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Two Proposals to Lower Prescription Drug Prices: Generic Name Prescribing & Repeal of the Antisubstitution Laws

The new public awareness toward prescription drug prices can be attributed in large part to Wisconsin Senator Gaylord Nelson, and his efforts as Chairman of the Monopoly Subcommittee of the Senate Select Small Business Committee.¹ As an investigatory body, the Monopoly Subcommittee has held hearings since May, 1967, dealing with the costs of prescription drugs, the profits of drug manufacturers, and other aspects of the prescription drug industry.² The findings of the Subcommittee have been made available to the public, largely through coverage by the news media. Public attention has also been drawn by the positive action taken by Senator Nelson in the form of bills he has introduced into the United States Senate to curb what he believes to be exorbitantly high prices in a noncompetitive industry. He advocates the use of generic name prescribing to help reduce the price of prescription drugs.

Generic name prescribing is often thought of in conjunction with antisubstitution laws, although antisubstitution is actually a much broader concept. The meaning of these terms will become clear as the topics are developed herein. Prescription by "generic name only" will be dealt with as a proposal on the federal level to reduce drug prices; whereas antisubstitution for the purpose of this paper will be limited to state proposals that have the same goal.

A drug is alternately referred to by its chemical name, its brand name, or its generic name. The chemical name refers to the chemical or molecular structure; the brand name is the name by which a drug is referred to by its manufacturer; and the generic name refers to its established or nonproprietary name.³ In other words, brand names distinguish the product of one company from another, while generic names never mention the manufacturer's name. A drug usually has only one generic name, but it can have as many brand names as it has manufacturers. Physicians can usually tell the chemical make up of a drug by looking at its generic name, because it is often an abbreviation of the chemical name. Brand names,

¹ James L. Goddard, former commissioner of the FDA, believes that the public is not aware of prescription drug prices. His impression is that the increased consciousness of drug prices may be on the part of law makers rather than on the part of the public. *But see* Goddard, *The Drug Establishment*, ESQUIRE, March, 1969, at 116.

² STAFF OF SUBCOMMITTEE ON MONOPOLY, SENATE SELECT COMMITTEE ON SMALL BUSINESS, 92N CONG., 2D SESS., COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY—SUMMARY AND ANALYSIS v (Comm. Print 1972).

³ Food Drug and Cosmetics Act, 21 U.S.C. § 352 (e)(2) (1967); PHARMACEUTICAL MANUFACTURERS ASSOCIATION, BRANDS, GENERICS, PRICES AND QUALITY—THE PRESCRIBING DEBATE AFTER A DECADE 2 (1971) [hereinafter cited as BRANDS AND GENERICS]; Deichmann, *Proprietary Drugs v. Generic Drugs*, 35 GENERAL PRACTICE 174 (1967).

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on the other hand, do not indicate the chemical make up of a drug.⁴

Amendments to the Federal Food, Drug and Cosmetic Act, require drug companies to write the generic name beside the brand name, in type at least one-half as large as the brand name, to be repeated each time the brand name is featured.⁵ At the time this regulation was promulgated, it was hoped by the Food and Drug Administration (FDA), that doctors would prescribe generically once they were aware that a drug was required to be made available by its generic name.⁶

Senator Nelson, displeased with the lack of voluntary generic prescribing by physicians, has advocated a change in the present law because he feels a savings would result to the customer if doctors were required to prescribe by "generic name only," rather than by brand name. He introduced a proposed amendment to the Federal Food, Drug and Cosmetic Act on October 30, 1973, which would, ". . . prohibit the use of any name in connection with any prescription drug other than the official name designated for such drug by The Secretary of Health, Education, and Welfare."⁷ The official name referred to would probably be an abbreviation of the chemical name, or, the generic name, and would be the only one that can appear on any label or advertisement. Consequently, the drug manufacturer could not include the name of the company producing the drug or the brand name. In effect, the same drug manufactured by every company would be called by the same name. The pharmacist, in turn, would fill a doctor's prescription with the brand he had in stock, which he purchased in the competitive market. The majority of drugs have only one manufacturer, so the pharmacist would have no choice in filling most orders, but in the remaining cases, he would have a choice.

An ant substitution law is one that requires a pharmacist to dispense the exact drug the physician has prescribed. Every state, with the exception of Kentucky, Maryland and the District of Columbia, has such a law.⁸ The North Carolina ant substitution statute, typical of most, reads in part:

Any person or corporation engaged in the business of selling drugs, medicines, chemicals, or preparations for medical use or of compounding or dispensing physicians' prescriptions, who shall . . . knowingly sell or deliver to any person a drug other or different from the drug . . . ordered or called for by such person, or called for in a physician's prescription, shall be guilty of a misdemeanor. . . .⁹

The ant substitution laws were initially passed so that the unethical

⁴ Ruge, *Prescription Drug Advertising*, 32 LAW & CONTEMP. PROB. 654 (1967).

⁵ Food Drug and Cosmetic Act, 21 U.S.C. § 352 (e)(1)(B) (1967).

⁶ Ruge, *supra* note 4, at 656.

⁷ S. 2633, 93rd Cong., 1st Sess. (1973).

⁸ Health Research Group, *An Outline for Consumer Action On Prescription Drug Prices*, No. 56, Jan. 22, 1973, at 5.

⁹ N.C. GEN. STAT. § 90-76 (1937).

pharmacist could not substitute one chemical drug for another without breaking the law.¹⁰ As in many such laws,¹¹ no mention of the word "generic" or "brand" is made in the North Carolina antisubstitution statute.¹² In the 1950's, the National Pharmaceutical Council interpreted such legislation to mean a pharmacist could not substitute a generic name for a brand name drug.¹³ This interpretation still holds true today, and restricts the pharmacist to the brand name specified. On the other hand, if the physician wrote the prescription order using the generic name of the drug, then the pharmacist could choose which brand name drug he would use in filling the order.

While on the federal level Nelson has strived to achieve generic name prescription, on the state level, parallel forces are striving to achieve a repeal of the state antisubstitution laws to allow pharmacists to substitute a cheaper generic name drug for the predictably more expensive brand name drug. The antisubstitution issue is not limited to generic name prescribing, even though it is often so construed. It also means that one brand name drug cannot be substituted for another brand name though they are the same chemical drug.

If a state does repeal its antisubstitution law, then the pharmacist would be allowed to fill an order for a prescription with any brand or generic name drug that is chemically the same as the drug prescribed. If Nelson's amendment to the Federal Food, Drug and Cosmetic Act is passed, any state without an antisubstitution law would have one official name for each chemical compound, thus obviating the brand name/generic name issue. The passage of the amendment, without a state's repeal of the antisubstitution law would point the impact of "substitution" back to its initial meaning, which was to stop pharmacists from dispensing one chemical drug in place of another, omitting any reference to brand names.

