Improving Michigan's Generic Drug Law

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IMPROVING MICHIGAN’S GENERIC DRUG LAW

During 1974 consumer advocates\(^1\) and the Michigan Pharmaceutical Association,\(^2\) convinced the Michigan Legislature to enact a law\(^3\) designed to bring down the price of drugs for consumers. This legislation is popularly known as the drug substitution\(^4\) or generic drug\(^5\) law.

Those who supported enactment of the generic drug law identified lack of competition as a major cause of high prescription drug prices.\(^6\) They reasoned that this situation was fostered by the common medical practice of prescribing drugs by brand name rather than by generic name.\(^7\) A “generic” name is a non-proprietary name used to designate drug products with the same active ingredients in the same dosage form.\(^8\) It is also referred to as the usual, established, or official name.\(^9\) A “brand” or “trade” name is a designation given to a drug by a manufacturer, which, if registered, can be used exclusively by that firm. A brand name is not required in order to market a drug but is often used to distinguish one company’s drug product from other products in the same generic category.\(^10\)

Prior to passage of the generic drug law, a pharmacist filling a prescription written by brand name was required to dispense only that brand-name product to the customer,\(^11\) regardless of the availability of lower cost chemical equivalents marketed under other brand names or simply under the generic name of the drug. The Michigan generic drug law, under certain circumstances, now permits a pharmacist to dispense a chemically

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\(^1\) The Michigan Citizens Lobby, a Detroit-based consumer group, was a major force in passage of the new law. Detroit Free Press, July 6, 1975, at 3A, col. 1.


\(^7\) See note 16 infra.

\(^8\) Note, Products Liability for Prescription Drugs—The Effects of Generic Substitution on the Consumer and the Pharmacist, 23 Syr. L. Rev. 887, 887 (1972).


\(^10\) Note, supra note 8, at 888.

\(^11\) See notes 23, 24 and accompanying text infra.
equivalent drug in place of a prescribed brand-name product. In other words, the law authorizes "generic substitution."\textsuperscript{12}

This note will describe the conditions which existed prior to enactment of the Michigan drug substitution law, will discuss the history and provisions of that legislation, and will identify certain problems which the law fails to correct.

I. THE PRICE DIFFERENTIAL PROBLEM

The price differences between brand-name and generic-name drug products can be substantial.\textsuperscript{13} An Oklahoma study which compared the prices paid by pharmacists for brand-name versions and their generic-name equivalents of eight major drugs showed that, in general, the brand-name prices were more than three times the prices for the generic-name products.\textsuperscript{14} It is questionable whether such marked variations in price accurately reflect any differences in quality. A drug product is frequently manufactured by one pharmaceutical company and then sold to other firms which market it under their own brand names. Price differences among these

\textsuperscript{12} Other states have instituted similar reforms. For example, see Ark. Stat. Ann. §§ 72-1047 to -1049 (Supp. 1975) (A pharmacist may dispense a lower cost generic equivalent unless it appears on a Non-Equivalent Drug Product List promulgated by the State Health Officer. A prescriber or the patient may demand that the prescription be dispensed as communicated.); Cal. Bus. & Prof. Code §§ 4047.6-.7 (Ch. 1144 [1975] 7 Deering Advance Leg. Service 442) (Substitution of a lower cost drug product which does not appear on a state formulary is permitted unless the doctor has written "Do not substitute." See notes 116-19 and accompanying text infra.); Fla. Stat. Ann. § 465.30 (Supp. 1975) (Every prescription must bear the phrases "Substitution Allowed" and "Prior Approval Required," one of which must be initialed by the prescriber. Only a less expensive equivalent may be dispensed.); Ky. Rev. Stat. Ann. §§ 217.818-19, 217.822 (Supp. 1974) (Pharmacist may substitute from a state formulary and must do so if the purchaser requests, unless the prescriber has written "Do not substitute." See notes 112-15 and accompanying text infra.); Me. Rev. Stat. Ann. tit. 32, § 2806 (Supp. 1975-76) (A pharmacist may substitute an equivalent drug listed in the National Formulary or United States Pharmacopeia unless the doctor has indicated otherwise. The price of the dispensed drug may not exceed the price of the prescribed drug.); Md. Ann. Code art. 43, § 273A (Cum. Supp. 1975) (A pharmacist may substitute an equivalent product pursuant to a state formulary or federal regulations unless the prescriber has indicated otherwise. See note 115 infra. The savings in cost must be passed on to the consumer.); Mass. Gen. Laws Ann. ch. 112, § 12D (1975) (A physician who prescribes a drug listed on the state formulary is required to include the generic name of such drug.); Minn. Stat. Ann. § 151.21 (Ch. 101 [1975] Minn. Session Law Service 295) (A pharmacist may substitute with the purchaser's consent unless the prescriber has indicated the prescription is to be dispensed as written. The substituted drug must not bear a higher retail price than the product prescribed, and any savings must be passed on to the purchaser. See notes 88, 102-03 and accompanying text infra.); Ch. 218, §§ 3-4 [1975] Ore. Laws 287 (Unless the purchaser instructs otherwise, or unless the prescriber prohibits substitution, a pharmacist may substitute a generic equivalent, which is in his professional opinion therapeutically equivalent. The substitution must result in a savings or no increase in cost to the purchaser.)

