Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws

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NOTE

CONSUMER PROTECTION AND PRESCRIPTION DRUGS: THE GENERIC DRUG SUBSTITUTION LAWS

INTRODUCTION

Special legislation is often necessary to protect consumers when they lack the knowledge and bargaining power to deal effectively with the suppliers of goods.¹ Most consumers know very little about medicines; upon receiving a prescription, most people do not know what has actually been prescribed and certainly cannot determine if they have been supplied with the correct drug. They must trust the doctor and pharmacist to supply the proper drug.² Thus consumer protection legislation is particularly necessary in the field of prescription drugs.

In recognition of this vulnerability there is much drug legislation designed to protect the unknowledgeable consumer. In 1938 the Federal Food, Drug, and Cosmetic Act³ was passed. It protected against adulterated and misbranded⁴ drugs and

₁ See generally S. Morganstern, Legal Protection for the Consumer (2d ed. 1978).
² When the consumer reposes a high level of trust and confidence in the expertise of a provider of goods or services, the law commonly treats this vendor in a fashion different from the manner in which it treats other suppliers of goods and services. Accordingly, the law regulates the professions to a greater extent than other occupations. This scrutiny stems largely from the inability of the public to protect itself adequately in a situation where its members engage the professional on the understanding that he will put their interests before his own. Because the professional is deemed to be a fiduciary, the rule of caveat emptor does not apply. This is clearly the case with the professional pharmacist. He stands as a fiduciary for most transactions, and particularly in the case of prescription drugs, the public must trust the ability of the pharmacist to dispense properly those commodities on which health and life depend.
provided, among other things, performance standards for established\(^6\) and new\(^7\) drugs. Most states, in turn, adopted at least some type of pure food and drug legislation.\(^8\) In addition, every state, in an effort to ensure competence and high standards, has statutes regulating the pharmacies and pharmacists who dispense the drugs.\(^9\)


Pharmacy laws generally provide for:

1. The educational and experience qualifications which pharmacists must meet at the time of examination or registration.
2. The agency, usually known as the State Board of Pharmacy, charged with the enforcement and administration of the law.
3. The granting of permits for the conduct of a community pharmacy or drug store. In most states permits are issued for one year and application must be made for their renewal.
4. The minimum of professional and technical equipment and apparatus which the pharmacy must, at all times, possess. The [United States Pharmacopeia] and the [National Formulary] are generally included in this requirement.
5. Periodic re-registration of pharmacists. In most states certificates of registration are granted for the period of one year.
6. The conditions under which certificates of registration or store permits may be canceled or revoked.
7. The prominent display of the certificates of registration in the store or pharmacy in which the holder is employed.
8. Penalties for violations. Infractions of pharmacy laws are punishable by fines in most instances.
9. Reciprocal registration. A pharmacist licensed by examination in one state may, by conforming to more or less nominal rules, become registered in another state, the latter registration being without examination.
10. The discretion vested in boards of pharmacy. While the Board is authorized to make rules and regulations for the enforcement and administration of the pharmacy law, such rules and regulations must be strictly in accord with the expressed or implied purposes of the law. The Board is an administrative, not legislative, agency. It may not exercise any power or authority not clearly delegated to it, or which by reasonable implication is necessary to the proper functioning of the pharmacy law.
11. The sale of proprietary and patent medicines, and commonly used household and domestic remedies by dealers other than pharmacists. As a rule, such dealers are unrestricted in the sale of preparations falling in these classifications, although in some states permits by the Board of Pharmacy are required.

These measures have provided protection for the consumer as to *quality*, yet they have failed to protect the consumer as to *value*. Drugs received may be of high quality but are they actually worth the high price the consumer is paying? The consumer can do very little about prescription drug prices.\(^{10}\) Physicians prescribe certain drugs, often by brand name, and, in many states, the pharmacist must supply *that* brand of drug.\(^{11}\) Even if permitted to substitute, many pharmacists do not substitute lower priced drugs. Under these conditions, consumers could save money on drugs only by comparison shopping at various pharmacies. Such a practice is not only impractical since prescription drugs are not accessible to shoppers, but it would probably result in only a small savings.

To provide the consumer with some protection as to the value of drugs purchased, many states have enacted generic drug substitution laws. In fact, legislation of this type has mushroomed in recent years.\(^{12}\) This Note will examine the nature of generic drugs and the types of laws that have been enacted to encourage their use. Attention will be focused on the structure of these laws and some of the problems with them. Finally, other means of protecting the consumer in the field of prescription drugs will be evaluated.

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Adding to the problem of high price is the fact that only a small number of firms produce prescription drugs. Approximately 95% of all the drugs sold in the United States come from 136 manufacturers and over 60% of the 500 largest selling drugs are produced by only 24 firms. Green, *Welfare Losses From Monopoly in the Drug Industry: The Oklahoma 'Antisubstitution Law*, 5 *Antitrust L. & Econ. Rev.*, No. 3, 97, 100 (1972).

11 It is for this reason that drug manufacturers have traditionally aimed their advertising at physicians rather than the actual consumer. Willig, *supra* note 2, at 16.

12 As one commentator put it:

I am convinced that consumer protection is not a passing fad; it has been our chief concern in the food and drug field for many years and will continue to be so. As we move into the 70's, and as the voice of the consumer is heard more and more throughout the land, it is the obligation of all of us to harken to that voice. It is the obligation of all of us to work to preserve and protect the consumer by giving him a better and more informed choice in a marketplace of safer, more effective, better quality and less hazardous products.

I. GENERIC DRUGS

Any particular drug ordinarily has three names by which it is identified. The first is the chemical name which describes the structure of the drug in chemical terms. The second is the nonproprietary or generic name which indicates the chemical class to which the drug belongs. Finally, there is the trademark or brand name which is a registered name of the manufacturer. Drugs are like most other consumer goods in that the same generic drug is often made by several different manufacturers and simply given their respective brand names. As with other goods, drugs sold under a brand name generally cost more than those sold under the generic names. In addition, there are often large price differences between various brands of the same drug and between brand name and generic varieties of the same drug. The generic drug substitution laws are de-

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13 REMINGTON'S PHARMACEUTICAL SCIENCES 1309 (15th ed. 1975). For example, the names of one drug are: "Aspirin," the nonproprietary or generic name; "acetylsalicylic acid," the chemical name; and "Bayer," the trademark or brand name.

Thus, the term "generic" refers to "a class of chemical substances having the same biological properties." Feldmann, Brand Versus Generic Drugs, 9 J. AM. PHARM. A. 8 (1969). Drugs sold under a generic and not a brand name are referred to as "generic drugs" or "generics."

14 For example, in the grocery line canned corn (generic name) is manufactured by several different companies under such names as Green Giant and Libby's, but the basic product is still the same. In the drug line the drug ampicillin (generic name) is manufactured by several different companies under such names as Amcill, Omnipen, Pen A, and Polycillin (brand names).


16 A sample of the average wholesale prices of various brands and the generic form of the drug Ampicillin are set out below.

