasonable notice of the breach within a reasonable time after the buyer discovers or should have discovered the breach. Otherwise, the buyer is barred from recovery.[58] The Code specifically requires notice by the buyer, but it is unclear whether third parties other than the buyer of a drug who are protected under the extension discussed in the above paragraph are required to give notice of a breach, and if so, to whom. This may not be a problem since in the case of prescription drugs, it appears that there will be few, if any, extensions of protection to third parties.

An express warranty may be negated or limited by words or conduct. An implied warranty of merchantability may be excluded or modified orally or in conspicuous writing with language mentioning merchantability. An implied warranty of fitness may be excluded or modified with a conspicuous writing.[59] Implied warranties may be excluded by the use of language such as "as is", by the course of dealing or usage of trade, or when the buyer has examined the goods before entering the contract. If offered an opportunity to examine goods before purchase and a buyer refuses to do so, the implied warranty does not cover defects which an examination should have revealed.[60] Failure to inspect the drug does not appear to present much of a problem since most defects in drugs are latent and not discoverable to the consumer.

Remedies and damages may also be limited, but generally, an attempt to limit recovery for personal injury involving consumer goods is prima facie unconscionable and usually not enforced by the courts.[61]

6. Summary

A person involved in the production and marketing of drugs may be criminally liable for a violation of the federal and state food, drug, and cosmetic acts and may also be civilly liable under state common law for injuries suffered by a consumer as a result of use of the drug.

The federal and state drug acts prohibit certain actions relating to adulteration or misbranding of drugs, principally where the drug's strength is different from or its quality and purity is lower than that established by an official compendium, or that which it purports to have; where the drug is unsafe; where the drug's label or container is false or misleading or fails to give adequate warnings about potential side effects or adequate directions for use; and where a drug for which a prescription is required is dispensed other than as provided by the acts. A person may be liable under the drug acts even though the person was unaware of the violation.

The state drug act further prohibits the dispensing of a different drug or brand of drug in substitution for the drug or brand ordered or prescribed without the express permission of the person ordering or prescribing. This prohibition against substitution apparently applies only to prescription drugs. It also requires the permission of the prescribing physician with the patient having no right to order substitution.

A person may be liable in a civil action to a person injured by a drug based upon the defendant's negligence, i.e., a breach of the duty of due care, which proximately caused plaintiff's injury. The drug manufacturer, distributor, physician, pharmacist, and even the State may be liable for a negligent act causing injury to the consumer. The drug manufacturer may be liable for negligence in manufacturing a defective drug, and the pharmacist may be liable for negligently filling a prescription, inadvertently substituting the wrong drug, or intentionally substituting a drug which is not therapeutically equivalent. The physician may be liable for negligently prescribing the wrong drug or for negligently filling the prescription.

The State may be liable for the negligence of its employees in administering a generic drug substitution law, e.g., in drafting of generic substitutions which are in fact not therapeutically equivalent, but liability could be excluded by statute.

Compliance with the federal or state drug act does not negate strict liability and may not be enough to establish due care to negate negligence. On the other hand, failure to comply with the federal or state drug acts might establish (negligence) the lack of due care.

A person may also be liable to the injured party for any false statements of fact or concealments of material facts relating to the drug in question, and liability is imposed even though the defendant made the statements innocently or without intent to deceive and even though the plaintiff did not purchase the drug from the defendant.

A physician may be liable under the tort theory of battery for injuries caused by administration of a drug with detrimental side effects where the

defendant failed to obtain the plaintiff's consent after informing the plaintiff of the possibility of side effects.

A person may also be liable under strict liability, regardless of using due care in producing and marketing the drug, where the defendant sells a drug in a defective condition unreasonably dangerous to the ultimate consumer, the defendant is engaged in the business of selling drugs, and the drug is expected to and does reach the consumer without substantial change in the condition in which it was sold. Strict liability clearly applies to the manufacturer, distributor, and pharmacist, but apparently does not apply to the physician.

The drug could be defective either because of an impurity therein or even if pure because of the failure to warn of potential side effects which are known or should have been known at the time of the sale. Generally, a manufacturer may avoid strict liability on this basis by warning the physician, but where the drug is to be used in mass immunization clinics where individual decisions to administer the drug are not made, then the manufacturer must warn each consumer.

A defendant may also be liable for a breach of an express warranty where an affirmation of fact or promise, description, or sample relating to the drug are made part of the bargain and the defendant-seller thereby warrants that the drug shall conform to the affirmation or promise, description, or sample even though formal wording is not used.