The essential point is that there are individuals and organizations working at the federal and state levels to reduce the price of prescription drugs. The repeal of the state antisubstitution laws and the federal bill to require "generic name only" prescribing are two tools with which this goal is being sought. There are many more. For example, an administrative agency may simply make a ruling, thus obviating the necessity of a bill passage through Congress. To illustrate, HEW Secretary, Caspar W. Weinberger, "... plans to limit drug reimbursements under Medicare and Medicaid to the lowest cost at which the drug is generally available unless there is a demonstrated difference in therapeutic effect."¹⁴ This

¹⁰ Health Research Group, *supra* note 8, at 5; Editorial, *The Plea of a Jacksonville Druggist*, 220 J.A.M.A. 853 (1972).

¹¹ Health Research Group, *supra* note 8, at 5.

¹² N.C. GEN. STAT. 90-76 (1937).

¹³ Health Research Group, *supra* note 8, at 5.

¹⁴ The News and Observer (Raleigh, N.C.), Dec. 20, 1973, at 3, col. 1.

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means that the government will shop for the best price. A doctor who prescribes an expensive brand name drug rather than a cheaper generic equivalent for his patients under these two programs, will have to justify his reason for doing so before the government will reimburse him.

While brand name prescription and antisubstitution laws have their enemies, they also have staunch advocates, who argue that prescription drug prices are not high compared to costs in other major industries. This comment will look at both sides of the antisubstitution controversy and the pros and cons of "generic name only" prescriptions. Often the same arguments used in support of the repeal of the antisubstitution laws will be used for favoring generic name prescribing, but in other contexts, the arguments for each will differ. Two important questions to keep in mind while studying each side are, 1) whether prescription drug prices are too high, and 2) if so, would the proposed remedies be effective in lowering the prices.

There is a great deal of confusion today over the terms "generic" and "brand." Often, "generic" is used to connote an inferior drug, this inference being due largely to the efforts made by the drug companies to convince doctors to prescribe by brand names only. Often a generic product is as effective as a brand name product. In fact, in many cases, the company that produces a brand name will also produce generic drugs. For example, Eli Lilly, one of the largest brand name drug manufacturers, also makes generic drugs that can compete with any brand name of the same drug on the market. There are good and bad brand name producers and good and bad generic name producers.¹⁵

Nelson believes that doctors have been "sold" by the major drug companies to prescribe their brand name products, which are generally more expensive.¹⁶ The result is that doctors prescribe the more expensive medicine, even in cases where the same company makes the identical drug and sells it by both its generic name and its brand name. Another situation is where one drug company charges much more for its brand name than its competitor charges for the same drug manufactured under its generic name. A look at the drug, Reserpine, for example, illustrates the great differences in cost between the generic and brand names. The five major drug companies that manufactured Reserpine by a brand name sold it from a high of \$46.00 to a low of \$9.12. The eighteen generic manufacturers wholesaled the same quantity of Reserpine from a high of \$2.80 to a low of \$.58.¹⁷ Nelson's point is that the company that sells the drug for \$.58 is making a profit, so there is no reason the same company or another company should sell the same drug for \$46.00, simply to reap an unconscionable profit.

¹⁵ Boston Herald Traveler, Aug. 11, 1969, at 10, col. 1.

¹⁶ 119 CONG. REC. 10820 (daily ed. June 11, 1973).

¹⁷ R. BURACK, THE NEW HANDBOOK OF PRESCRIPTION DRUGS 314 (1970).

There are also companies that sell their brand name drugs to pharmacists at very high prices and turn around and sell the very same drug by its generic name to the United States government or other governments for very little. For example, CIBA Company sold its brand name drug, Serpasil, to druggists for \$39.50, but charged the United States Department of Defense only \$.60 for the same quantity of the drug sold by its generic name.¹⁸

When questioned about the fact that Schering Corporation charges a druggist \$170.00 for the same amount of Metricorten for which it charges the government only \$8.20, Mr. Conzen, the president of the company, replied that sales are made on the basis of a two price system. In the price established for the government, only incremental costs are included, consisting of the price of raw materials and the cost of labor. None of the manufacturing costs or business operation costs, such as research, administration and taxes, are considered. This is done so that the company may receive a government contract by submitting the lowest bid. This has significance to the company, because to win a government bid means that its brand name product will be used in government hospitals, institutions and military camps. Such use has promotional value, because physicians prescribing the product in that context will continue to do so when they leave government service. So while a company could not stay in business if it charged druggists the same low price, it will go to great lengths to have its product used by governmental institutions.¹⁹

Accordingly, since it would seem that generic name drugs are generally cheaper than brand name drugs, (at least on the wholesale level—from the manufacturer to the druggist), Nelson argues that a law that would require generic name prescribing would result in a savings to the customer. There are at least two fallacies in that argument. The first is the presumption that generic name drugs are always cheaper than brand name drugs. There are top quality generic manufacturers that spend a great deal of money on research, testing and quality control devices, just like the brand name producers. To cover these costs, and the cost of advertising to promote their generic drugs, these producers sell their drugs at a high price. Since they spend the money to reach the doctor, who prescribes the drug, their high priced drugs sell. Generic drugs of this top quality would not save the public much money, because they will often be in the same price range as brand name drugs.²⁰

However, if it is assumed that most generic name drugs cost less than brand name drugs on the wholesale level, as Nelson has pointed out in numerous examples, the second fallacy in his argument is that the pharmacist is

¹⁸ 119 CONG. REC. 10821 (daily ed. June 11, 1973); SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 16.

¹⁹ SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 16.

²⁰ Boston Herald Traveler, *supra* note 15, at 10, col. 1.

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going to pass the savings on to his customer.²¹ With an "official name only" prescribing rule, formerly brand name products would be forced to replace their brand name labels with the official names and doctors would have to write out prescription orders using the official names only. The higher-priced companies would be forced to reduce the price of their drugs to compete on the open market for the pharmacists' business, and the pharmacist, who at one time had to buy the expensive brand name, could now purchase the cheapest drug on the market to fill the doctor's prescription order. It is still within the discretion of the individual pharmacist to decide the price he will charge the customer. He can keep all the profit that he has saved by buying the cheapest drug, or he can choose to pass some or all of the savings on to the consumer. His decision would probably take into consideration his overhead expenses and local competition.