<table>
<thead>
<tr>
<th>AMPICILLIN (250 mg. capsule form)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Alpen</td>
</tr>
<tr>
<td>Amcill</td>
</tr>
<tr>
<td>Amperil</td>
</tr>
<tr>
<td>Omnipen</td>
</tr>
<tr>
<td>Pen A</td>
</tr>
<tr>
<td>Penbritin</td>
</tr>
<tr>
<td>Pensyn</td>
</tr>
<tr>
<td>Polycillin</td>
</tr>
<tr>
<td>Principen</td>
</tr>
<tr>
<td>SK-Ampicillin**</td>
</tr>
</tbody>
</table>
signed to allow the consumer to take advantage of these differences in prices of the same drug. To understand how these new laws operate it is first necessary to understand laws which prevent the consumer from taking advantage of these differences in drug prices.

A. The Antisubstitution Laws

Originally, a substitution referred to the use of a drug with a different generic or chemical makeup than the one prescribed. It was widely accepted that such substitution was dangerous and should be prohibited. However, substitution has come to mean "[a]ny act resulting in a variation between the prescription pharmaceutical requested and that pharmaceutical dispensed." In the early 1950's the drug industry began pushing for antisubstitution laws that would include a prohibition against the substitution of one brand of drug for another. The American Pharmaceutical Association joined in supporting these laws, and by 1972 forty-seven states had laws making it illegal to substitute even a chemically equivalent drug.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supen</td>
<td>Reid-Provident Labs</td>
<td>11.95</td>
</tr>
<tr>
<td>Totacillin</td>
<td>Beecham Labs</td>
<td>13.75</td>
</tr>
<tr>
<td>Vampen</td>
<td>Vanguard Labs</td>
<td>8.00</td>
</tr>
<tr>
<td><strong>Generic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Bocan Drug Co.</td>
<td>6.75</td>
</tr>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>Bell Pharmacal</td>
<td>6.46</td>
</tr>
<tr>
<td></td>
<td>Paramount Surgical Supply</td>
<td>5.25</td>
</tr>
<tr>
<td></td>
<td>Pure-Pac Pharmaceutical</td>
<td>6.31</td>
</tr>
<tr>
<td></td>
<td>Zenith Labs</td>
<td>6.00</td>
</tr>
</tbody>
</table>

*only available in 500

**Manufactured by Bristol

Prices are from Drug Topics Red Book (1978). All of these brands were found to be therapeutically equivalent by the Kentucky Drug Formulary Council. 902 Ky. Ad. Rgs. 1:020 (1978). See notes 32-40 and accompanying text infra for an explanation of therapeutic equivalency.

[17] Willig, supra note 2, at 2. The substitution of one drug for another is not a recent problem; the practice dates from the 8th century B.C. Id., at n.3.


[20] Chemical equivalents are defined as "[d]rug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendial standards." Office of Technology Assessment, Drug Bioequivalence Study Panel, Drug Bioequivalence, vi (1974) [hereinafter cited as
for the particular brand named in the prescription.  

As a result, the drug companies aimed advertising campaigns directly at doctors in the hope that once doctors became familiar with a brand name it would become a habit to write all future prescriptions for that drug by brand, rather than generic, name. As long as the prescription was written for a particular brand no other brand or even the generic form could be used to fill that prescription. However, if a doctor wrote the prescription using the generic name of the drug, then any company's product could be used. The campaigns were very successful for the drug companies and by 1972 approximately ninety percent of all prescriptions were written for the brand name drugs.

The cost of this advertising by brand name manufacturers was, of course, reflected in the increased cost of their drugs. It is for this reason that the use of generic drugs became attractive as a means of reducing drug prices. The first attempt to make use of generic prescribing resulted in the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act. These amendments sought, among other things, to reduce drug prices by encouraging physicians to prescribe by generic rather than

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Drug Bioequivalence. The present compendial standards refer to standards for drug products listed in the United States Pharmacopeia and the National Formulary. Id. See Green, supra note 10, at 108. For example, one antisubstitution law reads as follows:

The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription [is unprofessional conduct for which the pharmacist's license can be revoked]. Mo. Ann. Stat. § 338.055 (5) (Vernon Supp. 1979).

The drug companies were aided in their campaign by the fact that for the 17-year life of the patent on any new drug only the patentholder's brand was available and the physicians would become accustomed to only writing prescriptions for that brand. When the patent expired other companies started making and selling the drug under its generic name but the doctor's habit of writing prescriptions for the brand name was hard to break. Another incentive to prescribe by brand name is the fact that brand names are often simpler than generic names. For example, the brand name “Dexedrine” is much easier to write than the generic name of “dextroamphetamine sulfate.”


It has been estimated that large drug manufacturers' advertising expense amounts to 24% of every sales dollar. Willig, supra note 2, at 16.

brand name.²⁶ A movement then began to repeal the antisubstitution laws and allow the pharmacist to exercise professional expertise in selecting which manufacturer’s product to use, regardless of which brand the prescription named. This was the beginning of the generic drug substitution laws in the early 1970’s. However, a problem arose in connection with antisubstitution laws: Even though generic drugs might be more economical, are generic drugs really equivalent to their brand name counterparts?

B. The Problem of Equivalence

Consumers often hesitate to buy a cheaper, non-brand name product for fear that the lower price is due to poorer quality. This fear is the basis for some of the opposition to substitution with generic drugs. Many people feel that the generally smaller firms that manufacture generic drugs do not provide for the quality controls of the larger brand name manufacturers, and may not follow good manufacturing practices required by the official compendia.²⁷ A study on drug product safety concluded: “Drug products from different sources may differ in quality in several respects. These differences, individually or collectively, may lead to substantial differences in therapeutic effect and/or safety.”²⁸ While this does not prove


²⁷ Generic name prescribing was encouraged by assuring physicians that all drugs manufactured in the United States met a specified standard of quality whether they were made by a large brand name manufacturer or a small generic name manufacturer. Also, generic names were brought to the attention of physicians by requiring that all advertising carry the generic as well as any brand name. Id.

²⁸ See Note, supra note 23, at 889-97.

Two groups of drug manufacturers have been identified: (1) The brand name firms which provide full service and do their own research and development, and (2) the “marginal” operators who do not do their own research but simply imitate previously marketed drugs. See Feldmann, supra note 19, at 377. A compendium is an official source of information regarding strength, quality, purity, packaging and labeling of drugs.

²⁷ AMERICAN PHARMACEUTICAL ASSOCIATION ACADEMY OF PHARMACEUTICAL SCIENCES, Drug Product Quality, 10 J. AM. PHARM. A. 107, 116 (1970). In addition, it is feared
that generic drugs are of a lesser quality than brand names, it
does illustrate that there are differences in manufacturing
which affect the usefulness of the drug. Supporters of generic
drug substitution have pointed out that the size of a company
does not necessarily indicate the quality of its products. Senator Gaylord Nelson pointed out that “some of the best-known
drug companies have violated—some repeatedly—the good
manufacturing practices (GMP) provisions of the law." No
widespread difference between the products of large brand
name manufacturers and small generic name manufacturers
has been documented.

