Background Paper 79-11

GENERIC v. BRAND-NAME DRUGS

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BACKGROUND

Prescription drug use in the United States has increased approximately 400 percent since 1950. Americans now purchase more than two billion prescriptions each year at an estimated cost of $10 billion. Per capita expenditures for drugs rose from $19 in 1960 to $45 in 1974. Persons over 65 years of age pay 25 percent ($103 per capita in 1974) of the nation's drug bill but comprise only 11 percent of the population. Many of them are on fixed incomes and Medicare covers only in-hospital prescriptions. In fact, according to a survey conducted by the National Center for Health Statistics, 75 percent of the 1.7 billion outpatient prescriptions in 1974 were paid for by the consumer.

There are several factors that influence the use and cost of prescription drugs: Promotion by the pharmaceutical industry, prescribing habits of physicians, anti-substitution laws, the public demand for drugs and inflation. In 1971, for example, drug manufacturing firms spent over $1 billion on promotional activities, including $700 million for retailing, $167 million for journal and direct mail advertising, and $150 million for convention displays, education seminars and so forth. In 1971, however, there were only 300,000 practicing physicians, meaning the industry spent $3,333 per physician.**

Prior to World War II the pharmaceutical industry supplied bulk medicinal chemicals to the pharmacist. He filled his own capsules, rolled his own pills and made his own liquid tinctures. Sulfa drugs were introduced in 1936 and their widespread use and the needs of the war effort revolutionized the industry following World War II. Research efforts to make drugs safer and more effective were increased and drugs, such as penicillin,

* Most drug products have three names: A chemical name which describes the drug product's chemical structure (an example is dextro 3-methoxy-N-methylmorphinan hydrobromide); a generic name, which is a simpler version of the chemical name, and is the name most commonly used in scientific literature (the generic name of the above example is dextromethorphan hydrobromide); and the brand-name which is assigned to the drug compound by the manufacturer to distinguish it from identical compounds made by other firms (the active agent in the product "Romilar", produced by Hoffman-LaRoche, Inc., is the above generic name).

** Mark C. Hornbrook, "Prescription Drugs: Problems for Public Policy," Current History. (May/June 1977), p. 220.

streptomycin and tranquilizers, were introduced. Another effect of the war was the military's need for drugs in finished, dosage form. The pharmacist no longer compounded the drugs. The trend was toward factory-made drugs, making the brand-name all important. By 1960, brand-name drugs constituted 94 percent of the prescription market.* Large-scale promotional campaigns became an integral part of the industry's activities. But many of the so-called "new" drugs were only new salts or minor molecular variations of existing drugs. The price of these drugs was very high and long-term drug therapy, which most elderly people needed, was nearly prohibitive.

Significant public criticism of the industry lead to hearings in December 1959 by the U.S. Senate Antitrust and Monopoly Subcommittee, under the chairmanship of Senator Estes Kefauver (D-Tennessee). The majority views, expressed in the subcommittee's final report, charged the industry with "unreasonably high prices, monopolistic restriction of the market, abuses of the patient privilege and excessive wastes of resources in their selling efforts." A bill was introduced to correct some of these alleged abuses; however, it did not pass. The subject was addressed again in 1962 following a set of unfortunate circumstances which occurred in several West European countries in 1959-60. Many babies were born with seal-like deformities of their arms and legs (phocomelia) as the result of a drug, thalidomide, taken by their mothers during pregnancy. In response to this, the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (1938) were passed by Congress in 1962. These amendments only addressed the safety and therapeutic value of prescription drugs.

By 1972 every state had enacted a drug anti-substitution law, which prohibited pharmacists from substituting a generic drug for a brand-name drug. These were passed in response to "counterfeit" drugs manufactured during the 1950's. Counterfeit drugs were duplicate products produced by a manufacturer who also made brand-name drugs. Manufacturers would encourage pharmacists to dispense the brand-name product and would also clandestinely produce a counterfeit drug which looked similar to the brand-name but was of unknown quality, content and origin. Unwitting or unscrupulous pharmacists would pass these on to the consumer. As a result, anti-substitution laws were passed (the Nevada state board of pharmacy promulgated an anti-substitution ruling in 1963).

* "Drug Product Selection," Staff Report to the Federal Trade Commission (hereinafter referred to as FTC Staff Report). January 1979, p. 145.

By the early 1970's the anti-substitution laws were questioned during the development of state Medicaid programs. Several states adopted welfare formulas imposing cost limits on the drug products listed in them and they encouraged prescribing and dispensing by generic, rather than brand-name. For example, the California Health and Welfare Agency in 1965 issued preprinted prescription forms that allowed pharmacists to dispense chemical equivalents when the prescription cost more than the stated maximum. The California Attorney General issued an opinion in 1965 stating that pharmacists who followed the preprinted statement did not violate the state's anti-substitution law. In addition, the American Pharmaceutical Association in 1970 called for the repeal of anti-substitution laws.*

GENERIC DRUGS ARE CHEAPER, BUT ARE THEY SAFE & EFFECTIVE?