Similar results could occur if the antisubstitution laws were repealed. The only difference would be that a doctor could prescribe a brand name drug that he favors, and the pharmacist could substitute a cheaper generic drug that is chemically the same. Again, the choice belongs to the pharmacist, whether to pass along the savings to the customer, or pocket it himself.

There is very little evidence as to whether pharmacists pass on the savings at the retail level, because most of the states have antisubstitution laws and Nelson's amendment has not been passed to require generic prescription. Nelson draws most of his conclusions about savings to the customer by looking at the difference in wholesale price between generic and brand name drugs, and from his extensive surveys in Washington, D.C. area pharmacies. Thus, most of his evidence is speculation.

In a 1969 report, HEW's Task Force on Prescription Drugs listed sixty-three drugs that were available generically at a lower price than the brand name equivalents. There were 346 drugs that were not available by a generic name, but had to be purchased from its one producer by its brand name. The 409 drugs on the list represented 88 percent of all the drugs prescribed for the over sixty-five population. Dealing with the sixty-three drugs that were available at a lower cost by their generic names, the Task Force found that a 55.3 percent saving would result on the wholesale level if these drugs were purchased generically. On the retail level, the Task Force speculated that if the druggist charged \$1.81 or \$2.00 to dispense the drugs in question, the savings to the customer would have been 6.1 percent or 5 percent respectively of what is presently being charged. The indications are that pharmacists would pass on some of the savings to their customers, the figure varying from store to store and taking many cost figures into account. The Task Force implied that a similar savings would occur if the antisubstitution laws were repealed.²²

²¹ *The Price of a Generic Rx Drug*, 35 CONSUMER REPORT 398 (1970).

²² HEW, TASK FORCE ON PRESCRIPTION DRUGS—FINAL REPORT, at 36 (1969) [hereinafter cited as TASK FORCE FINAL REPORT]; BRANDS AND GENERICS, *supra* note 3, at 21-23; Willig, *The Prosubstitution Trend in Modern Pharmacy Law*, 6 U. MICH. J. LAW REFORM 17 (1972).

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The Pharmaceutical Manufacturers Association (PMA) points out from using Task Force figures that it is doubtful that a five percent savings would have occurred, especially if pharmacists did not fill the prescription with the cheapest product on the market. Another factor to consider is that the Task Force did not include administration costs when figuring the five percent savings. HEW estimated that a program which emphasized generic name prescribing would cost \$11,600,000 the first year and then less each successive year. To include these figures would reduce the five percent to a virtual absence of savings.²³

Proponents of the antisubstitution laws point out examples of cases where pharmacists have broken the law and were tried and convicted for illegally substituting one drug for another. In these reported cases, pharmacists did not pass the savings on to their customers. Instead, each had filled a prescription with a cheaper drug and had charged the price of the drug the physician had prescribed.²⁴

However, there are other reports that refute the Task Force claim that a large savings would result if generic name prescribing were mandatory. One such report compared ten thousand prescriptions of welfare patients in Rhode Island in 1960.²⁵ The state concluded that a two percent savings would have resulted if the drug had been prescribed and filled generically where possible. In May and June of 1967 the American Medical Association released news of a survey it conducted in which 185 Chicago pharmacies filled 686 prescriptions of seven disputed products.²⁶ Its conclusion was that filling prescriptions generically would not mean an automatic savings to patients. In fact, the survey showed that the patient sometimes paid more for generic prescriptions.

The province of Alberta, Canada has permitted pharmacists to substitute generic name drugs for brand name drugs since 1962, that is, unless the doctor specifically prohibits it. A 1972 report showed that the average cost of prescriptions in Alberta had not reduced in the ten years. In fact, Alberta led all provinces in 1970 with an average prescription price of \$4.46. Canada's national average was only \$3.89.²⁷

In considering the extent to which generic name prescribing may reduce drug prices, another fact to keep in mind is that generic name prescriptions themselves are rapidly increasing in price. For example, their average

²³ BRANDS AND GENERICS, *supra* note 3, at 22-23.

²⁴ Address entitled Some Perspectives on the Proposed Repeal of Pharmacy's Antisubstitution Laws, by Robert W. Hammel, Professor of Pharmacy Administration at Univ. of Wisconsin, to the Rock County Pharmaceutical Association and to the Pierce-St. Croix Pharmaceutical Society, in reprint by the Pharmaceutical Manufacturers Association, at 1.

²⁵ BRANDS AND GENERICS, *supra* note 3, at 15-16.

²⁶ *Id.* at 19.

²⁷ Address entitled A Background Study of the Antisubstitution Laws and the Brand Interchange Concept, by the National Association of Retail Druggists, to the membership at the 74th Annual Convention, Oct. 1-5, 1972, in reprint by N.A.R.D., at 7.

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price increased 63.2 percent between 1959 and 1969. Retail prescription charges did not increase nearly as much. Between 1964 and 1969, the difference in cost between generic prescriptions and prescriptions in general narrowed by one-third. The Pharmaceutical Manufacturers Association suggests that there may be no difference within five years.²⁸

In an attempt to convince Congress to adopt his bill requiring generic name prescriptions, Senator Nelson has pointed out how much more Americans pay than foreigners for the same brand name drug. For example, Valium costs the druggist in England \$2.88 for one hundred 5 mg. tablets, and the druggist in America \$8.10 for the same amount. One hundred 10 mg. capsules of Librium cost \$2.40 in England and \$6.82 in the United States. While this seems like quite a difference, Nelson finds it even more astonishing that the British Ministry For Trade and Consumer Affairs was able to order Hoffman-LaRoche, a Swiss firm, to reduce the price of Valium and Librium, by 75 percent and 60 percent respectively, because the Monopoly's Commission found that the firm controlled 68 percent of the tranquilizer market in the United Kingdom. The Commission found that Roche was enjoying a 70 percent return on the capital.²⁹

The United States druggist pays almost three times as much for Valium and Librium than the British druggist, yet Roche does not have to reduce its price in the United States. The United States government, unlike the British government, does not have the authority to require a company to sell a drug at a lower price, even when Valium and Librium, number one and three in sales in the United States, will total more than one quarter of a billion dollars in 1973. Drug companies, such as Roche, that try to justify receiving a seventy percent profit, argue that competitive market conditions determine drug prices and keep them within reasonable bounds. Roche cites 600 other products with which it competes. The British government disagreed with this contention by putting Roche's products in a class by themselves, since the total sales of the competitors only amounted to one percent of the market. Drug companies argue trust in a brand name as the reason doctors prescribe a certain drug, but opponents believe the reason to be the seventeen year statutory patent, and prescription of the same drug thereafter due to force of habit.³⁰

The American patent system allows a brand name product to dominate the market for seventeen years without competition. The patent holder does not even have to be the company that spent the time and money researching, testing and developing the drug. The originator can sell the patent rights to another company, thus giving it the exclusive right to sell the drug in the United States. Senator Nelson sees the monopolistic

²⁸ BRANDS AND GENERICS, *supra* note 3, at 25.