While the debate over the relative quality of generic drugs
continued, a more serious problem in the movement toward
substitution was recognized in the early 1970's: bioequiva-

cency. It was discovered that "some drugs may be 'generically

that the smaller manufacturers may have so few assets as to be substantially judgment
proof from any liability they may incur on account of their drugs.

It has been suggested that pharmacists may oppose generic drug substitution on
the ground that they may incur liability in making such substitutions. See Note, supra
note 23, at 897.

Feldmann, supra note 19, at 379. For example, one of the largest drug manufac-
turers in the United States was criticized by a Senate subcommittee for its "extremely
poor manufacturing practices that resulted in numerous mixups, recalls, adulterated
and misbranded products." Id.

Big Boost For Generic Drugs, Drug Topics 14 (Dec. 15, 1977). However, the
president of the Pharmaceutical Manufacturers Association stated that quality may
vary depending on manufacturing know-how. Id.

Donald Kennedy, a Food and Drug Administration commissioner, has been
quoted as saying that there is no evidence of widespread differences between the
products of large and small firms, or between brand-name and generic-name products.
Big Boost For Generic Drugs, Drug Topics 18 (Dec. 15, 1977).

In order to understand the bioequivalency problem, some basic definitions are
necessary.

Two drugs are chemically equivalent when they contain the same amount of the
same active ingredients. As explained in note 20 and accompanying text supra generic
and brand name drugs are chemically equivalent.

The bioavailability of a drug refers to a measurement of the rate and extent to
which an administered drug reaches general circulation in the blood stream. This is
often indicated by means of a graph showing the serum level of the drug over a period
of time.

Two chemically equivalent drugs are also bioequivalent if when administered in
the same amount to the same individual they result in essentially the same bioavaila-

Finally, two chemically equivalent drugs are therapeutically equivalent if when administered in the same amount to the same individual they result in essentially the
same therapeutic response. See Drug Bioequivalence, supra note 20, at vi; Remington's Pharmaceutical Sciences 1368 (15th ed. 1975).
equivaiuent' but 'therapeutically nonequivalent.' That is, two drugs that have the same chemical ingredients may not have the same effectiveness in treating a disease or condition. Most drug products are mixtures of active and inert ingredients that go through a complicated manufacturing process before reaching the form in which they are sold. Even small differences in this manufacturing process may result in differences in the therapeutic efficacy of the final drug products. For example, two drugs may have the same active chemical ingredients but, because of differences in the inert ingredients or manufacturing techniques, have different dissolution rates. Thus, one of the drugs would dissolve and start working before the other. In situations where the speed of a drug is important, differences in the dissolution rate could be critical. Therefore, the faster acting drug would be more therapeutically effective.

The difference in therapeutic efficacy usually corresponds with a difference in the bioavailability of the two drugs. Differences in bioequivalency can result even though the manufacturers have complied with good manufacturing practices. Two drugs can meet all the standards in the official compendia and still vary in bioavailability. As a government study on drug bioequivalency concluded:

Current standards and regulatory practices do not insure bioequivalency for drug products.

Since the studies in which the lack of bioequivalency was demonstrated involved marketed products that met current compendial standards, these documented instances constitute unequivocal evidence that neither the present standards for testing the finished product not the specifications for materials, manufacturing processes, and controls are adequate

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33 REMINGTON'S PHARMACEUTICAL SCIENCES 1309 (15th ed. 1975).
34 For an explanation of bioavailability see note 32 supra.
35 The reason why these generic products exhibit varying blood levels [bioavailability] is a result of complex manufacturing techniques required to put the raw drug in a final dosage form. Most drugs are not administered in the form of a simple drug entity, but more often as complex mixtures of the drug with various other ingredients required to make a precise, effective, stable, and convenient dosage form. There are as many as thirty-two different factors which can affect the efficacy of a drug.
Note, supra note 23, at 892 (footnotes omitted). See also REMINGTON'S PHARMACEUTICAL SCIENCES 1309 (15th ed. 1975).
to insure that ostensibly equivalent drug products are, in fact, equivalent in bioavailability.

Present compendial standards and guidelines for Current Good Manufacturing Practices 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.38

The problem is, again, not just the quality of drugs, but also the therapeutic inequivalency of the same drug produced by many different manufacturers, or, indeed, the same drug as made by one manufacturer at different times.

This makes substitution harder because it is very difficult to determine when two drugs are therapeutically equivalent. Therapeutic equivalency can only be conclusively determined from clinical tests which measure how a person reacts to certain drugs. Such tests are practically impossible to conduct accurately. Therefore, the general practice is that bioequivalence tests are conducted and it is assumed that if two drugs are biologically equivalent then they are therapeutically equivalent.39 However, such an assumption is not necessarily correct. “The critical relationship between bioavailability measurements and therapeutic efficacy is in most cases still ambiguous.”40 Even if the correlation between bioequivalency and therapeutic efficacy is accepted, there is still no general source of bioavailability data on every drug. Bioavailability tests are not included in the compendia because pharmaceutical scientists can not agree on the standards.41 It is possible to seek bioavailability data from the manufacturer of the drug, but most manufacturers’ tests differ so that comparison of results for different products is almost impossible.42 Given the increas-

36 Drug Bioequivalence, supra note 20, at 11, 12, 25.
37 Remington’s Pharmaceutical Sciences 1310 (15th ed. 1975). “Thus, if two preparations are generally equivalent and yield similar blood absorption and urinary excretion curves for the active ingredient after administration, they are assumed to be therapeutically equivalent and to elicit similar pharmacologic effects.” Id.
39 Feldmann, supra note 13, at 12.
40 Individual practitioners had often requested bioavailability data from manufacturers, only to find that the information provided raised more questions than it answered. Few studies were parallel in any way; each involved
ing recognition of the importance of bioequivalency of drug products, much more testing and research is needed.

This, then, was the major problem faced by those who wanted to repeal the antisubstitution laws. If substitution is allowed, how can the pharmacist and consumer be assured that the substituted drug is truly equivalent to the drug originally prescribed?\(^4\) Generic drug laws had to incorporate consumer protection against non-equivalent drugs as well as protection against high prices. Yet, generic drug laws could not be expected to solve the therapeutic equivalency problem since equivalency is a problem even for brand name drug products.\(^4\)

### II. THE GENERIC DRUG SUBSTITUTION LAWS

#### A. In General

Between 1972 and 1979 thirty-one states and the District of Columbia\(^4\) abandoned their antisubstitution laws and en-
acted various types of laws permitting substitution. Although these laws have many common characteristics, there are significant differences among them. Two characteristics serve to distinguish "generic drug" laws: the degree of permissiveness in making substitution and the method of designating which drugs are equivalent for substitution purposes (the formulary).45

1. The Degree of Permissiveness in Substituting

Basically there are two types of generic drug laws—permissive and mandatory.46 While this may appear to be a fairly clear cut distinction, the various state statutes actually form a continuum between these two extremes. No state provision is totally mandatory, but the states that are closest to the mandatory pole are Kentucky,47 Florida,48 Rhode Island,49 Vermont,50 and Wisconsin.51 The statutes in these states provide that a pharmacist shall substitute a lower price equivalent drug. While this seems like a mandate that the consumer shall always receive the lowest cost equivalent drug available.