Liability for breach of an implied warranty of merchantability is imposed upon a seller who is a merchant, i.e., someone who deals in the drug in question, where the drug is not fit for the ordinary purpose for which it is used or the drug does not conform to the promises or affirmations of fact made on the drug's container or labeling.

An implied warranty of fitness for a particular purpose is breached by a seller where at the time of contracting the seller has reason to know the particular purpose for which the drug is sought and that the buyer is relying upon the seller's skill or judgment to select or furnish suitable drugs. In Hawaii, liability for a breach of this implied warranty is imposed at the retail level upon the pharmacist as well as at the wholesale level upon the manufacturer and distributor under the Uniform Commercial Code. Some courts outside the State apply the original sealed package doctrine holding that there is no breach of implied warranty of fitness by the retailer where the retailer sells a product still in its original package.

Warranties may require some reliance by someone. For instance, an express warranty requires that the affirmation of fact or promise, description, or sample be made part of the bargain, and an implied warranty of fitness requires the seller to have reason to know of the buyer's reliance upon the seller's skill or judgment.

Hawaii does not require privity, and the plaintiff, even though not the person who purchased the drug from the defendant, or even if not involved in any purchase of the drug, may recover for a breach of warranty if that plaintiff is one who may reasonably be expected to use the drug and is injured by the drug. Thus, the consumer of the drug, most likely limited to the person for

whom the prescription was written as the only person who may be reasonably expected to consume the drug, could sue the manufacturer of the drug directly.

An action for breach of warranty is limited in that the buyer is required to give reasonable notice of the breach to the seller. The express or implied warranties may be limited or excluded by appropriate disclaimers, but damages and remedies which could otherwise be limited, are probably unconscionable and unenforceable in the case of bodily injury.

A civil suit might further be affected by the acts of third parties, e.g., cutting the chain of causation from the defendant's negligence to the plaintiff's injury, the plaintiff's contributory negligence, or the plaintiff's assumption of the risk. The various theories of recovery may overlap, and several theories might apply to a given situation. There is also a possibility of the plaintiff having the choice of which of several defendants to sue, especially with privity eliminated, and of a defendant joining other defendants who might be jointly and severally liable, in seeking contributions or indemnity from them, or bringing an action against the next person above in the chain of marketing.

D. Specific Examples of Possible Criminal and Civil Liability

The basic situation involves a drug manufactured by a drug manufacturer, distributed in Hawaii by a distributor, and sold by a pharmacist to a patient who has a prescription written by a physician. Since this study involves the question of generic substitution, it will focus on the substitution of a generic drug for the brand name drug prescribed.

The consumer of a generic drug substitute might be injured in one of several situations:

(1) The generic drug substitution is defective because of an impurity and therefore not therapeutically equivalent to the brand name drug;

(2) The generic drug substitution is defective because of failure to give adequate directions for use or to warn of dangerous side effects;

(3) The generic drug substitution is not therapeutically equivalent to the brand name drug prescribed because the drug, even if properly prepared and pure, unlike situation (1), is not therapeutically equivalent and the belief that they were is erroneous;

(4) The generic drug substitution is not therapeutically equivalent to the brand name drug because although no substitution is intended, the pharmacist mistakenly substitutes a wrong drug for the brand name drug or the pharmacist intends to fill a substitute prescription drug but makes a mistake in doing so; or

(5) The physician mistakenly prescribes the wrong brand name drug, and the generic drug substitution therefore injures the patient.

In situations (4) and (5), injury occurs because of the negligence of the pharmacist and the physician, respectively, and the drug manufacturer and distributor are not liable since the drugs were not defective. These two situations do not really involve generic drug substitution since in situation (4), no substitution was intended or the prescription was erroneously filled and in situation (5) there was an error in making the prescription. There is no criminal liability under the federal and state drug acts since there is no misbranding or adulteration of the drugs. The pharmacist might be liable in a civil suit for negligence in making the unintended substitution or in misfilling the prescription, or for misrepresentation, or breach of express and implied warranties. The physician might be liable for negligence in prescribing the wrong drug and possibly for breach of express or implied warranties in dispensing the wrong drug. Since situations (4) and (5) do not involve the generic drug substitution being studied herein and are the results of mistakes by the pharmacist and physician, the pharmacist and physician should continue to remain liable under present law, and no change in liability is recommended.