\textsuperscript{13} See M. Silverman & P. Lee, Pills, Profits, and Politics 334 (1974) for examples of price ratios ranging from 5.7:1 to 35.9:1 [hereinafter cited as M. Silverman].

\textsuperscript{14} Green, Welfare Losses from Monopoly in the Drug Industry: The Oklahoma 'Antisubstitution Law,' 5 Antitrust Law & Econ. Rev. 97, 100 (Spring 1972).
brands have also been found to vary by over 300 percent, in spite of the fact that they come from the same source.15

Most prescriptions are written by brand name.16 This is partly attributable to the fact that trade names are generally shorter and easier to spell than their corresponding generic designations.17 Brand-name prescribing also can be attributed to the fact that a new drug formula can be patented. Throughout the seventeen years when its manufacturer has a monopoly on its production, the drug is usually marketed exclusively under a brand name.18 During this period, the brand name becomes so closely associated with the drug in the minds of physicians that they continue to write it when prescribing the drug long after the patent has expired.19 The association of drug formulas with brand names is fostered by major pharmaceutical firms which carry on extensive advertising programs.20 The core of these promotional campaigns is the company detail man,21 who makes personal visits to physicians in order to inform them of newly available drugs and to promote the represented company's products.22

15 The following examples were cited by Richard P. Penna, Pharm. D., in testimony before the Michigan Senate Agriculture & Consumer Affairs hearing on H.B. 4145 on April 23, 1974. Testimony, 12 Mich. Pharm. 6, 16 (July 1974).

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Distributor</th>
<th>Average Wholesale Price (per 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral</td>
<td>R. P. Scherer</td>
<td>Squibb $5.00</td>
</tr>
<tr>
<td>Hydrate (500 Milligram Capsules)</td>
<td>Leennon Pharmacal</td>
<td>2.90</td>
</tr>
<tr>
<td></td>
<td>Stanlabs</td>
<td>2.15</td>
</tr>
<tr>
<td></td>
<td>Alliance Labs</td>
<td>1.75</td>
</tr>
<tr>
<td></td>
<td>McKesson</td>
<td>1.75</td>
</tr>
<tr>
<td></td>
<td>Pure Pac</td>
<td>1.48</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Milan</td>
<td>A.H. Robins 3.25</td>
</tr>
<tr>
<td>HCL (250 Milligram Capsules)</td>
<td>Smith, Kline &amp; French</td>
<td>3.40</td>
</tr>
<tr>
<td></td>
<td>Wyeth</td>
<td>2.06</td>
</tr>
<tr>
<td></td>
<td>Towne Paulsen</td>
<td>1.50</td>
</tr>
<tr>
<td></td>
<td>Alliance Labs</td>
<td>2.50</td>
</tr>
<tr>
<td></td>
<td>Central Pharmacal</td>
<td>2.50</td>
</tr>
</tbody>
</table>

16 The 15th Annual Prescription Survey of the Albany College of Pharmacy (1971) indicated that almost 90 percent of all prescriptions were written by brand name. Note, supra note 8, at 888. In a recent Michigan survey, doctors were asked how often they write prescriptions generically. Thirty-eight percent stated they "sometimes" prescribe generically; another 23 percent claimed that they prescribe generically "whenever possible." T. Goldberg, W. Moore, et al., Preliminary Report of Survey of Attitudes and Intended Behavior of Physicians and Pharmacists, at 19, Nov. 16, 1975 (Dept. of Community Medicine, Wayne State U.) [hereinafter cited as T. Goldberg]. The executive director of the Michigan Pharmaceutical Association estimates that about 10 to 15 percent of all prescriptions are written generically. See Sesti, Testimony on H.B. 5325, 13 Mich. Pharm. 6 (Aug. 1975).

17 See M. Silverman, supra note 13, at 323-26. For example, Declomycin is a brand name for the generic drug demethylchlortetraycline. Id. at 324.

18 Green, supra note 14, at 102.

19 Id.; M. Silverman, supra note 13, at 36.

20 M. Silverman, supra note 13, at 36, 54-57.


22 Id. at 14-15.
Before the current generic drug law was passed, if the detail man could "educate" a doctor to prescribe his firm's product by its trade name, a Michigan pharmacist filling the prescription was restricted to dispensing only that brand, even if lower cost equivalents were available. To "substitute any drug or device knowing or intending that it shall be used" was a misdemeanor.\(^{23}\) The word "substitute" was defined as "to dispense without prescriber's authorization a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed."\(^{24}\) A pharmacist could dispense a different brand of product by telephoning the prescriber for his permission, but this was not always possible or convenient.

The former antisubstitution law thus created a twofold problem. First, the consumer with a prescription for a drug product obtainable from different sources was prevented from exercising any choice among diversely priced equivalents if his prescription was written by trade name. The irony of this situation was that in many cases the prescribing doctor had no real preference as to brand but was simply writing the name which was most familiar to him, without considering the factor of cost.\(^{25}\) Second, companies which succeeded in familiarizing doctors with their brand-name products were able to escape the competitive pressures of a normal market because the individuals choosing the drug products were not the ones paying the bills.\(^{26}\) As a result, certain drug suppliers were able to charge prices that were much higher than prices charged by their "competitors." The element of competition was lacking in one additional respect. In shopping for over-the-counter drug items the consumer could easily compare the prices charged by various retailers in his vicinity by simply referring to their price tags. To ascertain the price being charged for a prescription drug, however, it was necessary to ask the pharmacist.