"These laws appear to have acquired the popular name of "generic drug laws" even though a more technically correct name may be "drug substitution laws."

46 The formulary system is a process whereby a group of drug experts determines which drugs may be safely used as substitutes for a particular drug. Thereafter any prescription for that particular drug may be filled with any one of the drugs on the formulary list of substitutes. This formulary system is a means of getting around the problem of nonequivalence.

The formulary system is also often used in large hospitals where prescription forms bear legends consenting to substitution and a committee of physicians, administrators and pharmacists determine what drugs will be on the hospital formulary. Willig, supra note 2, at 6.

47 Permissive laws allow pharmacists to substitute but do not require them to do so. Mandatory laws require pharmacists to substitute and thereby deny them any choice.

KRS § 217.822 (1977). For a more detailed discussion of the Kentucky law see notes 115-30 and accompanying text, infra.

whenever having a prescription filled, that result does not always follow. Two of these statutes—Kentucky’s and Florida’s—appear to have loopholes. These statutes require substitution of lower price drugs only if the original prescription is written for a brand name drug. Thus, if the original prescription is written by generic name the pharmacist may fill it with any manufacturer’s form of that drug, not necessarily the drug with the lowest cost. While the importance of this loophole may be slight given the small number of prescriptions that are written generically, it nevertheless represents a temptation to unscrupulous druggists that could easily have been avoided. Actually this temptation to use a higher price generic may be small given the competition between pharmacies. However, the states with more mandatory provisions appear to have taken the position that competition is not sufficient to ensure the use of lower cost drugs. If this is their position then they should require the use of the lowest cost equivalent when the prescription is written for the generic name drug as well as when it is written for the brand name. Wisconsin avoids this problem in part by simply stating that every prescription shall be filled with a lower than average cost equivalent. Vermont provides the most benefit for the consumer by providing that if the prescription is by either the generic or brand name the pharmacist shall select the lowest priced equivalent drug. Although the statutes of these states are the closest to mandating substitution, they all provide an exception when the prescriber specifies that no substitution should be made. In addition, the

3 “Where the physician writes the prescription using only the generic designation, the pharmacist is permitted to select any company’s product.” Note, supra note 23, at 888.
4 The price difference may be significant even among the generic manufacturers. See note 16 supra for an example of the variation.
5 Approximately 10% of new prescriptions are written generically, but the number is increasing. See How Pharmacists’ Generic Preferences Have Changed, 172 Am. Druggist 23 (1975).
6 It is ironic that a physician who writes a prescription for a drug by its generic name may end up costing the consumer more than if it had been written for a brand name.
7 See Wis. Stat. Ann. § 450.075 (2) (West Supp. 1978). Note that this statute only requires a lower than average cost, not the lowest.
9 See Fla. Stat. Ann. § 465.30(2) (West Supp. 1978); KRS § 217.822 (2) (1977);
consumer may request that substitution not be made.60

The next group of statutes along this mandatory-permissive continuum also requires that substitution of a less expensive drug shall take place unless the prescribing physician indicates otherwise. This type of statute works very much like the first group in that unless substitution is expressly prohibited by the physician, it is required—the pharmacist has no choice. Yet, these statutes61 are different in that they force the physician to either consent to substitution or specify that it should not take place. All prescription forms are required to have two signature lines—one indicating that substitution is required and the other indicating that substitution is not allowed.62 Whenever physicians write a prescription they must make a choice in signing the prescription as to whether substitution is required. Apparently the purpose of the two signature lines is to make the prescriber consciously consider whether substitution should be permitted in that particular case. The danger with this is that a physician may sign one line or the other out of habit.

The next type of generic drug statute also uses the procedure of requiring two signature lines on all prescriptions; however, these statutes are more permissive: one signature line indicates that substitution is not allowed and the other that the pharmacist may substitute.63 Thus the pharmacist does not have to substitute the lower cost generic drug. Again, this type

60 See, e.g., the Pennsylvania statute which states: "The bottom of every prescription blank shall be imprinted with the words 'substitution permissible' and 'do not substitute' and shall contain two signature lines for the physician or other authorized prescriber's signature on the line immediately above the chosen option." PA. STAT. ANN. tit. 35 § 960.3(A) (Purdon 1977).


Georgia also requires that the lowest priced equivalent be used when the prescription is written generically. GA. CODE ANN. § 79A-408.2 (b) (Supp. 1978).
of statute permits an unscrupulous pharmacist to choose the higher price brand name drug and thus defeat the purpose of the law: to lower drug costs to the consumer. However, states having permissive substitution statutes apparently feel that the competitive market provides sufficient incentive for pharmacists to make use of lower price generic substitutes. Indeed, it may be preferable to leave the final decision regarding substitution to the pharmacist, who has had five years of training in pharmacology and is probably in a better position to compare the various forms of a drug than a physician with only a limited amount of training in this field. This type of statute allows a pharmacist freedom to exercise professional judgment while also providing an easy veto for the prescriber who feels that no substitution should take place.

The largest group of state generic drug laws simply permits substitution unless the prescriber indicates in some manner that substitution is not allowed. Two signature lines are not provided on the prescription form. This provides the pharmacist with a degree of choice regarding the substitution without requiring the prescriber expressly to authorize substitution. These statutes have the advantage of simplicity—if the prescri-

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61 This is, of course, assuming that the pharmacies in a particular area are truly competitive. In a survey of Michigan pharmacists after the adoption of a generic drug law in that state, 60% said they substituted frequently or whenever possible. Michigan Pharmacists Now Substituting More, DRUG TOPICS 13 (Jan. 17, 1978).

One danger with relying on competition to encourage substitution is that a pharmacist may substitute when unsure of the equivalency of the products in order to avoid an unfavorable competitive position. See Note, Generic Drug Bill, 30 Ark. L. Rev. 376, 377 (1976).

62 See Feldmann, supra note 19, at 377. Although pharmacists may have training superior to that of physicians in the field of drugs, they still face problems in choosing equivalent substitutes. See notes 92 and 93 and accompanying text infra for a discussion of the difficulty in determining equivalent drugs.

63 Along similar lines is the Alaska statute which provides for prescription forms that contain boxes labeled “Dispense as written” and “Substitution allowed” which the prescriber is supposed to check. If the “Substitution allowed” box is checked then the pharmacist may substitute, but if no indication is made or if the “Dispense as written” box is checked then the pharmacist may not substitute. ALASKA STAT. § 08.80.295 (a)-(c) (Supp. 1978).