In situations (1), (2), and (3) above, where the generic drug substitution is impure, mislabeled, or not therapeutically equivalent, the drug manufacturer, distributor, and pharmacist are subject to criminal liability under the federal and state drug acts. An impure drug is adulterated and misbranded. A drug without proper warnings or directions for use is misbranded. A drug which is pure but is not the therapeutic equivalent of the brand name drug is misbranded if claims of equivalency were made leading to the mistaken belief of equivalency. Both the federal and state drug acts provide for certain exceptions to criminal liability where the defendant acts in good faith.[62]

In situation (1) where the drug is impure, the manufacturer may be liable for negligence in manufacturing the defective drug, and the manufacturer, distributor, and pharmacist may be liable under either strict liability or for breach of express or implied warranties. The physician is apparently not liable to anyone in this situation when acting only as a prescriber of the drug. Where the physician acts as a dispenser of the drug, some courts might treat the physician as a pharmacist.

In situation (2) where the generic drug substitution is mislabeled, the manufacturer, distributor, and pharmacist may be liable under strict liability for failure to warn of possible side effects, misrepresentation or fraud and deceit, or for breach of express or implied warranties. The physician might be liable under the tort theory of battery or negligence in failing to warn the patient of the possible side effects of the drug.

In situation (3) where the generic drug substitution is pure but not therapeutically equivalent to the brand name drug, and the pharmacist makes the substitution mistakenly thinking that they were equivalent, the pharmacist may be liable for negligence in selecting the substitute drug. The manufacturer and distributor may be liable if they made any claims on which the false belief of therapeutic equivalency was based, e.g., a claim that the generic drug had the

same therapeutic effect as the brand name drug even though it does not. Liability of the manufacturer and distributor may be based upon breach of express and implied warranties, negligence in discovering the non-equivalency, and fraud and deceit or misrepresentation. It should be noted that situation (3) is not likely to occur since federal law requires testing before marketing of a new drug and any nonequivalency should be evident at that time. Situation (1), where the generic drug if pure has therapeutic equivalency but because of adulteration in a particular batch lacks such equivalency, is more likely to occur.

Where the mistaken belief of therapeutic equivalency is based upon state action, e.g., a generic drug list, there is a possibility that the State may also be held liable in a civil action. The State is immune from tort liability due to its sovereign immunity but has waived immunity for the negligent acts of its employees. Liability of the State is allowed by statute, however, and could be excluded by statute.[63]

It should be noted that state action, e.g., a generic drug list might be indicative of good faith and create an exception for criminal liability under the federal and state drug acts. The defendant's reliance upon state laws in a civil action, however, is probably not a valid defense to strict liability or breach of warranty and is only evidence of due care in a negligence action.

It should be noted that the situations discussed herein are simplified and do not consider the actions of third parties or of the plaintiff which might affect the outcome of any action. Even if held liable, one defendant might then seek indemnity against another person who is ultimately liable, i.e., usually the manufacturer. Generally, the plaintiff would probably seek to hold the pharmacist (or physician) liable since these defendants are more easily reached and would let these defendants seek indemnity against the manufacturer.

E. Amendment of State Laws Relating to Liability Alternatives

State legislation in this area might be designed (1) to remove the prohibition against substitution of generic drugs and leave it to the judgment of the pharmacist, (2) permit substitution except as excluded by a generic drug list, or (3) permit substitution only as allowed by a generic drug list, with variations allowing decisions to be made by the physician, pharmacist, or patient and to immunize against civil and criminal liability accordingly.

In situations (2), (4), and (5) above where injury is caused by negligence resulting in unintentional drug substitution or by failure to give adequate warnings about side effects, and not by the generic drug's lack of therapeutic equivalency, the problem is not one of generic drug substitution. Thus, state legislation affecting generic drug substitution will not affect these three situations, and liability of the parties involved should not be changed.

Situations (1) and (3) above, however, where the generic drug substitute does lack therapeutic equivalency, either because of a defect in the drug or because of its formula, are directly related to the problems of generic drug substitution. It may be necessary in encouraging generic drug substitution to provide some limitation upon the liability of the pharmacist in making the

substitution, whether based upon the pharmacist's own judgment or upon a state generic drug list. It may also be necessary to provide a similar limitation upon physician's liability for the same reasons. Allowing expanded generic drug substitution does not necessarily mean increased liability. A New York study showed that there were no known cases involving liability due to proper substitution of a generic drug and that physician's and pharmacist's liability insurance did not increase as a result of the generic substitution law.[64] It should be noted, however, that the study was completed only about a year after enactment and perhaps with more time liability would have increased.

It is the recommendation of the Office of the Legislative Reference Bureau that any liability limitation be restricted to pharmacists and physicians in situations (1) and (3) above. Drug manufacturers and distributors are not involved in generic drug substitution which occurs at the retail level and limiting their liability would not encourage generic drug substitution but would leave the plaintiff without any person to seek to hold liable. The extent of the pharmacist's and physician's immunity, e.g., absolute, subject to due care, etc. should be made clear. A provision excluding liability of the State may also be necessary.