²⁹ 119 CONG. REC. 19636 (daily ed. Oct. 30, 1973).

³⁰ *Id.*

patenting and licensing policies in the United States as another reason drugs are higher priced here than abroad. By the time generics can enter the field with lower prices seventeen years later, brand name prescribing habits keep the original manufacturer on top, and reduced prices are not necessary to retain customers.³¹

Prescription drug manufacturers also contend that drug prices are not high compared to prices in other industries and in comparison to other health related fields. Figures show that of all the areas of expenditures in the medical field, that of drugs requires the least amount of outlay, and its price growth rate has increased less than the other areas.³² When drug prices are compared to prices outside the drug industry, the Wholesale Price Index, put out by the Department of Labor's Bureau of Labor Statistics, shows that the level of all commodities has risen since 1965, while the price level of prescription drugs has declined.³³ Another observation shows that between 1957 and 1971, the average prescription cost rose only two percent, and when an increase in the package size was taken into account, the price actually declined by three percent.³⁴

Other government reports show a rise in the price of consumer goods in 1972 by 3.3 percent, and in medical care by 8.4 percent. In contrast, the increase of prescription drug prices in the same year was only 0.4 percent, which was only the fourth increase in over fourteen years. In fact, since 1962, there has actually been a nine percent decrease in retail prescription drug prices.³⁵

Senator Kefauver, ideological predecessor of Senator Nelson, argued that doctors prescribed by brand name even after the seventeen year patent period ended because of the promotion campaign run by major drug companies, and because of force of habit. He would have had the people believe that the most expensive brand name of each generic drug had a monopoly in its field. As proof, he quoted the prices of two drugs, Reserpine and Prednisone, which were manufactured by their originators and sold for exorbitant prices, and sold subsequently by other companies under their generic names at greatly reduced prices. However, Kefauver quoted only the great differences in prices between the brand and generic name drugs. He never told the public that the original manufacturers lost the market to the companies that sold the drugs generically. This would at least in part refute Kefauver's, and later Nelson's claim, that doctors continue

³¹ 119 CONG. REC. 12782 (daily ed. July 9, 1973); SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 25.

³² HEW, NAT'L CENTER FOR SOCIAL STATISTICS REP. (chart prepared and released by Nat'l Pharmaceutical Council, Washington, D.C.) nos. B-2 (FY-70), B-5 (FY-70), F-1 (FY-70), F-3 (FY-70), (Mar. 1973).

³³ PHARMACEUTICAL MANUFACTURERS ASS'N, PRESCRIPTION DRUG INDUSTRY FACT BOOK 22 (1972) [hereinafter cited as PMA FACT BOOK].

³⁴ *Id.* at 25-26.

³⁵ *Id.* at 28.

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to prescribe the original brand name when cheaper brand or generic names are available.³⁶

The point is that the doctor will often be controlled by the market when there is more than one drug available of the same quality. Thus, the market place has a reductive effect on drug prices to this extent in instances where a competitive market exists. Promotion and habit may play a role in the decision of a doctor when he fills a prescription, but today many doctors are becoming increasingly aware of price differences and will prescribe with this in mind if they trust the product. In cases where doctors are reluctant to change, it may be because they have either developed a trust in the brand they already know, or they are not familiar with the other drugs that may be available at a cheaper price.

The responsibility for prescribing a drug to a patient is presently on the doctor. The American Pharmaceutical Association, made up of one of every three pharmacists, is supporting measures that would repeal the state antisubstitution laws.³⁷ In effect, this would take the control over the prescription of drugs out of the hands of the doctors, the only persons who have knowledge of the patient's medical history, and leave it to the discretion of the pharmacist. The danger of this practice becomes paramount when illustrated by the argument of therapeutic equivalency as distinguished from chemical equivalency.

Rather than repeal sorely needed antisubstitution laws, the American Medical Association (AMA) recommends retention of them, and inter-professional communications between physicians and pharmacists. Consultation on generic substitution and drug prices can make doctors aware of the great differences in prices between drugs, and of the high quality of drugs they never before bothered to prescribe. Doctors should be encouraged to write prescriptions using the generic name when they feel all companies' drugs are the same. This allows the doctor to control the situation, as it should be, and to shift the burden of choice to the pharmacist only on proper occasions. However, the doctor should retain the power to prescribe by brand name when he feels that a particular brand is of better quality than brands put out by other companies.³⁸

The AMA has refuted the American Pharmaceutical Association's argument that a pharmacist is best qualified to prescribe drugs because of his knowledge of drugs. The AMA contends that the pharmacist generally has no more information on the drug than the doctors, and that the doctor, unlike the pharmacist, has no economic impetus to stock the cheapest drug in order to realize a larger profit on its sale. Additionally, a pharmacist, regardless of the extent of his technical knowledge of medicines, has not

³⁶ BRANDS AND GENERICS, *supra* note 3, at 14-15.

³⁷ Editorial, *Substitution of Drugs*, 212 J.A.M.A. 1369 (1970).

³⁸ *Id.*

examined the patient. These three factors point to the doctor as being best qualified to prescribe drugs.³⁹

Nelson believes that the promotion of prescription drugs by major companies has been a vital factor in keeping brand name drugs more costly than generic name products. In 1971, the sale of drugs amounted to four billion dollars, 25 percent of which was spent for advertising and promotion. On the average, drug companies spend about \$5,000 a year for each of the 200,000 doctors in the United States, in order to convince them to prescribe certain drugs.⁴⁰ He states that high powered advertising has not only increased the price of drugs but has also convinced doctors that expensive drugs are more reliable than generic drugs.⁴¹ Nelson believes that this promotion encourages doctors to prescribe drugs even when they are unnecessary. Madison Avenue advertising firms design ads so that a drug can be prescribed to cover a wide range of symptoms, many being just the ordinary frustrations of daily living. A considerable number of claims made by drug advertisements are false, but by the time the FDA requires the company to run a corrective ad saying the drug does not do everything it was promoted to do, it is too late—the initial promotional drive was so great that the drug continues to benefit from the false campaign.⁴²

Studies reveal that doctors receive most of their information on drugs from detail men who sell them the drugs, journal advertisements, direct mail advertisements, and samples, all of which Nelson labels as biased.⁴³ The *Journal of the American Medical Association*, one of three hundred regularly published United States medical journals, receives one half of its twenty million dollar annual budget from advertising.⁴⁴ Approximately \$700 million of the manufacturers' advertising budget is spent with detail men who are drug company salesmen.⁴⁵ Results of such expenditures are shown in one study which revealed that 46 percent of the doctors in general practice base their decisions on whether or not to prescribe a drug solely upon the word of detail men.⁴⁶

The PMA represents 135 major drug companies. Although eighty are major operations, thirty-five of them actually control the drug industry. Because these thirty-five are able to afford the best advertising, both in quantity and quality, doctors may be brain-washed into believing the drugs presented favorably in these ads are the best. Since doctors prescribe

³⁹ Editorial, *Drug Substitution—How to Turn Order Into Chaos*, 217 J.A.M.A. 818 (1971).