II. HISTORY OF THE ACT

The ban on substituting a different brand of drug in place of the brand prescribed\(^{27}\) aroused the opposition of consumers and pharmacists alike. However, these groups proposed different solutions to the antisubstitution problem.

The Michigan Pharmaceutical Association (MPA) advocated outright repeal of the antisubstitution law. The pharmacists therefore asked Michigan Representative Joseph Forbes to introduce a bill which would change the definition of "substitute" by striking out all reference to "brand of drug."\(^{28}\) It was expected that a simple repeal of the prohibition against


\(^{26}\) Green, supra note 14.

\(^{27}\) See notes 23, 24 and accompanying text supra.

\(^{28}\) H.B. 4145 Analysis, supra note 2, at 7. Mich. Comp. Laws Ann. § 338.1101(u) would thus read: "Substitute means to dispense, without the prescriber’s authorization, a different drug in place of the drug prescribed."
brand interchange would maximize the scope of pharmacists' professional responsibility in selecting which drug products to dispense. House Bill 4145, which embodied the MPA's recommendation, was introduced by Representative Forbes on February 14, 1973.

Consumer advocates, on the other hand, formulated a bill which combined a concern for insuring efficacious drug therapy with the goal of cutting pharmaceutical costs. This bill was introduced by Representative Forbes and Representative H. Lynn Jondahl as House Bill 4593 on April 30, 1973. The consumer version would have created a nine-member drug equivalency commission charged with preparing a formulary of drugs and pharmaceuticals. The formulary would list brand-name drugs and generic counterparts which the commission had determined were therapeutically equivalent. A pharmacist who received a prescription for a brand-name drug listed on the formulary would be permitted to dispense an equivalent drug from the list and would be required to do so upon the purchaser's request. A doctor could write "Do Not Substitute" on a prescription if he felt an equivalent drug should not be dispensed. Any savings resulting from the substitution were to be passed on to the consumer. Another provision of House Bill 4593 called for pharmacists to post conspicuously their current retail prices for the one hundred most frequently prescribed drugs. The Department of Health was to gather and record these posted prices, publish a list of drugs and their retail prices, and distribute copies of the list to interested parties.

House Bills 4145 and 4593 were both referred to the House Committee on Consumers and Agriculture, where an effort was made to synthesize them into a bill which could be supported by consumers and pharmacists. The MPA opposed both the consumers' proposal that prices be posted for the most frequently prescribed drugs and the restriction of professional responsibility which the formulary concept entailed. Eventually a compromise was reached, and it was agreed to retain the price posting require-

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29 See H.B. 4145 Analysis, supra note 2.
31 See H.B. 4145 Analysis, supra note 2, at 7.
33 Id. § 2(1).
34 Id. § 4.
35 Id. The bill was strikingly similar to KY. REV. STAT. ANN. §§ 217.818-19, 217.822 (Supp. 1974).
37 Id. at § 5(2).
38 Id. at § 5(3).
39 Id. at § 9(1). The Department of Health was to determine which drugs were to be included on this list. Id.
40 Id. § 11.
42 See H.B. 4145 Analysis, supra note 2, at 7, 22.
43 Id. at 8, 22.
This compromise solution was drawn up as a substitute bill and reported out of committee on February 7, 1974. One section of the bill redefined the word "substitute" as urged by the pharmacists. Another section embodied the consumers' proposals regarding generic substitution, except for the provision for a drug formulary. The bill was extensively debated in both the House and Senate, where numerous amendments were proposed and over a dozen adopted. These amendments render the law as finally passed susceptible to contradictory interpretations.

III. PROVISIONS OF THE CURRENT GENERIC DRUG ACT

A. Circumstances Under Which Generic Substitution Is Permitted

The core of the generic drug law is section 14a, which provides that a pharmacist may dispense a generically equivalent drug product in place of the brand prescribed if the substituted product is lower in cost. The section further commands that the resulting savings be passed on to the consumer. Both the name of the prescribed drug and the brand or generic name of the dispensed drug must appear on the prescription label whenever substitution occurs. Section 14a provides several methods, however, by which prescribers can prevent generic substitution altogether. The law also permits a pharmacist to dispense a product which is higher in cost than the brand prescribed if the purchaser consents.

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44 The House Committee on Consumers and Agriculture evaluated the experience with 'formularies' in Massachusetts and Kentucky and observed a multitude of problems in their operations. In addition, the estimated costs of creating a State Drug Equivalency Commission were substantial enough to raise the question of whether the product would be equivalent to the investment.


46 MICH. H.R. JOUR. No. 15, at 287 (Feb. 7, 1974).


48 Substitute H.B. 4145, 77th Leg., § 14a (1973).


50 See part III A 1 infra.

51 MICH. COMP. LAWS ANN. § 338.1114a (Supp. 1975-76).

52 MICH. COMP. LAWS ANN. § 338.1114a(1) (Supp. 1975-76).

53 MICH. COMP. LAWS ANN. § 338.1114a(2) (Supp. 1975-76).


55 MICH. COMP. LAWS ANN. § 338.1114a(4) (Supp. 1975-76).
1. *Is a Purchaser Request a Prerequisite for Generic Substitution?*— Even before the generic drug law took effect, language in section 14a(1) generated conflicting interpretations. The major controversy is whether the phrase "and the purchaser requests a lower cost generically equivalent drug product"\(^{57}\) implies that the customer must first request generic substitution before the pharmacist can dispense a different brand of drug than the brand prescribed.