It should be noted that a limitation upon criminal liability under the state drug act is also necessary should the legislature decide to allow expanded generic drug substitution. Such a limitation will apply only to state law and could not affect the federal drug act.

FOOTNOTES

Appendix I

1. 21 U.S.C. sec. 333; *Hawaii Rev. Stat.*, sec. 328-29.
2. *Hawaii Rev. Stat.*, sec. 328-6(15).
3. 21 U.S.C. sec. 331; *Hawaii Rev. Stat.*, sec. 328-6.
4. 21 U.S.C. sec. 351; *Hawaii Rev. Stat.*, sec. 328-14.
5. *U.S. v. Park*, 421 U.S. 658 (1975); *U.S. v. Guardian Chemical Corp.*, 410 F.2d 157 (2d Cir. 1969); 21 U.S.C. sec. 333; *Hawaii Rev. Stat.*, sec. 328-29.
6. 21 U.S.C. sec. 352; *Hawaii Rev. Stat.*, sec. 328-15.
7. 21 U.S.C. sec. 353; *Hawaii Rev. Stat.*, sec. 328-16.
8. *Hawaii Rev. Stat.*, sec. 328-6(15).
9. 57 Am Jur. 2d *Negligence*, sec. 1 (1971).
10. *Ibid.*, sections 127, 274, and 288; *Hawaii Rev. Stat.*, sec. 663-31.
11. *Ohio County Drug Co. v. Howard*, 210 Ky. 346, 256 S.W. 705 (1923); *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 17 Cal. App.3d 958 (1971).
12. 63 Am Jur. 2d *Products Liability*, sec. 26 (1972).
13. *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 588, 528 P.2d 522 (1974).
14. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 17 Cal. App.3d 958 (1971).
15. *Ibid.*; *Gault v. Poor Sisters of St. Frances Seraph*, 375 F.2d 539 (6th Cir. 1967); *Hamilton v. Hardy*, 549 P.2d 1099 (1976).
16. *People's Service Drug Stores v. Somerville*, 161 Md. 662, 158 A.12 (1932).
17. *Wilcox v. Butt's Drug Stores*, 38 N.M. 502, 35 P.2d 978 (1934).
18. *Krueger v. Knutson*, 261 Minn. 144, 111 N.W.2d 526 (1961).
19. *Pooler v. Stewart's Pharmacies, Ltd.*, 42 Haw. 618 (1958); *Cook v. Hollister Drug Co.*, 13 Haw. 681 (1901).
20. *Hawaii Rev. Stat.*, sec. 662-2.
21. *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 251 Cal. App.2d 689 (1967); 63 Am Jur. 2d *Products Liability*, sec. 75 (1972).
22. *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 588, 528 P.2d 522 (1974); 63 Am Jur. 2d *Products Liability*, sec. 76 (1972).
23. 37 Am Jur. 2d *Fraud and Deceit*, sec. 12 (1968); 63 Am Jur. 2d *Products Liability*, sec. 151 (1972).
24. 63 Am Jur. 2d *Products Liability*, sec. 151 (1972).
25. *Ibid.*, sec. 153.
26. *Ibid.*
27. *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 251 Cal. App.2d 689 (1967); *Crocker v. Winthrop Laboratories*, 512 S.W.2d 429 (1974), citing *Restatement of Torts 2d*, sec. 402B.
28. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 17 Cal. App.3d 958 (1971).
29. 63 Am Jur. 2d *Products Liability*, sec. 123 (1972); *Restatement of Torts 2d*, sec. 402A.
30. *Ibid.*
31. *Ibid.*
32. *Ibid.*
33. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 17 Cal. App.3d 958 (1971).
34. 63 Am Jur. 2d *Products Liability*, sec. 129 (1972).
35. *Grinnell v. Charles Pfizer & Co.*, 79 Cal. Rptr. 369, 274 Cal. App.2d 424 (1969).
36. *Hamilton v. Hardy*, 549 P.2d 1099 (1976); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 251 Cal. App.2d 689 (1967); *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), cert. den. 419 U.S. 1096; *Restatement of Torts 2d*, sec. 402A, comment k.
37. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 17 Cal. App.3d 958 (1971); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 251 Cal. App.2d 689 (1967); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973); *Restatement of Torts 2d*, sec. 402A, comment k.
38. *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super 418, 307 A.2d 449 (1973).
39. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).
40. *Grinnell v. Charles Pfizer & Co.*, 79 Cal. Rptr. 369, 274 Cal. App.2d 424 (1969); *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).
41. *Hawaii Rev. Stat.*, secs. 490:2-313, 490:2-314, and 490:2-315.
42. *St. Luke's Hospital v. Schmalz*, 534 P.2d 781 (1975); 63 Am Jur. 2d *Products Liability*, sec. 7 (1972).
43. *Hawaii Rev. Stat.*, sec. 490:2-313.
44. *Jacobs Pharmacy Co. v. Gipson*, 116 Ga. App. 760, 159 S.E.2d 171 (1967).
45. *Hawaii Rev. Stat.*, sec. 490:2-314.
46. *Ibid.*