⁴⁰ Other sources quote figures to be as low as \$3,000 and \$3,750 per doctor. Goddard, *supra* note 1, at 152; Ashe, *Detail Men and Doctors*, 4 BEVERLY HILLS B.J. 15 (1970).

⁴¹ 119 CONG. REC. 10821 (daily ed. June 11, 1973).

⁴² 119 CONG. REC. 2059 (daily ed. Feb. 5, 1973).

⁴³ 119 CONG. REC. 2961 (daily ed. Feb. 21, 1973).

⁴⁴ Ashe, *supra* note 40, at 15.

⁴⁵ 119 CONG. REC. 2059 (daily ed. Feb. 5, 1973).

⁴⁶ H. DOWLING, *MEDICINES FOR MAN—THE DEVELOPMENT, REGULATION, AND USE OF PRESCRIPTION DRUGS* 274 (1970).

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these expensive brand name drugs with which they are most familiar, competition may be effectively eliminated, thus allowing a few dominating companies to charge exorbitant prices.⁴⁷

However, the PMA holds that the drug market is highly competitive, and that the degree of concentration of influence within the hands of a few is markedly below that found in a majority of the other industries. To illustrate how competitive the industry is, the PMA points out the number of new products on the market, and the number of companies that either rose to or fell from the rankings on the list of the top one hundred companies in the new prescription market, according to net sales.⁴⁸

In order to justify high drug prices, manufacturers contend that investment in drug research involves a substantial element of risk, and that therefore it is necessary to have high profit margins to attract research investors. For example, of every six thousand compounds tested by manufacturers, only one becomes marketable. The drug industry spends more for research and clinical testing than any other industry; and even when a new drug reaches the market, another new drug could come along and replace it before any profit is realized.⁴⁹

To refute the claim of the drug industry about the burden of research expenditures, Nelson states that the 6.2 percent of their annual sales that they do so spend, is not very large compared to the 25 percent they spend on advertisements and promotion.⁵⁰ In addition, much of the research by the various companies is duplicative and is not primarily intended to advance medical progress, as drug companies tend to imitate drugs that have proven successful on the market.⁵¹ Nelson believes that the risk factor is induced by the industry itself, because of "copying" companies continually coming up with similar rather than new drugs.⁵² Evidence shows no companies going out of business because of the risks involved or the losses suffered.⁵³ According to Nelson's findings, private American drug companies have over-distorted facts, in order to take credit for much of the research performed by the United States and foreign governments.⁵⁴

Drug companies argue that it is this continual research which produces new and better drugs. By giving the power of selection to the pharmacist through repeal of the ant substitution laws, drug research would be stifled

⁴⁷ Goddard, *supra* note 1, at 116. The PMA recognizes its active membership to be 115 firms rather than 135. PMA FACT BOOK, *supra* note 33, introduction.

⁴⁸ PMA FACT BOOK, *supra* note 33, at 12-13.

⁴⁹ SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 31-32.

⁵⁰ 119 CONG. REC. 2961 (daily ed. Feb. 21, 1973).

⁵¹ *Id.*; TASK FORCE FINAL REPORT, *supra* note 22, at 8; Goddard, *supra* note 1, at 121.

⁵² SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 32-33. The similar drug is just different enough not to infringe on the originator's seventeen year patent right. Goddard, *supra* note 1, at 121.

⁵³ SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 33.

⁵⁴ Sanford, *In Brands We Trust*, 158 THE NEW REPUBLIC 9 (1968).

because the doctor prescription has always been the method by which new drugs have been accepted and recognized. To do otherwise would impede medical progress.⁵⁵

The drug industry often quotes the figure of eighteen dollars as the amount an American spends on prescription drugs each year. This amount, when compared with amounts spent on other products, is seen to be reasonable. Critics reply that eighteen dollars is not indicative of where the major burden of drug prices falls. For instance, those over sixty-five years of age make up only 10 percent of the population, yet they buy over 25 percent of the prescription drugs, thus spending considerably more than eighteen dollars a year. This group lives on a fixed income and is least able to afford high drug prices.⁵⁶

Many of the poor in our society find themselves in the same situation involving a fixed income, often because they receive some type of public assistance. Due to their poor health surroundings, they incur heavier expenditures than the eighteen dollars per year would indicate. Thus, the poor, the elderly, and any other person who must take daily medication, carries the brunt of the burden of high drug prices. Nelson sees "generic name only" prescriptions as a way to help reduce the prices to these segments of our population.⁵⁷

Drug companies argue that to require generic prescription or repeal the state antisubstitution laws would not necessarily effect prices charged, because it is still up to the pharmacist to pass the savings on to the customer when he fills a prescription generically. Some surveys have shown that ghetto drug stores often charge high prices for prescription drugs for a number of reasons. Ghetto customers are often not aware of the large differences in prices between stores; people often find it cumbersome to obtain transportation out of their local area to price shop; and they quite often do not feel well enough to shop around for the best prices. Thus, their local druggists often charge whatever price the market will bear.⁵⁸

There are some who believe that a repeal of the antisubstitution laws would lead to cut-rating techniques and customers would find it worthwhile to shop for the lowest price. This interaction, Nelson believes, would stimulate competition and therefore lower prices. While theoretically the idea is good, its practical application could lead to serious problems. Some druggists would stock a drug while others would refuse to do so because of its questionable quality. The danger exists that ethical pharmacists may be pressured into ordering inferior goods in order to compete with those who would order the cheapest drugs in an attempt to win the public's

⁵⁵ Goddard, *supra* note 1, at 121.

⁵⁶ 119 CONG. REC. 10820 (daily ed. June 11, 1973); Health Research Group, *supra* note 8, at 2.

⁵⁷ Health Research Group, *supra* note 8, at 2.

⁵⁸ *Daylight on Prescription Drugs*, MONEY, Oct., 1972, at 31-33.