64 See, e.g., Ark. STAT. ANN. § 72-1047 (Supp. 1977); CAL. BUS. & PROF. CODE § 4047.6 (West Supp. 1978); COLORADO REV. STAT. § 12-22-118.5 (Supp. 1978); IOWA CODE ANN. § 155.37 (1)(a) (West Supp. 1978); MONT. ANN. CODE art. 43, § 273A (b) & (c) (Supp. 1978); MONT. REV. CODES ANN. § 66-1530 (Supp. 1977); Neb. REV. STAT. § 71-5403 (1) (Supp. 1978); OHIO REV. CODE ANN. § 4729.38 (A) (Page Supp. 1978); OR. REV. STAT. § 689.835 (1) & (2) (1977); S.C. CODE § R 99-22 (b) (1976).
ber writes an ordinary prescription then the druggist may substitute. One drawback, however, is that by not forcing physicians to make a choice when signing the prescription, the physician may not really consider the advisability of substitution. Thus, the decision as to whether to use a lower priced generic drug may often be left solely to the pharmacist. Another drawback, mentioned earlier, results from the possibility that the pharmacist may actually sell a higher priced drug even though a lower priced one of equal quality is available.

Finally, two states, Massachusetts and New Hampshire, have adopted a unique approach to generic drug laws. These states prepare formularies of interchangeable drugs. Massachusetts requires the physician, when prescribing drugs listed on the formulary, to include the generic name of the drug, while New Hampshire requires the words “or its generic equivalent drug listed in the New Hampshire drug formulary” to be written on the prescription when the drug is listed on the formulary. Pharmacists may then substitute the equivalent drug. This appears to put an unnecessary burden on the physician who must check all prescriptions against the formulary to ensure compliance. This task could more easily and efficiently be performed by the pharmacist who will probably check the formulary anyway in the process of filling the prescription. Another problem with these statutes is that they do not give the physician the option of indicating when substitution should not take place. Instead, the formulary is conclusive as to the prescriber, but the pharmacist still has the option of using the brand name of the generic drug. Therefore, these laws are mandatory as to the physician but permissive as to the pharmacist.

2. Use of a Formulary

It has been suggested that there are three general patterns of generic drug statutes. Such a statute either (1) “allows sub-
stitution only within a predetermined list of drugs or formul-
yary," (2) "allows substitution of any drug that is not specifi-
cally forbidden," or (3) "allows for substitution of any drug
without any reference to a formulary either positive or nega-
tive."74

The first pattern is what is referred to as a "positive" or
"equivalent" formulary. This means that a list of drugs has
been determined to be biologically or therapeutically equiva-
lent and may be substituted for one another.75 The determi-
ation of equivalency can be made by either a group of experts
in the drug field76 or by individual pharmacists.77 Several
states78 and the District of Columbia79 have positive formu-
laries. These formularies represent an attempt to guarantee that
any drugs substituted are truly equivalent to those originally
prescribed. For this reason many of the states that have more
mandatory substitution requirements use the positive formu-
laries.80 In this way they can ensure that substitution is only
compelled for truly equivalent drugs.

The idea of having a panel of experts decide which drugs
are equivalent and only allowing substitution within their pre-
pared list presents practical problems.81 It requires a good deal
of testing to determine when two drugs are biologically or ther-
apapeutically equivalent. This testing takes time so that develop-

71 Goldberg, supra note 26, at 64.
72 See notes 32-40 and accompanying text supra for a discussion of equivalence.
73 These groups of experts, often called Formulary Boards, generally include phy-
sicians, pharmacists, and pharmacologists. See, e.g., D.C. CODE ANN. § 33-831 (Supp.
74 See, e.g., Fla. STAT. ANN. § 465.30 (5) (West Supp. 1978); Ohio REV. CODE ANN.
75 See, e.g., Ariz. REV. STAT. ANN. § 32-1963.01 (B) (Supp. 1978); Fla. STAT. ANN.
§ 465.30 (6) (West Supp. 1978); K.R.S. § 217.819 (1977); Mass. ANN. LAWS ch. 17, §
STAT. ANN. § 24:6E-6 (West Supp. 1978); N.Y. PUB. HEALTH LAW § 206 (McKinney
Supp. 1978); Ohio REV. CODE ANN. § 4729.36 (H) (Page Supp. 1977); Pa. STAT. ANN.
tit. 35, § 960.5 (B) (Purdon 1977); R.I. GEN. LAWS § 42-18.1-3 (Supp. 1978); Tenn. CODE
ANN. § 52-1224 (Supp. 1978); Vt. STAT. ANN. tit. 18, § 4601 (4) (Supp. 1978); Va. CODE
77 See, e.g., Fla. STAT. ANN. § 465.30 (West Supp. 1978); KRS §§ 217.19 & . 822
(1977); N.J. STAT. ANN. §§ 24:6E-6 & 7 (West Supp. 1978); N.Y. EDUC. LAW § 6816-a
STAT. ANN. tit. 35, §§ 960.3 (A) & .5 (B) (Purdon 1977); Vt. STAT. ANN. tit. 18, §§ 4601
(4) & 4605 (Supp. 1978); Wis. STAT. ANN. §§ 140.90 (1)(d) & 450.075 (West Supp. 1978).
78 See generally Note, supra note 15, at 407-08.
ing a positive formulary is a slow process. This means that, until an exhaustive list has been prepared, the number of drugs that can be substituted is small. Even though the number may increase over time, it is questionable whether such a formulary could ever catch up with the more than 20,000 drug products now available and the new drugs that are added every year. In addition to being slow, the process of developing a positive formulary entails a great deal of expense. Therefore, it is limited by the amount of appropriations allocated by the legislature. Furthermore, limited funds may encourage formulary boards to be less careful in determining equivalence. For all of these reasons the benefits of a positive formulary may be outweighed by the problems of developing such a list.

The second statutory pattern is the "negative" or "non-equivalent" formulary which lists drugs that have been found not to be or are suspected of not being biologically or therapeutically equivalent and provides that substitution of such drugs is forbidden. The theory behind this type of law is that most chemically equivalent drugs are also therapeutically equivalent and that substitution should be freely allowed unless there is some reason to suspect inequivalence. In this way a measure of protection is provided without the expense and delay a positive formulary would involve. The negative

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[130] The budget for the Kentucky Drug Formulary Council was $185,000 for fiscal year 1978-79 and is $194,300 for fiscal year 1979-80. Kentucky Executive Budget 1976/78.
[131] For example, they may rely on information and testing done by manufacturers rather than on their own testing.
[132] A study conducted by the federal government suggested one possible solution. It was suggested that a distinction be drawn between drugs in which bioequivalency is critical and those in which it is not so important. For those drugs where bioequivalency is not essential, substitution would be permitted even though they had not been determined equal and placed on the formulary. For those drugs in which bioequivalency is essential substitution would not be allowed until they were placed on the formulary. More drugs would be available for substitution sooner under this approach. See Drug Bioequivalence, supra note 20, at 57. See also Note, supra note 23, at 904.
[134] As a government study concluded: "It is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products." Drug Bioequivalence, supra note 20, at 21.
formulary represents a compromise between restricting substitution to the drugs on a positive formulary and providing no guidelines at all for substitution.88

The problem with using a negative formulary, however, is that it does not protect against the previously undiscovered inequivalency of two products that are generically the same.89 Presumably, a positive formulary would discover any inequivalencies before a drug is placed on the list and used as a substitute.90 Thus, while a negative formulary may be easier to develop, it may not provide as much protection for the consumer as a positive formulary.