47. *Hawaii Rev. Stat.*, sec. 490:2-315.

48. 63 Am Jur. 2d *Products Liability*, sec. 115 (1972).

49. *Berry v. G. D. Searle & Co.*, 56 Ill.2d 548, 309 N.E.2d 550 (1974).

50. *Magee v. Wyeth Laboratories, Inc.*, 29 Cal. Rptr. 322, 214 Cal. App.2d 340 (1963).

51. *Highland Pharmacy v. White*, 144 Va. 106, 131 S.E. 198 (1926).

52. *Davis v. Radford*, 233 N.C. 283, 63 S.E.2d 822 (1951).

53. *Higbee v. Giant Food Shopping Center*, 106 F. Supp. 586 (E.D. Va. 1952).

54. *Hawaii Rev. Stat.*, secs. 490:2-314 and 490:2-315.

55. *Hawaii Rev. Stat.*, sec. 490:2-315.

56. *McLeod v. W. S. Merrell*, 174 So.2d 736 (1965).

57. *Hawaii Rev. Stat.*, sec. 490:2-318.

58. *Hawaii Rev. Stat.*, sec. 490:2-607(3)(a).

59. *Hawaii Rev. Stat.*, sec. 490:2-316.

60. *Ibid.*

61. *Hawaii Rev. Stat.*, secs. 490:2-718 and 490:2-719.

62. 21 U.S.C. sec. 333; *Hawaii Rev. Stat.*, sec. 328-29.

63. *Hawaii Rev. Stat.*, ch. 662.

64. New York, Office of Legislative Oversight and Analysis, *Special Report to Honorable Speaker Stanley Steingut, Assemblyman Harvey L. Strelzen* (1978).

Appendix J

The following letter was sent to the following:

Mr. Roy M. Yamauchi, President
Hawaii Pharmaceutical Association
c/o Payless Drug Store
1505 Dillingham Blvd.
Honolulu, Hawaii 96817

Ms. Florence A. Huntington
Chief Pharmacist
Leahi Hospital
Department of Health
3675 Kilauea Avenue
Honolulu, Hawaii 96816

Ms. Rebecca A. Kendro
Administrative Assistant,
Community Affairs
Hawaii Medical Association
320 Ward Avenue, Suite 200
Honolulu, Hawaii 96814

Mr. Robert F. Miller
Deputy Attorney General
Antitrust Division
Department of the Attorney General
Suite 402
225 Queen Street
Honolulu, Hawaii 96813

Mr. Morris M. Comer
Executive Secretary
Board of Pharmacy
Department of Regulatory Agencies
1010 Richards Street
Honolulu, Hawaii 96813

Mr. Ed Speegle
Manager of Government Affairs,
West Coast
Sandoz Pharmaceuticals
5227 Dredger Way
Orangevale, California 95662

Mr. Roger L. Miller
Manager, Public Affairs
Eli Lilly and Company
555 Capitol Mall, Suite 715
Sacramento, California 95814

Mr. Clarence L. U. Yee
Sales Supervisor
Eli Lilly and Company
117 Poipu Drive
Honolulu, Hawaii 96825

Mr. Crispin G. Nickolas
Regional Director
State Health Affairs West
McNeil Laboratories
1399 Ygnacio Road, Suite #21
Walnut Creek, California 94598

Samuel B. K. Chang
Director

C
O
P
Y

LEGISLATIVE REFERENCE BUREAU
State of Hawaii
State Capitol
Honolulu, Hawaii 96813
Phone 548-6237

January 29, 1979

0916-A

Mr. James K. Asato
Past President
Hawaii Pharmaceutical Association
c/o McKesson & Robins Drug Co.
720 South Street
Honolulu, Hawaii 96813

Dear Mr. Asato:

Please find enclosed a draft of the report on generic drug substitution done by our office. This is a draft for your, or your associate's, review and should be kept confidential until formally released. Please feel free to make any comments on the report, cite errors, or state any objections. Your comments will be considered and revisions made if necessary.