Presently 40 states have drug product selection laws.** There are two overriding issues regarding the adoption of drug product selection laws: Does the consumer save by purchasing a generic drug instead of a brand name? Are generic drugs equivalent to brand-name drugs?

A study by the Federal Trade Commission's Bureau of Economics shows that the annual wholesale price savings could be between $400 and $500 million.*** In Michigan, a Wayne State University study matched the retail prices of actual substituted prescriptions with the retail prices of comparable nonsubstituted prescriptions for the same drug and estimated that the potential savings in Michigan could range from $11 to $15 million a year. If this were extrapolated nationwide, consumers could save from $260 to $450 million.**** There have been nine major studies which have tried to estimate consumer savings derived from drug product selection.***** While these studies differ in methodology, scope

* FTC Staff Report, p. 153.

** Alabama, Hawaii, Indiana, Louisiana, Mississippi, New York, Nevada, North Carolina (except for Medicaid), North Dakota, Texas and Wyoming do not have drug product selection laws.

*** FTC Staff Report, p. 196.

**** Ibid.

***** Ibid.

and findings, they do reach one conclusion: Drug product selection laws will result in substantial savings for the consumer. Finally, an independent study, conducted for the Pharmaceutical Manufacturers Association in 1974, found that brand-name prescriptions cost consumers 19 percent more than generic ones.*

However, the Wayne State Study, mentioned earlier, points out that Michigan's drug product selection law is reducing drug prices by only $200,000 a year instead of the potential $13.5 million. Pharmacists in Michigan attribute this to people with health insurance who have all but $2 of their prescriptions paid for, therefore, they request the doctor's prescription.**

The FTC, et. al., have found that the cause is related to the effectiveness of drug product selection laws. The Wayne State University study found an 18-20 percent rate of drug product selection in Wisconsin but only 1.5 percent in Michigan. One reason for this is that the law in Michigan was interpreted to require that the purchaser request a generic equivalent before the pharmacist could dispense it (Attorney General's opinion, February 5, 1975. This requirement was removed in 1977). The FTC conducted a similar study in 1978. They questioned 723 pharmacists in seven states (Arkansas, California, Delaware, Minnesota, Oregon, Pennsylvania, and Wisconsin) that had drug product selection laws. All the pharmacists said they were aware of the selection laws in their states, however, less than 30 percent said their stores' policy was to substitute when possible. (Two exceptions are Delaware and Wisconsin where 60 percent said they would substitute when possible.) In Pennsylvania, the only state surveyed that requires substitution, less than one-quarter of the pharmacists said they complied. (However, nearly 75 percent of the pharmacists thought that a selection law resulted in lower retail prices with the consumer saving an average of about 20 percent!***) Finally, in November 1978, the New York City Consumer Affairs Department visited 25 randomly selected pharmacies and found 13 were violating the substitution law and 27 of 74 pharmacies in the state failed to stock leading generic drugs. The New York Public Interest Research Group also reported that

* Ibid., p. 8.

** Wall Street Journal, December 7, 1978, p. 27.

*** FTC Staff Report, p. 190.

only 28 of the 60 pharmacies they checked supplied a generic drug when required.*

Are generic drugs equivalent to brand-name drugs? With the passage of the Pure Food and Drug Act, the United States Pharmacopeia (U.S.P.) and the National Formulary were recognized by the federal government as the official compendium for the U.S. The U.S.P. sets forth the standards of strength, quality and purity for drugs and admits a drug on the basis of its therapeutic value. There are three types of equivalence: Chemical equivalents, which are drug products with identical amounts of the same active drug ingredient; bioavailability (biological availability) which measures how fast and how much of the drug gets into the body or appears in the blood; and therapeutic equivalents which are two or more drugs that are equally effective in treating a particular disease state. Drug product selection laws can be implemented with or without a drug formulary (30 states do have a formulary). These formularies may be either positive, listing which drugs have a substitute, or negative, stating which drugs cannot be substituted because their therapeutic equivalence is questionable. New York, for example, has adopted a positive formulary (1978) of approximately 800 drugs which have been certified by the Food and Drug Administration as safe, effective and therapeutically equivalent.