Some states91 do not provide for a formulary, but allow substitution based on the pharmacist's own professional judgment. While it may be argued that the pharmacist is especially trained in the drug field and should be able to make such decisions, even the experts have a difficult time determining therapeutic equivalency.92 Thus the danger exists that non-equivalent drugs will be substituted,93 or a pharmacist may be overly cautious and refrain from substituting,94 thereby defeating the purpose of the generic drug law.

Colorado and Nebraska have adopted novel approaches to the problem of ensuring equivalency and developing a formulary.95 These states do not have a state formulary but rather use a list of drugs, prepared by the federal government, that are suspected of not being biologically equivalent.96 This negative

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88 Note, supra note 15, at 408.
89 A “positive” formulary gives the pharmacist and consumer more assurance of the drugs' equivalency before substitution takes place. See Note, supra note 64, at 377.
90 Whether or not non-equivalence is discovered depends on the extent of testing done by a Formulary Board.
92 See notes 37-38 and accompanying text supra for a discussion of this difficulty.
93 Pharmacists given a list of prescription drugs and asked to identify possible substitutes for those drugs averaged only 57% correct. See Goldberg, supra note 26, at 69.
96 This list is not a regular formulary but a list of “multiple-source drugs” for which the government will only pay a set “maximum allowable cost” (MAC) when
formulary appears to be the optimal solution. Since drug bioequivalence is a nation-wide problem it is more practical to have a national list rather than have each state develop its own. “Rather than patchwork state-by-state legislation, it would seem incumbent on the federal government to measure up to its public obligation and promulgate more stringent procedures in order to prevent the marketing of inefficacious drugs.” In addition, this list provides the pharmacist with some guidelines in making substitution and the state is spared the expense of developing a formulary.

3. Other Characteristics of Generic Drug Laws

While the permissibility of substitution and the type of formulary are the basic variables of any generic drug law, all such laws contain other provisions which are included to improve the operation of the law. The nature of these additional provisions varies greatly from state to state; however, there are some fairly standard ones that are noteworthy.

To ensure that generic drug substitution laws actually decrease the cost of prescription drugs, many states provide that a pharmacist may only substitute a lower cost generic equivalent. In addition, there may be a provision requiring that the cost savings resulting from the substitution be passed on to the consumer and that the pharmacist may not charge a higher fee for dispensing a generic drug than for dispensing a brand name drug. Some states try to protect the consumer as to reimbursing for prescriptions under Medicare and other government assistance programs. See 45 C.F.R. §§ 19.1 - .6 (1977).

In furtherance of the MAC program the federal government has developed procedures for determining bioavailability and requires bioavailability data on certain drugs. See 21 C.F.R. §§ 320.1 - .62 (1978).

Note, supra note 23, at 904. It has been suggested that the Food and Drug Administration may publish a positive formulary of interchangeable drugs, probably as an effort to enforce its MAC program. See Haddad, Generic Drugs—Tomorrow’s Market, 33 Food, Drug, Cons. L. J. 488, 490 (1978).


See, e.g., Cal. Bus. & Prof. Code § 4047.6 (c) (West Supp. 1978).

quality by providing conditions which a drug must meet before it may be used as a substitute. These conditions require that drug manufacturers provide adequate quality control and stand behind their products.\textsuperscript{102}

Another common provision in generic drug laws is the requirement that the consumer be notified of the substitution.\textsuperscript{103} In addition, some states allow the consumer to refuse the substitution.\textsuperscript{104} While it may seem like a good idea to allow the consumer the freedom of choice, it may have some undesirable side effects. Drug manufacturers are now advertising directly to consumers,\textsuperscript{105} suggesting that generic substitutes are not of the same quality as brand name drugs.\textsuperscript{106} To the extent manufacturers are successful in their effort to encourage consumers to refuse generic drugs, the effectiveness of the generic drug laws will be impaired.\textsuperscript{107}

\begin{footnotesize}
\begin{itemize}
\item For example, one statute provides that certain manufacturing standards must be met before a drug of the particular company may be used as a substitute. The company must be one that: "(1) Marks capsules and tablets with identification code or monogram; (2) Labels products with their expiration date; (3) Provides reasonable services to accept return goods that have reached their expiration date; (4) Maintains reasonable resources for product information; and (5) Maintains recall capabilities for unsafe or defective drugs." S.D. CODIFIED LAWS § 36-11-46.4 (Supp. 1978).


This represents a shift from the former practice of advertising toward physicians. See Willig, supra note 2, at 16.
\item One advertisement by the Pharmaceutical Manufacturers Association reads: "Before you ask your pharmacist for a cheaper version of the medication prescribed by your doctor, consider. In making the 'same' drug, different companies may exercise different levels of skill and care. They formulate and manufacture the 'same' product differently." Advertisement, SATURDAY REVIEW (Feb. 3, 1979).
\item In fact manufacturers are conducting a campaign for the passage of laws which "would allow a consumer to specify a brand name in states where substitution is permitted or mandated." Haddad, supra note 97, at 489.
\end{itemize}
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Finally, there are provisions which set a standard of care for pharmacists or limit their potential liability when making substitutions. These provisions generally state that "[t]he liability of a . . . [pharmacist] in substituting . . . shall be no greater than that which is incurred in the filling of a generically written prescription." Such provisions are included in some generic drug laws because of fears of increased liability if the druggist takes a more active role in selecting the drug product to be dispensed, and to avoid deterring pharmacists from making substitutions. While these provisions may help protect a pharmacist against claims of negligence, they do not protect against other theories under which a pharmacist may be held liable, such as strict products liability or breach of implied warranty. In order to provide full protection it might be necessary to "enact a statutory exemption which would absolve the pharmacist from liability caused by dispensing a generic substitute." However, it may not be desirable to lessen any liability. Substitution will probably still take place because of the competitive advantage it provides, and potential liability may make pharmacists more careful in selecting which products to use as substitutes.

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As to the general standard of care for a pharmacist: "A druggist is not an absolute insurer; it is his duty to act with due, ordinary care and diligence in selling and dispensing drugs, that is, such care as is ordinarily possessed and exercised by members of his profession." Annot., 79 A.L.R.2d 301, 315-16 (1961).

110 See generally Myers and Fink, supra note 94, at 33.

The increased liability may come from substituting drugs that are chemically equivalent but not therapeutically equivalent. These fears of liability are directed mainly at the pharmacist who is given the choice of substitution. Presumably where substitution is mandated by statute from a "positive" formulary the pharmacist could not be held liable if the substitution was made according to proper procedures.