The Michigan Pharmaceutical Association has taken the position that a prior request is not necessary.\(^{58}\) According to the MPA, the Act's redefinition of the word "substitute"\(^{59}\) makes it "entirely the prerogative of the pharmacist to perform drug product selection."\(^{60}\) The MPA views section 14a(1) simply as mandating that, if a customer does request a lower cost equivalent, the substitution must result in a savings to him unless he agrees to the contrary.\(^{61}\) An additional purpose of the section, as interpreted by the MPA, is to prohibit substitution where the prescriber has indicated that the prescription is to be dispensed as written.\(^{62}\)

The MPA contends that it was not the intent of the bill's sponsors to make a request by the purchaser a prerequisite of substitution,\(^{63}\) and the legislative history of the generic drug act lends support to this position. When reported out of committee, Substitute House Bill 4145 originally read:

> When a pharmacist receives a prescription for a brand name drug product, and the purchaser requests a lower cost drug product, the pharmacist shall dispense a lower cost drug product if available in the pharmacy . . . .\(^{64}\)

In drafting the compromise bill, the committee had attempted to combine the desire of pharmacists for more professional responsibility with the desire of consumer advocates to save money. The pharmacists were accommodated by removing words which prohibited brand interchange from the definition of "substitute." The consumers, on the other hand, were given the right to demand substitution of lower cost generically equivalent drugs, if available in the pharmacy. Therefore, as originally written, the "purchaser request" clause merely compelled the pharmacist to substitute generic equivalents upon consumer demand. Although the bill did not explicitly state that the pharmacist was free to substitute when the purchaser

\(^{57}\) *Mich. Comp. Laws Ann.* § 338.1114a(1) (Supp. 1975-76) reads in pertinent part as follows:

> When a pharmacist receives a prescription for a brand name drug product, and the purchaser requests a lower cost generically equivalent drug product, the pharmacist may dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy . . . .


\(^{60}\) *Understanding H.B. 4145*, *supra* note 58, at 8.

\(^{61}\) *Id*.

\(^{62}\) *Id*.


\(^{64}\) Substitute H.B. 4145, 77th Leg., § 14a(1) (1973) (emphasis added).
expressed no preference on this matter, the removal of the language which had prohibited brand interchange implied such authority.

During debate, however, the House of Representatives passed an amendment which removed the obligation of the pharmacist to honor a customer's request for a lower cost substitute. The amendment replaced the verb "shall" in the first sentence of section 14a(1) with the word "may." As a result, the clause which had been intended to specify when a pharmacist is compelled to substitute now seemed designed to specify when a pharmacist is permitted to substitute. Nevertheless, it is possible that the amendment was not intended to restrict the pharmacist's authority to substitute. It may have been directed at allowing the pharmacist to refuse to substitute in situations where he did not feel a generic equivalent would provide the same therapeutic effect as the prescribed brand-name drug.

A subsequent attempt to amend the bill in the House also supports the conclusion that a purchaser request is not required before a pharmacist can substitute a generic equivalent. This amendment, which would have stipulated that a generically equivalent drug product could not be dispensed unless agreed to by the purchaser, failed to pass.

One month after the Michigan Pharmaceutical Association explained its understanding of the new law in its state professional journal, the Board of Pharmacy requested an opinion of the Michigan Attorney General on the question "whether a pharmacist may dispense a generically equivalent drug product in the absence of a request by the purchaser." The Attorney General ruled that, with one exception, the answer to this question was negative.

The Opinion of the Attorney General briefly mentions the deletion of any reference to the phrase "or brand of drug" in the definition of "substitute," stating that this change now permits a pharmacist to dispense a generic equivalent in place of a prescribed brand without first obtaining the prescriber's authorization. The Opinion continues that, "having narrowed the definition of substitution," the legislature set forth "simply and succinctly" the circumstances under which generic substitution could take place. Four conditions must first be met, one of which is a request from the purchaser.

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66 See part IV A infra.
68 Although the amendment failed, it was supported by 54 of the 110 members of the House of Representatives serving. Id. The sponsor of the amendment succeeded in getting the House to reconsider it (id. at 478), but subsequently withdrew it. Mich. H.R. Jour. No. 26, at 521 (Feb. 26, 1974).
69 Understanding H.B. 4145, supra note 58.
72 Id.
75 The four conditions are: (1) a prescription written by brand name; (2) a re-
An important exception to the purchaser request requirement was identified, however. If, pursuant to section 14a(3)(b), the prescriber used a pre-printed prescription blank bearing the statement, "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed D.A.W.," then a purchaser request would not be a prerequisite to generic substitution. The Opinion reasoned that such a statement itself serves as authorization by the prescriber for the pharmacist to dispense a generic equivalent. In other words, the prescription is essentially written by generic name. According to the Opinion, not only would a patient request then be unnecessary, but the language of section 14a(1), requiring that the drug dispensed have a lower cost than the product prescribed, would also be inapplicable. However, section 14a(4) would still limit the total cost for the drug dispensed to the cost of the drug prescribed.