We would like your review to be returned to us by February 14, 1979. Do not hesitate to mark up and return the draft in lieu of a formal reply. If you have any questions, please feel free to contact the undersigned or our Director, Samuel B. K. Chang, at 548-6237.

Thank you for your attention to this request and assistance in the conduct of the study.

Very truly yours,

Calvin Azama
Researcher

CA:my
Enc.

NOTE: Replies received as of February 15, 1979 are included in Appendix K.

Appendix K

REPLIES RECEIVED AS OF FEBRUARY 22, 1979

GEORGE R. ARIYOSHI
GOVERNOR

TANY S. HONG
DIRECTOR

DICK H. OKAJI
LICENSING ADMINISTRATOR

BOARD OF PHARMACY
STATE OF HAWAII
PROFESSIONAL & VOCATIONAL LICENSING DIVISION
DEPARTMENT OF REGULATORY AGENCIES
P. O. BOX 3469
HONOLULU, HAWAII 96801

February 9, 1979

Mr. Calvin Azama
Researcher
Legislative Reference Bureau
State Capitol
Honolulu, Hawaii 96813

Dear Mr. Azama:

Thank you for sending your confidential draft of the report on generic drug substitution for my comments.

Your report was very well done and most comprehensive. I have only a couple of comments which you may wish to consider.

1. Name of manufacturer, packer or distributor need not be included on prescription label of the container given to the patient. This serves no purpose. Requiring name of manufacturer, packer or distributor on the original prescription shall serve for documentation, if follow-up is needed.

2. Having a state drug formulary as a requirement for generic equivalency dispensing may prove to be a very costly administrative burden. Have you researched the cost benefits of those states that have a state formulary?

   May I suggest you consider recommending using the FDA list of approved generic and bio-equivalent drugs. The cost benefits should be favorable.

3. I feel the physicians, pharmacists and public need to have some documentation that a number of generic drugs from different packers and distributors are manufactured by same manufacturer.

May I recommend that it be made mandatory to have all prescription drugs bear information of the actual manufacturer on the label and the name of the packer or distributor. This will facilitate acceptance of generic prescribing and public confidence in the generic issue. I understand that some states like California already have this regulation.

Sincerely,

for (Mrs.) Nellie S. L. Chang
Chairman, Board of Pharmacy

NSLC:pl

HAMILTON, GIBSON, NICKELSEN, RUSH & MOORE
ATTORNEYS AT LAW
20TH FLOOR HAWAII BUILDING
745 FORT STREET · HONOLULU, HAWAII 96813

DON C HAMILTON
FRANK D GIBSON JR
HAROLD W NICKELSEN
DWIGHT M RUSH
WILLSON C MOORE JR.
ANTHONY B CRAVEN
EDMUND BURKE
WILLIAM R LOOMIS
WAYNE M SAKAI
ANTHONY Y K KIM

MICHAEL F McCARTHY
KEN HARIMOTO
WILLIAM A STRICKLIN
RICHARD C SUTTON JR
G RICHARD MORRY
WALTER BEH II
RICHARD K INGERSOLL
HOWARD F McPHEETERS
EDWARD M SANPEI

ROBERT BRUCE GRAHAM JR
D SCOTT MacKINNON
JOHN D THOMAS JR
MICHAEL L FREED
WILLIAM A BORDNER
WILLIAM H GILARDY JR

STEPHEN K C MAU
JAMES T ESTES JR
KATHLEEN KIM COGHLAN
EARL T SATO
JERROLD Y CHUN
MARILYN P LEE

M B HENSHAW 1869-1970
HAROLD W CONROY
OF COUNSEL

CABLE "LAWYERS HONOLULU"
TELEX 7430043
TELEPHONE (808) 521-2611

February 15, 1979

Mr. Calvin Azama
Legislative Reference Bureau
State Capitol Building
Honolulu, Hawaii 96813

FEB 19 1979

Re: Generic Drug Substitution Feasibility for Hawaii Report

Dear Calvin:

We are the attorneys in Hawaii for the Pharmaceutical Manufacturers Association. Following up on my telephone conversation with you, we have the following comments on your report entitled Generic Drug Substitution: Feasibility for Hawaii:

(1) The Lannet case: In order to market a new brand name drug, a manufacturer must submit an NDA. Manufacturers of generics, on the other hand, need only submit an ANDA. Unlike NDA's, ANDA's need not be accompanied by bioavailability evidence. FDA's attempt to require manufacturers of generics to provide bioavailability data was rejected by the U. S. Circuit Court of Appeals for the Third Circuit in the Lannett case. In its legal briefs seeking a rehearing the FDA stated that the Lannett case:

> ". . . significantly curtails the FDA's ability to insure that generic drugs will be safe and effective as name-brand drugs. A 'pioneer' drug and its me-too emulator may appear to be identical when subjected to chemical and sterility analysis. Both products may satisfy the standards set forth in recognized compendia. Nevertheless, the me-too may release its active ingredients not at all, too slowly to achieve therapeutic blood levels, or so rapidly that the patient experiences toxicity when a rapid release product is substituted for a moderate release product. Only specially designed tests conducted on each manufacturer's product can determine whether the me-too drug is bioequivalent to the pioneer drug."
> (Emphasis added.)

We suggest that the Lannett case be discussed in your section entitled New Drug Application and Abbreviated New Drug Application that begins on page 15 of the preliminary draft of your report. Understanding the Lannett case is crucial if the Legislature is to believe FDA's public claim that they can provide a safe formulary.

(2) Survey of the 100 most commonly prescribed drugs: On page 55 of the preliminary draft we suggest you include the following:

> "(4) Only three (3) drug products are substitutable under all eight state formularies. These three drugs accounted for 3.1% of all prescriptions for the 100 most commonly prescribed drug products."

It is our position that the above fact is of import to two issues, safety and cost savings. First, the art of determining what drug products are substitutable can hardly be called an exact science. If it were an exact science, one would expect a greater consensus regarding what is substitutable. Second, potential cost savings are dependent on whether commonly prescribed drugs are substitutable.

(3) Liability: The real issue of liability with respect to drug substitution is whether the formulary is defective. For purposes of analysis, one must assume that the drug product was manufactured properly, but that the formulary sanctioned the substitution of a non-therapeutically equivalent drug product for a prescribed name brand drug product. In this event, the generic drug manufacturer will not be liable unless it warranted that its drug product was substitutable for the prescribed name brand drug product.

Thus, Appendix I, "Legal Aspects: Liability in Production and Marketing of Drugs" fails to address itself to the real issue.

One final point on liability. Any decision with respect to pharmacist or physician liability should not be dependent on whether releasing them from liability will encourage substitution per se, but, rather, whether it will protect the consumer. Pharmacists and physicians are professionals. As such, consumers rely upon their professional judgment, and they, in turn, expect a free hand in exercising their professional judgment. That is how it should be. However, "freedom to exercise professional judgment" is just the other side of the coin of "responsibility for exercising professional judgment." If a professional is released from liability, the consumer loses the safeguard that the professional will exercise his or her judgment carefully and non-negligently. In other words, one cannot exist without the other.

(4) Comments on Chapter 7, Recommendations: We suggest that your report emphasize that the cost of administering and implementing a generic drug substitution law should not outweigh the projected actual savings, if any, that such a law would bring to the consumer. Unless this threshold issue is met, it is moot to recommend what kind of formulary Hawaii should have, whether

containers should be labeled, etc. Also, in determining the cost of administering and implementing a generic drug substitution law, the costs of potential lawsuits against the State should be calculated in.

FTC's estimation of $1.2 million in savings for Hawaii consumers should be examined. The $1.2 million figure is for projected "potential" savings, which may be nowhere close to "actual" savings. As stated on page 29 of the draft, "cost-savings do not approach the potential maximum."

One last point: market factors and common business practice may preclude any cost savings:

(1) If it is true that the large manufacturers presently produce some of the drugs that small distributors sell as generics, large manufacturers could stop that practice if they were losing money. People only go into business to make money, not to lose money.

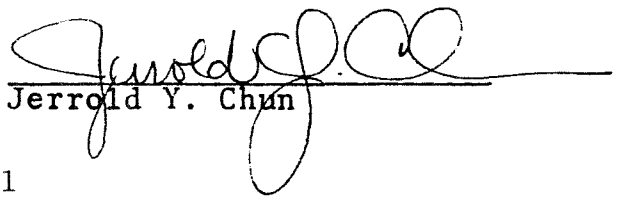
(2) At present, it costs an average of $55 million to discover, develop, and bring to market a new drug entity. Among the drugs recently developed are a revolutionary treatment for duodenal ulcers, a vaccine against pneumococal pneumonia, an agent to dissolve pulmonary blood clots, and several anticancer compounds. The present practice of "research" manufacturers is to spread the costs of research equitably among many hundreds of drug products.