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business.⁵⁹

While Nelson's main reason for wanting to prohibit the use of any brand name other than an official or generic one is to lower the price, he also wants to clear up the confusion resulting from having more than one name for the same drug. There are over 200,000 prescription drug products on the market, but only seven hundred different drug compounds. The antibiotic, tetracycline, for example, has over twenty-four different names, all of which have met the same government standards.⁶⁰

While some advocate elimination of brand name prescribing in order to avoid mistakes and increase public safety,⁶¹ others believe that the original manufacturer's name should appear on the label in order not to mislead or confuse those buying drugs. Those who favor this view believe that doctors should rely on reputable manufacturers because of the consistency in quality of the drugs they produce. To prescribe by generic name only would mean that a patient could be given a drug that is manufactured by a marginal or disreputable company.⁶²

One of the most contested areas in the fight over substitution is the "generic equivalency" controversy. HEW's Task Force stated in its report that the real issue is whether two drugs that are chemically equivalent will provide the same clinical affect.⁶³ Those who favor the repeal of antisubstitution laws and "generic name only" prescribing, take the stand that drugs that are chemically the same are equivalent to each other. Thus, a generic name or cheaper brand name drug that has the same amount of the same active ingredient in each dosage is equivalent to the better known brand name product. Pro-equivalency forces argue that all drugs manufactured in the United States have met the same chemical equivalency standards set down by the Federal Food, Drug and Cosmetic Act, and that therapeutic equivalency follows chemical equivalency. They also point to statistics that show that there have been few reports of significant differences in cases where chemical equivalents have been used over long periods of time.⁶⁴

Although manufacturers (who support brand name prescriptions) argue that chemical equivalency does not mean therapeutic equivalency, the Task Force concluded after a limited study that nonequivalency arguments were exaggerated.⁶⁵ The results of one study on 20,000 antibiotics over

⁵⁹ Address entitled *The Generic Issue*, by Vernon Trygstad, President, Nat'l Pharmaceutical Council, to Mid-year meeting of the Ind. State Pharmaceutical Ass'n, in Richmond, Ind., Jan. 21, 1968, in reprint by the Nat'l Pharmaceutical Council, at 18-19.

⁶⁰ 119 CONG. REC. 19637 (daily ed. Oct. 30, 1973).

⁶¹ *Id.*

⁶² Note, *Products Liability for Prescription Drugs—The Effects of Generic Substitution on the Consumer and the Pharmacist*, 23 SYRACUSE L. REV. 894-95 (1972).

⁶³ TASK FORCE FINAL REPORT, *supra* note 22, at 31.

⁶⁴ Willig, *supra* note 22, at 11-12.

⁶⁵ TASK FORCE FINAL REPORT, *supra* note 22, at 31.

a five year period concluded that there was no significant difference between brand and generic name antibiotics.⁶⁶ Another study on nineteen other classes of drugs reached the same conclusion in 1970.⁶⁷ Some pro-substitution forces agree in part but contend that while meeting the federal standards does not guarantee equivalency it does insure purity and potency.⁶⁸

The United States Pharmacopeia (USP) and the National Formulary (NF) set forth standards that drugs have to meet in order to be classified as effective. Any drug that meets these standards is classified as having met them, and bears the mark of NF or USP. Both these compendia are administered to by non-governmental bodies but they are recognized by federal law as the official standards.⁶⁹ While all drugs must meet the USP or NF requirements, it is possible for a drug to be put on the market without having complied. This occurs when drug companies give the FDA information and data required to evaluate drugs in light of the published standards. Since the companies have a financial interest in getting their drugs on the market, they may distort or withhold vital information. Before the drugs can be recalled by the FDA, time may elapse and the public may be endangered by use of inferior drugs. Nelson has proposed a bill that would establish a National Drug Testing and Evaluation Center, which he hopes will reduce cost, the time consumed in testing drugs, and bias through non-partisan evaluation.⁷⁰

There is nothing to stop a manufacturer from putting on the market a drug that has not met any compendial test. The government only checks to see if companies have complied with the requirements when an enforcement proceeding is involved. So when a drug meets the official requirements, this merely suggests that if it is ever tested it will have met the minimal requirements.⁷¹

Another way a drug can reach the market without complying is by being a copying drug, which enters the market to compete with the original manufacturer's product. It does not have to meet the rigid requirements that the original drug had to meet. Since it only has to prove chemical equivalency, the copying company saves money on research and testing that could demonstrate therapeutic equivalency.⁷² The effects of the original and copying drugs upon the user may be different. The copying company is

⁶⁶ 119 CONG. REC. 10820 (daily ed. June 11, 1973).

⁶⁷ *Id.*

⁶⁸ SUBCOMMITTEE ON MONOPOLY, *supra* note 2, at 46-53.

⁶⁹ Food Drug and Cosmetic Act, 21 U.S.C. §§ 351, 352 (b) (1967).

⁷⁰ 119 CONG. REC. 2961 (daily ed. Feb. 21, 1973).

⁷¹ Francke, *Bioavailability of Digoxin*, 6 DRUG INTELLIGENCE & CLINICAL PHARMACY 5 (1972); Willig, *supra* note 22, at 12.

⁷² There are those who believe that the imitating companies making chemical equivalents should be required to do the same clinical testing as the original manufacturers, in order to do away with inconsistent substandard drugs.

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able to produce the drug at a lower cost than the original manufacturer, because the standards he must meet are less demanding financially.⁷³ To claim therapeutic equivalency, the company would be required to provide the results of further research and testing.⁷⁴

Bio-pharmaceutics is a new field of pharmaceutical science that has been growing in importance since 1960. It seeks to determine how much of the drug reaches its intended destination. For example, a drug that is chemically equivalent to another drug may not be therapeutically equivalent because only part of the drug may reach the cells that are hoped to be affected. Bio-availability refers to the ability of a drug to reach those cells. If a drug takes three times longer to reach the cell and only three-fourths of its ingredients arrive there, it is not therapeutically equivalent. To determine how much will reach the cells, the amount of the drug must be measured in the blood stream at different intervals from the time it is taken. A difference in blood level readings establishes a difference in therapeutic effect.⁷⁵

Bio-availability, or biologic availability may also be called biologic equivalence. Since there are no standards to require biologic equivalency, doctors usually rely on reputable established manufacturers whose controls over quality are sufficiently reliable that a person taking the same drug will receive the same effect each time the drug is used. Reputable manufacturers, who maintain quality control, may be producers of brand or generic name drugs. The point is that a patient should be given the same company's drug each time, because drugs chemically the same but made by different companies are not necessarily biologic equivalents. The repeal of the ant substitution laws would allow a pharmacist to change one company's drug for another. A "generic name only" law would also permit a pharmacist to fill an order with any brand he has on stock. Consequently, a patient would not be assured of getting the same effect each time he takes a drug that is a chemical but not a biologic equivalent.⁷⁶

Tetracycline, for example, is produced by many companies, and available by its generic and brand name at a wide range of prices. The original and most expensive sells under the brand name, Achromycin. Dr. Modell, a professor of Pharmacology, thinks that the absorption pattern of this anticoagulant is a critical factor and there are many Tetracycline products on the market that absorb faster or slower than Achromycin, and are therefore thought by him to be inferior. It would seem that an assurance of

⁷³ To say a drug is therapeutically equivalent to another is representing that it will have the same effect as the other drug, even though it may differ chemically. Therapeutic equivalency thus refers to effectiveness.