An argument in support of the interpretation that a purchaser request is a prerequisite for substitution might be made based upon language in subsection 14a(3), which preserves the physician’s power to prevent substitution. This section states:

> The pharmacist shall not dispense a generically equivalent drug product under subsection (1) of this section if . . . [the prescriber indicates the prescription is to be dispensed as written].

This section only refers to substitution performed "under subsection [14a](1)," which grants the pharmacist authority to dispense an equivalent drug product in response to a request from the customer. Thus, subsection 14a(3) is silent as to substitution initiated by the pharmacist rather than by the customer. Since it is highly unlikely that the legislature intended to give doctors the power to veto generic substitution when initiated by the patient.

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78 It is difficult to understand why the Attorney General attributed such an effect to the inclusion of these words on a prescription blank. The phrase, "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed D.A.W.," merely reports what the law is. A prescription blank bearing such a statement therefore should not be considered any more of an authorization for generic substitution than a prescription blank which does not carry this restatement of the law. The ruling that the requirement for a purchaser request depends upon the type of prescription blank used by the prescriber is arbitrary. Although the words of the Act can be construed in this way, no purpose is served by linking the purchaser request requirement to the prescriber’s prescription form.


80 Id. (emphasis added). This language was added by amendment. Mich. S. Jour. No. 74, at 1047-48 (May 29, 1974).

but not when initiated by the pharmacist, the legislature must have considered generic substitution to be permissible only pursuant to subsection 14a(1). This undermines the position that "[t]he authority for the pharmacist to perform drug product selection . . . is inherent in the re-definition of the word 'substitute' . . . ."\textsuperscript{82}

In stating that the pharmacist may not dispense a generic equivalent in the absence of a request by the purchaser, the Attorney General failed to elucidate what is meant by "request." It is unlikely that a customer is required to "initiate" substitution. The law certainly cannot be construed as prohibiting pharmacists from discussing the provisions of the generic drug law. It follows that they may also suggest that generic substitution be performed.

A bill to amend the generic drug law was introduced on June 10, 1975, which, if passed, will clarify the legislative intent as to the need for a consumer request. House Bill 5325 proposes to amend section 14a(1) to read as follows:

When a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy except as provided in subsection (3).\textsuperscript{83}

This language apparently would permit substitution of a generically equivalent drug in place of the brand-name product prescribed by the doctor without the patient's consent or even his knowledge in some cases. The amendment's supporters deny this,\textsuperscript{84} on the ground that proper labeling as required by section 14a(1) would notify the customer of the substitution.\textsuperscript{85} This assumes, however, that the customer will read the label and that he will understand that a substitution has occurred. Furthermore, if the customer does discover the substitution, he has the burden of demanding, after the prescription has been filled and quite possibly after he as returned home, that his prescription be filled as written or that he get his money back. The Michigan Board of Pharmacy proposed amending the bill to insert the phrase "with the knowledge and consent of the patient" after the word "may."\textsuperscript{86} Nevertheless, the bill passed the House without it on October 28, 1975.\textsuperscript{87} Hopefully the Senate will add this requirement

\textsuperscript{82} Understanding H.B. 4145, supra note 58, at 7-8.
\textsuperscript{83} H.B. 5325, 78th Leg. (1975).
\textsuperscript{84} Sesti, supra note 70, at 38.
\textsuperscript{85} MICH. COMP. LAWS ANN. § 338.1114a(1) (Supp. 1975-76) provides in pertinent part:

If a drug is dispensed which is not the prescribed brand, the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed . . . .

\textsuperscript{86} Sesti, supra note 70, at 38.
when it considers House Bill 5325. Substitution should not take place without regard to the wishes of the customer. Since the main purpose of this legislation is to save the consumer money, he should have the option of refusing this benefit if he so desires.88

House Bill 5325 as proposed also would compel a pharmacist to substitute a lower cost generically equivalent product (if available in the pharmacy) whenever requested to do so by a customer. This would be unwise, since it has been demonstrated that not all drugs which are chemically equivalent (and thus generically equivalent) are therapeutically equivalent.89 In some circumstances, therefore, a pharmacist should not substitute. One might argue that under these circumstances the prescriber would indicate that the prescription be dispensed as written. Nevertheless, the pharmacist should serve as a "check" on the doctor in all events, and where he feels generic substitution would not be in the patient's best interest, he should not be forced to dispense a substitute.

2. The Savings in Cost Must Be Passed on to the Consumer—Three provisions of the generic drug law limit the price pharmacists can charge for an equivalent drug product dispensed in place of a prescribed brand-name drug.90 Subsection 14a(1) states that, when the customer requests a "lower cost" generic equivalent, the pharmacist may dispense "a lower cost but not higher cost" product.91 Subsection 14a(2) commands that when substitution occurs, "the pharmacist shall pass on the savings in cost to the consumer."92 Savings in cost is defined as "the difference between the wholesale cost to the pharmacist of the 2 drug products."93 Subsection 14a(4) prohibits the pharmacist from dispensing "a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser."94 This last section seems redundant, and it is not clear why it was included unless it was intended to clarify the fact that a purchaser can waive the "lower cost" guarantee of subsection 14a(1). However, if subsection 14a(1) is interpreted as applying to substitution only when performed in response to a purchaser request, subsection 14a(4) would prevent a pharmacist from dispensing a more expensive equivalent product when substituting on his own initiative (assuming that the pharmacist may select an equivalent drug product with-

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88 The Minnesota drug substitution law provides that a pharmacist who receives a prescription for a brand name legend drug may, with the written or verbal consent of the purchaser, dispense any drug having the same generic name. . . . MINN. STAT. ANN. § 151.21(2) (Ch. 101 [1975] Minn. Session Law Serv. 295) (emphasis added).