111 See generally Note, supra note 23, at 897.

This danger may be more imagined than real since "[t]hus far, no known reported cases have been found in which a pharmacist has been held liable for inappropriate prescription product sources selection [substitution]." Myers and Fink, supra note 94, at 33.

112 See generally Myers and Fink, supra note 94; Note, supra note 65.

113 Note, supra note 23, at 897.

114 This is particularly important in those states that allow substitution but provide no formulary for pharmacists to use as a guide.
B. The Experience in Kentucky

In 1966 the Kentucky Board of Pharmacy, pursuant to its powers to regulate the pharmacy profession, issued a regulation forbidding substitution of drugs without the consent of the prescriber. However, in 1972 the legislature overrode this antisyndigital regulation by enacting Kentucky’s first generic drug law. This law provided for the creation of a drug formulary council which was given the duty of preparing a formulary of therapeutically equivalent drugs (i.e., a “positive” formulary). When there were equivalent drugs listed in the formulary a pharmacist was permitted to substitute, and was required to do so if the consumer requested it. The Kentucky law was fairly permissive even though the number of instances in which the pharmacist had the option of substitution was limited to those where the drug was listed in the formulary. It was unlikely that any consumer would request substitution since the pharmacist was not required to inform the consumer of this option. Thus the pharmacist retained a great deal of control.

Then in 1976, in order to further the avowed legislative intent “that all citizens of Kentucky may be assured of high quality medicine at a reasonable cost,” the generic drug law was revised. The law was strengthened by providing that a pharmacist “shall select the lowest priced therapeutically

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118 Id. at § 6.
119 Id. at § 8.
120 At first there was some question as to whether a pharmacist could substitute even if the drug was not on the formulary since there was no prohibition against such substitution. The Board of Pharmacy cleared up this question by issuing a regulation stating:

Except as provided elsewhere by statute, whenever any registered pharmacist is requested to sell, furnish, or compound any drug, medicine, chemical, or pharmaceutical preparation by means of a prescription and substitutes or causes to be substituted therefor, any other drug, medicine, chemical, or pharmaceutical preparation without specific or express permission, approval or consent of the prescriber, the board may find such person guilty of engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public, and may revoke or suspend his license as prescribed by law.

equivalent drug listed by the drug formulary council which he has in stock, unless otherwise instructed by the purchaser or his physician.\textsuperscript{122} While it may seem that this mandatory substitution would ensure that the consumer receives prescription drugs at the lowest possible price, in actuality it is fairly easy to avoid the mandate of this law. This is done by limiting the drugs which are kept in stock since the statute says substitution only has to be made with the lowest equivalent drug in stock.\textsuperscript{123} Therefore, in practice the Kentucky pharmacist has some control just like pharmacists in states with more "permissive" generic drug laws.\textsuperscript{124} Thus, the extent of substitution still depends in part on the amount of competition in the prescription drug field.

The 1976 generic drug act also added some totally new provisions to the law. One was the requirement of a sign in every pharmacy advising consumers of the existence of and their rights under the generic drug law.\textsuperscript{125} But it appears that this sign has not been very effective. A 1977 survey of adult Kentuckians conducted for the Kentucky Drug Formulary Council showed that "31.5\% knew about the Generic Drug Law; 19.3\% had noticed a sign in their pharmacy; 7.8\% had discussed the law with either their doctor or pharmacist."\textsuperscript{126} Another new provision states that "[t]he substitution of any drug by a pharmacist . . . does not constitute the practice of medicine."\textsuperscript{127} The Office of the Attorney General interprets this as meaning that "a pharmacist incurs no liability for substitution so long as it was done pursuant to the law and not the

\textsuperscript{122} KRS § 217.822 (1977) (emphasis added). Of course, there is still the problem that, according to the wording of the current statute, when a prescription is written generically the lowest priced generic drug does not have to be used. See notes 52-58 and accompanying text supra for a discussion of this problem.

\textsuperscript{123} KRS § 217.822 (1977).

\textsuperscript{124} The difference is that a Kentucky pharmacist cannot decide about substitution in individual cases but can only decide generally by not stocking some or all of the generic forms of a particular drug.

This choice may not be such a bad thing. One commentator has said that pharmacists should not be required to dispense the lowest cost drug against their professional judgment because the individual pharmacist may be aware of specific product defects.\textsuperscript{128} See Cabana, Bioavailability/Bioequivalence, 32 Food, Drug, Cosm. L. J. 512, 526 (1977).

\textsuperscript{125} KRS § 217.894 (1977).

\textsuperscript{126} Minutes of Kentucky Drug Formulary Council meeting (Dec. 13, 1977).

\textsuperscript{127} KRS § 217.822 (3) (1977).
result of negligence on the part of the pharmacist."\textsuperscript{128}

Kentucky has made a good faith effort to see to it that consumers receive quality drugs at the lowest cost. And even though there are still problems with the generic drug law, revisions have been made to solve some of them. It is still unclear what effect this law has actually had. The Attorney General's Office says they have found "no evidence of widespread violations of the law."\textsuperscript{129} However, a survey conducted by a Kentucky newspaper discovered that while most pharmacies followed the law and substituted a generic drug, there were still large variations in price.\textsuperscript{130} Therefore, the question must be asked: What else could be done to better protect the consumer?

C. Solutions Other Than Generic Drug Laws

Solutions other than generic drug laws have been suggested to aid the consumer in the area of prescription drugs. Much of the early impetus in the consumer protection movement came in the area of prescription drug price advertising. Such advertising, which is constitutionally protected,\textsuperscript{131} is now provided for by statute in some states.\textsuperscript{132} Advertising is an aid to the consumer in that it facilitates comparison shopping, which is difficult to do in the prescription drug field where the products are not accessible to the consumer. To encourage this further, some states have made price posting for certain prescription drugs mandatory.\textsuperscript{133}

\textsuperscript{128} Letter from H. Regina Cullen, Assistant Attorney General for the Commonwealth of Kentucky (March 1, 1978).

\textsuperscript{129} See also Willig, supra note 2, at 30-31 for a discussion of the liability problem under the 1972 Act.

\textsuperscript{130} Letter from H. Regina Cullen, Assistant Attorney General for the Commonwealth of Kentucky (March 1, 1978).

\textsuperscript{131} Each violation of the generic drug law results in a fine of not less than $100 and not more than $500. KRS § 217.990 (10) (1977).

\textsuperscript{132} Anderson, Local Pharmacies Selling Generic Drugs, But Prices Vary Widely, Lexington Herald-Leader, Jan. 21, 1979, at 1, col. 1.