⁷⁴ Pharmaceutical Manufacturers Ass'n, PMA Newsletter Supplement vol. 9 no. 48, Dec. 1, 1967.

⁷⁵ *Products Liability*, *supra* note 62, at 891.

⁷⁶ Modell, *Drug Equivalence and Fixed Combinations*, MODERN MEDICINE, Sept. 6, 1971, at 43.

constant effect would be more important to the user of this drug than the cost of the drug.⁷⁷

Digoxin, a drug often prescribed to elderly patients to treat cardiac conditions, was developed by Burroughs Wellcome Company and given the brand name of Lanoxin. After patent rights ended, other companies began producing the drug and selling it under the generic name, Digoxin. Doctors, aware of the difference in price and hoping to save their patients money, began writing prescriptions generically, which allowed pharmacists to fill the order with any brand he had in stock. When reports were substantiated that some of the generics were not of good quality, an investigation followed, which led to the recalling of forty-seven million tablets from the market between October, 1968, and June, 1971, for failure to pass the USP test. Thirty-seven companies had their products recalled, but the original manufacturer, Burroughs Wellcome, was not one of that number.⁷⁸

Lanoxin, Burroughs Wellcome's brand of Digoxin, is recognized, even by the FDA, as being of such high quality and predictability that it has always been used as the standard measure for the other thirty-odd Digoxin products on the market. Clealand F. Baker, an executive of Burroughs Wellcome, stated that Lanoxin supplies over eighty percent of the Digoxin in the United States today. Due to an effective quality control system and years spent in costly research, Lanoxin has never been recalled from the market. Mr. Baker believes that a doctor should rely on the established reputation of the manufacturer when choosing a drug.⁷⁹

The above example brings out two points. The first is that it illustrates non-equivalence; the second is that the FDA did not detect the substandard drugs until they were already on the market. The public was exposed to the inferior drugs until the recall procedure responded to the situation. This process took time. The obvious conclusion is that the FDA cannot assure us that all manufacturers will comply with the federal standards, and even if that were possible some revision of the standards is necessary.⁸⁰

There are many drugs put on the market by competing companies whose biologic availability is suspect.⁸¹ The originator's quality control system

⁷⁷ *Id.* at 43-44.

⁷⁸ *Products Liability*, *supra* note 62, at 894.

⁷⁹ Letter from Clealand Baker to the editor, in NS13 J. AM. PHARMACEUTICAL ASS'N 602 (1973).

⁸⁰ *Products Liability*, *supra* note 62, at 894-95.

⁸¹ Address by Dr. M. Pernarowski to the annual meeting of the Can. Pharmaceutical Ass'n. at Vancouver, Aug., 1970, in 104 CAN. PHARMACEUTICAL J. 6 (1971); Pharmaceutical Manufacturers Ass'n, *supra* note 74; Blair, Barnes, Wildner, Murray, *Biological Availability of Oxytetracycline HCL Capsules*, 215 J.A.M.A. 251 (1971); Letter from Dr. George Brice and Dr. Henry Hammer to the editor, in 208 J.A.M.A. 1189 (1969); Dep't of Pharmaceutical Sciences, *Biological Availability*, 5 DRUG INTELLIGENCE & CLINICAL PHARMACY 117 (1969); Francke, *supra* note 71, at 5; Scheller, *Status Report on Drug Bio-Availability*, 27 AM. J. HOSP. PHARMACY 486 (1970).

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usually surpasses the required testing of the FDA. Laboratory tests and clinical studies enable them to produce consistency within each batch of drugs manufactured. Competing companies that copy the originator's drug often include only the essential ingredients in order to pass FDA standards, and have omitted additional expenditures necessary to assure consistency.⁸²

If all producers were required to perform clinical testing, the probabilities of therapeutic equivalency would improve.⁸³ However, it should be noted that such a requirement would entail great expenditures and thus add to the costs the imitating companies would have to pass on to the consumer in the form of higher prices.

As the drug industry spoke out against the dangers of biologic non-equivalence, HEW's Task Force on Prescription Drugs concluded in its 1969 Final Report that exact clinical or bio-equivalency was not important in the twenty percent of the drugs that could be duplicated. It also stated that the non-equivalency argument had been exaggerated, because there may be therapeutic value in a chemically equivalent drug even if exact therapeutic equivalence does not exist. The Task Force did, however, recognize the importance of further study in instances where exact bio-equivalence could be crucial.⁸⁴

One way to determine whether a drug meets the minimum standards set by the FDA is to look at the recall records. This is not always to be relied upon, though, as the testing procedures of the FDA allow many substandard drugs that are on the market to escape detection for long periods of time. A list of recalls by the FDA shows the number of recalls of products of twenty-six brand name companies with the total number of recalls for prescription and over-the-counter drugs on a weekly basis between January 7, 1971 and December 22, 1971. The result indicated that the number of recalls per week of products of the brand name companies was a very small fraction of the number of total recalls, thus indicating the quality and consistency that is put into brand name drugs.⁸⁵

The violations, as evidenced by the weekly drug recall lists, could be partially eliminated if producers abided by "Good Manufacturing Practices" (G.M.P.), established by the FDA. Non-compliance with these guidelines often bears a direct relationship to the number of drug recalls.⁸⁶ Consequently, it is logical to assume a causal relationship between laxity in manufacturing procedures and products of inferior quality. To determine

⁸² Pharmaceutical Manufacturers Ass'n, *supra* note 74.

⁸³ BRANDS AND GENERICS, *supra* note 3, at 46.

⁸⁴ TASK FORCE FINAL REPORT, *supra* note 22, at 31-32. The remaining 80 percent could not be duplicated because they either had a patent or were under license.

⁸⁵ HEW/NCSS, *supra* note 32.