89 See part IV A infra.

90 MICH. COMP. LAWS ANN. § 338.1114a(1), (2), (4) (Supp. 1975-76).

91 MICH. COMP. LAWS ANN. § 338.1114a(1) (Supp. 1975-76).

92 MICH. COMP. LAWS ANN. § 338.1114a(2) (Supp. 1975-76).

93 Id.

94 MICH. COMP. LAWS ANN. § 338.1114a(4) (Supp. 1975-76).
out a prior purchaser request). Subsection 14a(2) would apply to both situations.

These provisions are the very essence of the drug substitution act, since the purpose of permitting generic substitution is to decrease costs for the purchasers of prescription drugs. Without a stipulation that the savings realized through generic substitution be passed on to the consumer, the benefits of this legislation might well redound to pharmacists alone.

It is not clear how the state will enforce the requirement that the savings in acquisition cost be passed on to the consumer. Representative Bert Brennan, in explaining his vote against the generic drug law, stated that a representative from the Attorney General's office had "publicly admitted that the section [was] unenforceable." If the law is amended to permit substitution without a prior purchaser request, consumers will need to be aware of the existence and relative prices of generically equivalent drug products in order to protect their right to realize the savings when substitution takes place. The provision of the act which requires pharmacists to post the prices of the one hundred most frequently prescribed drugs should aid the public in this regard. It would also be helpful, however, to require any pharmacist substituting a cheaper equivalent in place of the brand of drug prescribed to verbally notify the customer of the substitution. This should alert the purchaser to expect to pay a lower charge.

3. The Doctor Must Not Have Exercised His Power to Prevent Substitution—The Michigan drug substitution law allows the prescriber to prevent drug substitution simply by writing "dispense as written" or "D.A.W." on a written prescription. The indication must be in the prescriber's own handwriting and cannot be preprinted on the prescription blank for an obvious reason: such easily taken action would completely circumvent the law. If the prescription is not in writing, that is, if it is given verbally, substitution is prevented if the prescriber "expressly indicates the prescription is to be dispensed as communicated." The "D.A.W." provision can be criticized on the ground that it gives prescribers power to thwart the law. This contention could be answered, however, by again pointing out that not all chemically equivalent drugs produce the same therapeutic effect. Since there must be some mech-

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95 See part III A 1 supra.
96 MICH. H.R. JOUR. No. 26, at 526 (Feb. 26, 1974).
97 MICH. COMP. LAWS ANN. § 338.1114c (Supp. 1975-76).
98 MICH. COMP. LAWS ANN. § 338.1114a(3) (Supp. 1975-76).
99 Id. The law further specifies that, if the prescriber has preprinted on his prescription blanks the statement "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed D.A.W.,” the prescriber may prevent substitution by writing the initials D.A.W. in a space, box or square adjacent to such statement. This provision was added by the Senate. MICH. S. JOUR. No. 74, at 1047-48 (May 29, 1974). Its inclusion seems unnecessary. Yet the Michigan Attorney General has interpreted it as creating an exception to the general rule requiring purchaser request prior to generic substitution. See part III A 1 supra. That this was the legislative intent seems unlikely whether or not the legislature intended a purchaser request to be a prerequisite for generic substitution.
100 See part IV A infra.
anism whereby the prescriber can specify that only one brand of drug be given to his patient, the requirement that he write out the words "dispense as written" or the initials "D.A.W." is a reasonable solution. Although a doctor is not prevented from writing "D.A.W." on every prescription if he so desires, an affirmative act, indicating a conscious decision on his part, is required. Unfortunately, in a survey conducted by the Department of Community Medicine of Wayne State University, 15 percent of the physicians responding reported that they intend to write "D.A.W." in all cases. Perhaps as consumers become more aware of this legislation, they will begin to question such doctors about their rationale for limiting the patient's options in this way.

The Minnesota drug substitution law also permits substitution of a generic equivalent only if a prescriber has not written in his own handwriting "dispense as written" or "D.A.W." However, even when the prescription is marked "D.A.W.," a pharmacist may substitute a generically equivalent drug product which is manufactured in the same finished dosage form having the same active ingredients and strength by the same manufacturer as the prescribed brand name drug.

This limits the doctor's prerogative of naming a specific brand, but only in the situation where one manufacturer has produced a single product which is then marketed by several drug companies under various names.

B. The Requirement that Drug Prices Be Displayed

The other major feature of the current legislation is a section compelling pharmacists "engaged in the business of selling drugs at retail" to post at each prescription counter the current selling prices of the one hundred most frequently prescribed drugs. This is a significant advance for the consumer, which will cost the state little in comparison to the benefits it will provide. The fact that drug purchasers can now easily compare prices charged in various pharmacies should foster competition in the retail sale of drugs.