If state laws force the use of drugs made by "imitator" manufacturers, "research" manufacturers will be faced with three alternatives: (1) lose money, which one can assume they will not take sitting down, (2) reduce research, or (3) make the price of new drugs reflect the costs of research. If the third alternative is chosen, the overall cost savings may be negligible, if any. Consumers who need the old drugs will save money; but consumers who need the new drugs that are protected by patents will have to pay more. The overall net effect may be that the consuming public will not save anything.

If you have any other questions regarding PMA's comments on your report, please contact me.

Very truly yours,

HAMILTON, GIBSON, NICKELSEN,
RUSH & MOORE

By 
Jerrold Y. Chun

JYC:rw

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

16 FEB 1979

Mr. Calvin Azama
Legislative Reference Bureau
State Capitol
Honolulu, HI 96813

Dear Mr. Azama:

Enclosed are copies of our staff report, model law, and the recent University of Florida study. As you also requested, I am presenting in writing the comments I made by telephone on your preliminary draft report.

On page 22, the draft discusses "two contradictory points" in the OTA Report, the first point being that "the quality of drug products is not guaranteed by existing standards and regulations". I don't think the two points are contradictory, but rather that they are different, which probably explains why the Report has been cited both by opponents and by proponents of substitution laws. I also think it should be made clear that "existing standards" refers to the standards of 1974. Since that time FDA has implemented several of the recommendations made by the OTA Panel, including the issuance of bioavailability/bioequivalence regulations, revised Good Manufacturing Practice regulations, and a list of therapeutically equivalent drug products.

On page 37, the draft notes that similar data are not available from Wisconsin. The Goldberg researchers have announced preliminary data showing a substitution rate within the Wisconsin formulary of 18-20% (see text at footnote 12 on page 186 of FTC Staff Report). The Florida study provides additional data concerning substitution rates and actual consumer savings.

On page 43, the draft refers to a Goldberg study report about the percentage of generically written prescriptions. I believe that the Goldberg study found that 20% of new multisource prescriptions were written generically. Thus, there may be little difference with the Pharmacy Times figure that 12.5% of all new prescriptions were written generically.

On page 67, the draft notes that apparently no liability suits have been brought against pharmacists for substituting. Equally significant perhaps, we found no evidence that any pharmacist had ever been held liable for filling a generically written prescription, an activity pharmacists have long been engaged in and one which also requires the pharmacist to select the drug source (Chapter IX.E. of the FTC Staff Report discusses the liability issue).

On page 68, I believe the $12.5 million figure refers to "drugs and drug sundries" and should read $12.5 billion.

I believe there are some relatively minor differences between the draft's characterization of certain state laws in Chapter 6 and our table of state laws (pages 177-182 of the FTC Staff Report).

On page 79, the draft recommends that the formulary committee consider several economic factors, such as financial stability and insurance coverage, as well as scientific criteria, such as bioequivalence data. I would raise several concerns about this issue. First, any positive formulary potentially can restrict competition, and the inclusion of financial criteria may increase that potential. Similarly, restricting all refills (even of items certified as therapeutically equivalent)to the product originally used to fill the prescription may allow a dominant firm to resist price competition once it has "locked in" pharmacists (see page 162 of the FTC Staff Report). Second, the inclusion of these additional criteria may significantly increase the administrative burdens of the formulary committee; for example, this information presumably would not be available from FDA but would have to be obtained from each manufacturer. Third, unlike bioequivalency determinations, these financial criteria do not relate to the safety and quality of substitutable drug products but rather to business decisions of the type pharmacists commonly make for both substituted and nonsubstituted prescriptions.

On page 81, the draft recommends absolving pharmacists and physicians of liability even in some cases in which they might otherwise be held negligent (for example, if the phramacist knew there was a defect in the substituted product even though it was listed on the drug formulary). You may wish to determine whether any limitation on liability would be constitutional under state law, and to consider whether a liability provision instead might define rather than limit liability. The purpose of a definition or restatement of liability would be to reassure health professionals that they will not be exposed to an unreasonable standard of liability.

Appendix I of the draft also discusses legal liability at great length. For example, at page 183 it states that strict liability clearly applies to the pharmacist. We were unable to find any cases indicating that strict liability or implied warranties have been applied to pharmacists; thus, it is not clear whether these legal theories would apply to drug substitution by the pharmacist (Chapter IX.E. of the FTC Staff Report, especially pages 266-67, discusses liability). If these forms of liability do apply, they may well apply to all instances of drug dispensing, whether or not substitution occurs. In any event, there are ways for pharmacists to offset any such liability.

If we can provide any additional information or assistance, please let me know. I also would appreciate receiving a copy of your final report when it becomes available.

Sincerely,

Peter D. Holmes

Peter D. Holmes
Staff Attorney and
Project Leader

Enclosures