⁸⁶ Feinberg, *Criteria for the Procurement of Drugs*, 6 DRUG INTELLIGENCE & CLINICAL PHARMACY 63-64 (1972).

compliance or noncompliance and to enforce "Good Manufacturing Practices," comprehensive inspections are needed.

The Federal Food, Drug and Cosmetic Act specifically requires the FDA to inspect drug producers at least once every two years to make sure they conform to "Good Manufacturing Practices."⁸⁸ A Report to the Congress by The Comptroller General of the United States revealed that many drug companies did not comply with the G.M.P. Even so, in cases where deviations were potentially critical, the FDA did not enforce compliance. Due to lack of manpower, government inspectors concentrated on inspecting the prescription drugs, and neglected the less potentially harmful non-prescription drugs. The general conclusion to be drawn is that the FDA is under pressure to enforce standards selectively because of its limited manpower. A change in the laws that would allow generic name drugs on the market in more frequent abundance would mean more inspections by an already overburdened staff. The Comptroller General's report concluded that the FDA had no means to insure that every drug producer would be inspected every two years. Also, a better inspection system was found to be needed in order that all producers are reached. It was recommended that new guidelines be established to insure early inspection of new drugs.⁸⁷

If substitution laws or a "generic name only" law was passed, a better inspection system would have to be created to sufficiently regulate the entry of generics on the market.⁸⁸ This would require more personnel in the Department of HEW, the parent of the FDA. Enactment of such a law would necessitate a stricter enforcement policy by the FDA at the production stage. This would add to the work load and increase the operational costs of the FDA.

CONCLUSION

As the public becomes aware of the disparity in prescription drug prices, pressure builds to reduce those prices seen as excessive. Many advocates of lower drug prices recommend the passage of an amendment to the Federal Food, Drug and Cosmetic Act, to require labeling and advertising by a drug's official or generic name only. On the state level, measures are supported which would repeal the ant substitution laws, thereby allowing a pharmacist to substitute an equivalent drug other than the one prescribed by the doctor.

It cannot be concluded that either of the above proposals will result in lower prescription drug prices if enacted. While it is true that there are

⁸⁷ COMPTROLLER GENERAL OF THE U.S., REPORT TO THE CONGRESS ON THE PROBLEMS IN OBTAINING AND ENFORCING COMPLIANCE WITH GOOD MANUFACTURING PRACTICES FOR DRUGS B-164031(2), at 1, 32-35 (March 29, 1973).

⁸⁸ *Prescription by Generic Name Should Not Be Required*, 118 J. LA. STATE MED. SOC. 520 (1966).

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great price differences among similar drugs, and that generic name drugs generally wholesale for much less than brand name drugs, it does not necessarily follow that filling of prescriptions with the lowest-priced whole-sale drugs will bring automatic savings to the ultimate consumer. In some cases, druggists have not passed the savings to the customer, while in others, he has passed on a partial savings. Even if it were conceded that a pharmacist would pass on a partial savings, critics say that this slight savings would disappear when administrative costs are added. Also, a program which requires generic name prescribing would require large expenditures on controls, in order to protect the consumer from substandard products.

While consumer advocates argue that the price of prescription drugs are too high, the major drug manufacturers argue that prices are not excessive compared to those in other industries. They point out that quality controls, research, and clinical testing make their drugs cost more than drugs of "copying" manufacturers. Major drug producers believe that a repeal of the state ant substitution laws or the passage of a federal "generic name only" law would jeopardize the quality of drugs and adversely affect research and growth in the drug industry. While these arguments merit consideration, it should also be pointed out that the companies' interest would be directly affected by the enactment of the federal law on the one hand, or the repeal of the state law on the other. They would be forced to lower their prices to compete with the lower-priced drugs, or to risk losing their business by maintaining relatively high prices.

Brand name drugs, as a general rule, cost more than generic name drugs. However, even companies that produce generic name drugs may charge high prices. This usually occurs because they, like producers of brand name drugs, have spent a great deal of time and money on research, testing and other good manufacturing practices. Conversely, the companies that produce generic name drugs at a low price are generally those which have not had to spend money on research and testing. Therefore, the controversy is not necessarily between generic and brand name producers, but between well-respected brand and generic name manufacturers on the one hand, and smaller, less-respected generic name manufacturers on the other. By cutting corners and reducing testing procedures, these latter producers are able to market drugs at substantially lower prices, but with greater risk of harm to the consumer.

A change in the present laws would increase this problem by reducing the power of physicians to specify a brand name he believes to be respectable, and by allowing the pharmacist to circumvent the physician's choice, or by requiring the physician to prescribe only generically. According to the proposed amendment to the federal law, the drug company's name would not even be mentioned.

The main reason to keep "generic name only" prescribing from becoming a reality, and to keep the ant substitution laws intact is that one drug is not the therapeutic or biologic equivalent of another and therefore a substituted drug could produce undesired effects. Many who agree with this statement admit that in many cases there would be no harmful effects where the substituted drug is chemically equivalent to the one originally prescribed. However, the fact that there are a few reported cases where substitution has been harmful, and an indication that more reports will follow as substitution proliferates, is sufficient grounds for arguing to keep the federal and state safeguards as they are. Until a therapeutic or biologic equivalency test can be established, changes in the present laws would be premature. If in the future a doctor could prescribe a generic drug with confidence that it would be therapeutically equivalent to the brand name drug, and that it has been through extensive clinical tests—at that point a change in the laws should be considered.

If prescription drug prices are indeed too high, then other remedies besides allowing substitution or generic prescribing should be considered to lower them. It has not been sufficiently proven that the proposed changes would result in a savings to the consumer. However, even if there was a savings, as long as there are even a few cases of therapeutic nonequivalency and the subsequent danger of serious or fatal injury occurring from this lack of equivalency, the present laws should remain intact.

MICHAEL DANA MASON

Equal Protection in Legislative Apportionment: A New Double Standard

INTRODUCTION: MALAPPORTIONMENT: INEQUALITY AND THE INDIVIDUAL'S VOTE

In *Mahan v. Howell*,¹ the Supreme Court gave legal sanction to limited malapportionment. In this apparent reversal of its prior stance, the Court in *Mahan* held, *inter alia*, that a Virginia statute which apportioned the House of Delegates by traditional county and city boundaries was valid

¹ 93 S. Ct. 979 (1973). The Virginia statute provided for a combination of 52 single-member multi-member, and floater districts from which 100 delegates were to be elected. 93 S.Ct. at 980. The term 'floater district' is used to refer to a legislative district which includes within its boundaries several separate districts or political subdivisions which independently would not be entitled to additional representation but whose combined population entitled the entire area to another seat in the particular legislative body being apportioned. *Davis v. Mann*, 377 U.S. 675, 686 (1964).