\textsuperscript{135} See, e.g., D.C. Code Ann. § 33-813 (Supp. 1978); Me. Rev. Stat. tit. 22, § 2204-
One ingenious proposal is to abolish or limit the trademark protection of brand name drugs.\textsuperscript{134} Thus, all drugs would be sold under their generic names and thus even under antisubstitution laws substitution would occur. The problem with this proposal is that without additional legislation this would not guarantee that the consumer would get the lowest cost product available. In addition, the drug manufacturers are moving toward "branded generics," which is an attempt to have the consumer request a particular manufacturer's product even though it is sold under a generic name.\textsuperscript{135}

CONCLUSION

In the final analysis, generic drug substitution laws are probably the best way of protecting the consumer. Admittedly, these laws have certain drawbacks, but many of the problems can be alleviated through statutory revision. Below is a suggested model statute that attempts to correct some of these problems by incorporating the best provisions of various state statutes and making changes where necessary.

Model Generic Drug Substitution Act

§ 1 Policy—It is declared to be the public policy of this state that all citizens receive high quality medicine at a reasonable cost.

§ 2 Definitions—As used in this act:

(a) "Brand name" shall mean the proprietary or trade name given to a drug product by its manufacturer or distributor;

(b) "Generic name" shall mean the official name, as determined by the United States Adopted Names as published by the United States pharmacopeial convention and accepted by the federal Food and Drug Administration, of those drug products having exactly the same active chemical ingredients in exactly the same strength and quantity;

(c) "Therapeutically equivalent" shall mean those drugs containing the identical active ingredients in exactly the same

\textsuperscript{134} See 1977 Legislative Outlook, AM. DRUGGIST 16 (Jan. 1977).

\textsuperscript{135} Haddad, supra note 97, at 489.
strength, quantity, and dosage form and of the same generic name, which, when administered in the same amounts will provide the same therapeutic effect as evidenced by the control of a symptom or disease;

(d) "Bioequivalent" shall mean those drugs containing the identical active ingredients in exactly the same strength, quantity and dosage form and of the same generic name, which, when administered in the same amounts, will provide essentially the same biological or physiological availability as measured by blood levels or other appropriate methods;

(e) "Drug" shall mean any chemical human medication with one or more known active ingredients;

(f) "Substitute" shall mean to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed;

(g) "Prescriber" shall mean any practitioner licensed by this state to write prescriptions for drugs, medications, or devices;

(h) "Pharmacist" shall mean any person licensed as such by the state board of pharmacy.

§ 3 Substitution of lowest priced equivalent drugs—

(a) Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute the lowest priced drug of the same generic name which in the pharmacist's reasonable professional judgment is therapeutically equivalent, unless otherwise instructed by the purchaser or prescriber. 134

(b) Whenever a pharmacist receives a prescription for a generic name drug, the pharmacist shall dispense the lowest priced drug of that generic name which in the pharmacist's reasonable professional judgment is therapeutically equivalent. 135

(c) If the lowest priced drug of the same generic name

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134 The act uses the word "shall" so as to make the substitution mandatory. However, the pharmacist is allowed some choice in determining which drugs are therapeutically equivalent. This is an attempt to avoid relying entirely on competition to guarantee substitution (as do the permissive statutes) while permitting the pharmacist to exercise professional judgment in determining which drugs are equivalent and appropriate as substitutes.

135 This section is included to ensure that prescriptions written generically are also filled with the lowest priced equivalent drug. See notes 52-58 and accompanying text supra for a discussion of this problem.
which in the pharmacist's reasonable professional judgment is therapeutically equivalent to the drug prescribed is not available in stock the pharmacist shall so inform the purchaser. The pharmacist may then substitute the lowest priced drug of the same generic name which in the pharmacist's reasonable professional judgment is therapeutically equivalent to the drug prescribed and which is available in stock, if the purchaser so consents.\textsuperscript{138}

§ 4 When substitution prohibited—
(a) No substitution shall be made with any drug product which has been found to be therapeutically inequivalent by the federal Food and Drug Administration, or which is listed as having a known or potential bioequivalence problem by the federal Department of Health, Education, and Welfare.\textsuperscript{139}

(b) The state board of pharmacy shall be required to publish and distribute such list of drugs determined to be therapeutically inequivalent or having known or potential bioequivalence problems.

(c) No substitution shall be made with a drug unless the manufacturer of that drug has shown that:

(1) All products submitted have an expiration date on the original package;
(2) The manufacturer maintains recall and return capabilities for unsafe or defective drugs;
(3) The manufacturer maintains quality control standards equal to those of the federal Food and Drug Administration.

§ 5 Price savings passed on to consumer—All differences in price between the drug prescribed and the drug dispensed shall be passed on to the consumer. In no event may the pharmacist charge a different professional fee for dispensing a different drug product than the drug product originally prescribed.

\textsuperscript{138} This provision is to encourage pharmacists to keep the lowest priced generic equivalent drugs in stock so as to avoid having to get the purchaser's consent before the next lowest priced equivalent can be used for the substitute. This method was chosen rather than requiring pharmacies to stock the lowest priced generic equivalents because of the difficulties of enforcing such a requirement. Pharmacies must rely on their wholesale suppliers for drugs and may not always be able to get certain drugs.

\textsuperscript{139} This section is designed to provide some guidelines for the pharmacist in determining equivalent drugs with which to substitute without requiring the expense of preparation of a formulary.
§ 6 Records and labeling—
(a) When a drug is substituted the pharmacist shall record on the prescription form the name and manufacturer of the drug substituted, and shall retain the form for inspection.
(b) When a drug is substituted the pharmacist shall label the medication container with the name of the drug substituted.

§ 7 Sign required notifying the public—Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescription drugs are dispensed stating, in block letters of not less than one inch in height, that "This pharmacy is required to dispense the lowest priced generic drug which is therapeutically equivalent to the one prescribed for you by your doctor unless you or your doctor do not approve."

§ 8 Posting of prices permitted—A pharmacist may display, within the confines of the pharmacy, lists of available drug products and current charges for the drug products in specified quantities.

§ 9 Liability of pharmacist—
(a) A pharmacist in making a substitution shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a generic name product.
(b) Substitution of drugs in accordance with this act shall not constitute evidence of negligence or improper pharmacy practice if the substitution was made within reasonable and prudent pharmacy practice or if the prescribed and substituted drugs were therapeutically equivalent.
(c) The substitution of any drug by a pharmacist under this act does not constitute the practice of medicine.

§ 10 Liability of prescriber—The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

§ 11 Enforcement and penalties—
(a) Failure to comply with the provisions of this act shall be a tortious injury and any person failing to comply shall be liable for treble civil damages to every person, including insurers and government agencies, injured thereby.140

140 Since it is often difficult for the state to investigate and enforce compliance with generic drug laws, this provision for treble civil damages is to encourage consumers to take some initiative in policing these laws.
(b) A pharmacist who violates a provision of this act shall be subject to a fine of not more than $500 for each occurrence, and shall be subject to discipline by the state board of pharmacy, including but not limited to suspension or revocation of license.\footnote{The author wishes to thank Ben H. Doyle and Joe C. McMurtry, registered pharmacists, for their assistance.}