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103 Id.; Minn. Stat. Ann. § 151.361 (Ch. 101 [1975] Minn. Session Law Serv. 296) requires that the container of any drug product sold for human use in the state be labeled with the name and address of the manufacturer of the finished dosage form of the product.
105 The State Board of Pharmacy was given the responsibility to publish and distribute posters showing the one hundred most frequently prescribed drugs. The cost of this was estimated to be approximately $2,600, based upon distribution of the list on a quarterly basis to the 2500 pharmacies in the state. Analysis Section, Mich. H.R., Analysis—H.B. 4145 (Nov. 6, 1974).
IV. PROBLEMS NOT ADDRESSED BY THE CURRENT GENERIC DRUG ACT

A. Therapeutic Equivalency

Serious questions have been raised as to whether drug products of the same chemical structure, drugs which are generically equivalent, are therapeutically equivalent.\textsuperscript{106} Drugs are considered therapeutically equivalent if, when administered to the same individuals in the same dosage regimen, they provide essentially the same efficacy and/or toxicity.\textsuperscript{107}

In April 1974 the Office of Technology Assessment convened an expert Drug Bioequivalence Study Panel in order to examine the relationships between the chemical and therapeutic equivalence of drug products and to assess the capability of current technology . . . to determine whether drug products with the same physical and chemical composition produce comparable therapeutic effects.\textsuperscript{108}

The Drug Bioequivalence Study Panel produced a report which was made public just one month after the Michigan generic drug bill was signed by the Governor. The study panel concluded that not all chemically equivalent drugs are therapeutically interchangeable.\textsuperscript{109} Furthermore, the problem of therapeutic inequivalence was viewed as an important one, in spite of the fact that the number of instances of demonstrable inequivalence is small.\textsuperscript{110} Nevertheless, the panel indicated that the goal of interchangeability was achievable within most classes of drug products and set out recommendations for meeting this goal.\textsuperscript{111}

Kentucky has dealt squarely with the issue of therapeutic equivalency. Its drug substitution law creates a Drug Formulary Council which is responsible for preparing a formulary of generic drugs which it determines to be therapeutically equivalent to specified brand-name drugs.\textsuperscript{112}


\textsuperscript{107} Drug Bioequivalence, supra note 106, at 78.

\textsuperscript{108} Id. at 5.

\textsuperscript{109} Id. at 13.

\textsuperscript{110} Id. at 14.

\textsuperscript{111} Id. at 58-60. An explanation of the factors leading to therapeutic inequivalence of chemically equivalent drugs is beyond the scope of this note. The reader is referred to Drug Bioequivalence and other sources cited in note 106 supra.

pharmacists may interchange only drugs appearing on this list. In practice, however, this solution has proved to be cumbersome. As of December 1, 1975, the Council had only agreed to place eighteen drugs on the formulary. It is questionable whether the value of this list will justify the cost of its production.

California may have more success with its "negative formulary." This formulary, to be established by the Director of Health, is to include generic drug types and drug products which the Director of Health determines demonstrate clinically significant biological or therapeutic ineqivalence and which, if substituted would pose a threat to the health and safety of patients receiving prescription medication.

The Director of Health is to rely upon testing and research as well as formularies drawn up by other states, the Department of Health, Education, and Welfare and any other reliable sources. A pharmacist is prohibited from performing generic substitution for drugs on this list.

The California plan is an excellent compromise between placing no restrictions at all on generic substitution and confining substitution to drugs listed on a "positive" formulary. This approach prevents the drug consumer from buying a drug which, while chemically equivalent to that prescribed by his doctor, has been shown to produce a different therapeutic effect. Furthermore, this benefit is achieved without expending vast sums of money or requiring the agreement of a body of experts. Library research will quickly turn up documented studies of demonstrated bioinequiva-

114 Letter from N. Earl Becknell to author, Dec. 1, 1975 (on file with the University of Michigan Journal of Law Reform). However, eleven more drug families were scheduled for addition, effective mid-December. Id. (The law creating the Council was enacted in 1972.)
115 The sum of $100,000 was appropriated to the Council for its first two years of operation. Id. Massachusetts law also provides for establishment of a formulary. MASS. GEN. LAWS ANN. ch. 17, § 13 (1973). However, rather than permitting a pharmacist to substitute from the list, the law requires that the doctor prescribing a listed drug must indicate the generic name on the prescription. MASS. GEN. LAWS ANN. ch. 112, § 12D (1975).
116 Maryland limits generic substitution to drugs listed in a state formulary or approved for listing by the Department of Health, Education, and Welfare according to regulations entitled Maximum Allowable Cost for Drugs, 45 C.F.R. Part 19. MD. ANN. CODE art. 43, § 273A (Cum. Supp. 1975). 45 C.F.R. § 19.5 (1975) establishes procedures for identifying "multiple-source drugs for which significant amounts of Federal funds are or may be expended . . . and for which there are or may be significantly different prices." Reimbursement (under federal programs) for selected drugs would be limited to the lowest price "at which the drug is widely and consistently available from any formulator or labeler." 45 C.F.R. § 19.3 (1975). See notes 127-29 and accompanying text infra.
118 Id.
119 Id.
A positive formulary is more difficult to compile because far less consensus exists in recognizing drugs which can be safely interchanged than in identifying products which should not be substituted.

The Drug Bioequivalence Study Panel recommended that the federal government compile a list of interchangeable drugs. A project of this magnitude would be an ambitious proposition for a state to undertake and its benefits would probably be outweighed by its cost. If the federal government were to undertake such a study, on the other hand, the effort would be considerably more worthwhile. Once a list of equivalent drugs was produced, states having generic drug laws could adopt the resulting list as a formulary from which the pharmacist could select substitutions.

B. Third-Party Payment Plans

In Michigan over three million citizens are covered by pre-payment benefits for pharmacy care. Yet the Michigan generic drug law provides no incentive for a consumer who has insurance to request substitution. In fact, the law now provides that the savings in cost need not be passed on to a third-party payment source when generic substitution occurs. This exception for purchases covered by third-party payment contracts was probably made because these contracts usually provide that the pharmacist will only be reimbursed the wholesale price of the drug dispensed plus a flat service fee. Nevertheless, the bill presently before the Michigan Senate would amend the law to require that the savings in cost be passed on to a third-party payment source if the prescription is covered by a third-party payment contract. This reform may not save much money for insurance companies, however, because purchasers covered by insurance will not necessarily desire a cheaper generic drug. On the contrary, they may well demand "the best money can buy" in spite of the fact that the increased costs of health care are reflected in the premiums charged for health insurance.

120 Differences in bioavailability (bioinequivalence) among some drug products may not be of concern in all cases. This is because many drugs have a wide range between the concentration of active ingredient in the body fluids which is needed to produce a desired therapeutic effect and that which produces unwanted toxic effects. On the other hand, for drugs with a narrow margin of safety, a difference in bioavailability can be crucial. DRUG BIOEQUIVALENCE, supra note 106, at 22-23. The Drug Bioequivalence Study Panel proposed guidelines for determining the drugs for which bioequivalence would be critical and therefore for which bioavailability studies are essential. DRUG BIOEQUIVALENCE, supra note 106, at 23-24. Presumably, these drugs would be placed on a negative formulary until such time as their bioequivalence was affirmatively demonstrated.

121 DRUG BIOEQUIVALENCE, supra note 106, at 57-60.

122 Present uncertainty about therapeutic equivalency may make pharmacists fear increased liability and therefore hesitate to substitute generically. For a discussion of liability issues, see Note, supra note 8, at 897-904.


125 Understanding H.B. 4145, supra note 58, at 8.

In some situations health insurers have attempted to decrease expenditures by reimbursing the insured only for the cost of certain approved expenses, for example, a semi-private hospital room. The Department of Health, Education, and Welfare is attempting to apply similar restrictions to the reimbursement of drug providers under federally funded programs such as Medicare.\textsuperscript{127} Drugs to which the “maximum allowable cost policy” will apply will be listed in the \textit{Federal Register}.\textsuperscript{128} Reimbursement for these drugs will be limited to the lowest cost at which each drug is widely available plus a reasonable dispensing fee.\textsuperscript{129}

If a list of interchangeable drugs were generated by the federal government as proposed by the Drug Bioequivalence Study Panel and were adopted by the state as a formulary, private insurers could reasonably limit reimbursement for any given multi-source drug to the amount for which it could be obtained from the least expensive source approved for inclusion on the formulary.

\textbf{V. Conclusion}

The Michigan generic drug law in its present form is an acceptable solution to the problem of delivering quality pharmaceutical care at competitive prices. The most effective way to achieve this goal would be to empower a panel of experts to compile a list of therapeutically equivalent drugs and permit substitutions from that list. However, due to the expense of such an undertaking and the fact that most drugs do not have known equivalency problems associated with them, this method was not adopted.\textsuperscript{130} Instead, the Michigan drug substitution law requires the consent of three persons before generic substitution can take place: the doctor must not prohibit substitution, the patient must request the exchange, and the pharmacist must be willing to select a brand other than the brand prescribed. This approach gives pharmacists broader latitude in the exercise of professional judgment and helps drug purchasers save money on prescriptions. It is unclear, however, whether a purchaser must initiate generic substitution or merely agree to it. The law should therefore be amended to remove the ambiguous “purchaser request” language, but the right of a consumer to be consulted about the selection of the drug product he will purchase should be retained.

Any amendment to the generic drug law must accommodate the policies of decreasing the cost of drugs, expanding the professional role played by pharmacists in drug product selection, and increasing the right of the consumer to choose the product he will purchase. The bill presently before the Michigan Legislature gives disproportionate emphasis to the factor of reducing drug cost. It would compel the pharmacist to substitute upon con-

\textsuperscript{128} 45 C.F.R. § 19.5 (1975).
\textsuperscript{129} 45 C.F.R. § 19.3 (1975).
\textsuperscript{130} The major benefits of a formulary can be achieved with relatively little expense by compiling a negative formulary, however. \textit{See} notes 116-20 and accompanying text \textit{supra}. 
sumer demand even where substitution in his judgment violated good pharmaceutical practice. It would also permit substitution to occur against the wishes of the consumer. Such a policy choice would be less objectionable if it were combined with either a positive or negative formulary. Until such a safeguard exists, however, consent of all three parties concerned in a patient's drug therapy should remain a prerequisite for generic substitution.

—Phyllis Greenwood Rozof