In 1969, a report issued by the HEW Task Force on Prescription Drugs said that some instances of bioinequivalence among chemical equivalents did exist, but it had been "grossly exaggerated as a major hazard to the public health." In 1974, the Office of Technology Assessment (OTA) issued a major study on drug bioequivalence that has been cited by both opponents and proponents of drug product selection. One of the major conclusions of the study is: "Current standards and regulatory practices do not insure bioequivalence for drug products." This supports the industry's argument that not all drugs are alike and that generic drugs should not be substituted for higher quality brand-name drugs. In his testimony before a Senate Subcommittee on Health in 1974, C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association, said that the FDA does not have the capability and/or the resources to assure the equivalence of marketed drugs. Based on OTA's conclusion, he says the problem of drug inequivalence is real; it is serious, and equivalency cannot be assured until new stringent criteria are met.

* New York Times, December 26, 1978, p. B-1.

However, OTA also concluded: "It is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products." The chairman of the OTA panel, Dr. Robert W. Berliner, said that "It is very important to point out * * * that two drugs may differ in bioavailability, that is be bio-inequivalent, but may still be therapeutically equivalent."*

Finally, Eli Lilly and Company released a study in 1978 that found prescription drug recalls were as much as seven times higher for products from companies that do little research (implying the generic drug manufacturers), than for the larger, research intensive brand-name companies. However, FDA's Commissioner Donald Kennedy said before a Senate subcommittee that the FDA's analysis of drug samples has shown "no evidence of widespread difference between the products of large and small firms, or between brand-name and generic name products."** Kennedy also pointed out that a major firm, that has had numerous recalls, was omitted from the Lilly study and that it emphasized products not listed by the FDA as therapeutically equivalent.

THE MODEL DRUG PRODUCT SELECTION ACT

In an effort to encourage and assist states in amending their laws to promote drug product selection, the Federal Trade Commission and HEW have designed a model drug product selection act. Its major provisions are: Pharmacists are allowed to select a lower cost generic drug from a positive formulary, listing drugs that are therapeutically equivalent according to the FDA. Physicians can prohibit drug product selection, pharmacists will share the savings with the consumer (an incentive for pharmacists to use generic drugs), customers can choose whether or not they want less expensive generic drugs, and an optional provision to assure pharmacists that there is no greater liability for using generic drugs instead of brand-name. Presently HEW has a program designed to ensure against the government paying more in reimbursement for drugs under Medicaid than is necessary. The Maximum Allowable Cost (MAC) Program began in 1973 and encourages the use of generic drugs. It has thus far established price maximums for only five drugs of various strengths and dosage forms.

* Statement before Senate Subcommittee on Monopoly, as found in FTC Staff Report, p. 238.

** Annabel Hecht, "Generic Drugs: How Good Are They?" FDA Consumer, (Febrary 1978), p. 19.

GENERIC DRUG LEGISLATION IN NEVADA

Identical drug product selection bills, A.B. 436 and A.B. 204, were introduced in the Nevada Assembly in 1975 and 1977, respectively (both of these bills died in committee). Those two bills would have allowed a pharmacist to substitute a generic drug for a brand-name drug except when the physician specified otherwise. The cost of the drug was to be reduced by at least the difference between the wholesale price for the brand-name drug and the generic drug. The hearings held in 1975 on A.B. 436 generally followed the argument outlined above: Generic drugs are cheaper but they may not be therapeutically or biologically equivalent. For example, the Consumer League of Nevada conducted a survey in 1972 and found that identical doses of the same drug varied in price by as much as 567 percent. Representatives of the league thought a drug substitution law would certainly reduce prescription prices. A representative of Northern Nevada Pharmacists said that the quality of generic drugs cannot be ensured; therefore, substitution should not be allowed.

SUMMARY

The price of health care has risen sharply. Between 1960 and 1970 the Consumer Price Index (CPI) for medical care increased 50 percent. Prescription drug prices rose sharply during the late sixties and early seventies. They accounted for 10 percent of the nation's health care dollars during this period. The prescription price component steadily increased to 14 percent of health care dollars between 1970 and 1976. Prescription drugs have become much more expensive.

Efforts to reduce the price of prescription drugs through substitution laws have been partially successful. They have not reached the ultimate goal, as seen in Michigan, but they have had an impact. The FTC estimates that the potential consumer savings from drug product selection in Nevada (using 60 drugs*) would be $622,000.** Whether or not generic and brand-name drugs are equivalent is still a highly controversial issue. Should Congress pass a new drug regulatory act in 1979, which seems likely, the FDA will issue a drug formulary which is the result of lengthy and intensive research.

* 60 randomly chosen multisource brand-name drugs from a dollar volume ranking of the leading 200 prescription drugs.

** FTC Staff Report, p. 206.

Two recommendations for a drug product selection law to be effective and successful are: (1) Posting of generic and brand-name prices which will make the consumer aware of price differences and more likely to ask for the generic drug, and (2) Part of the savings which result from the use of substitutions should be passed on to the pharmacist as an incentive to dispense generic drugs.

SUGGESTED READING

(Available In The Research Library Except As Noted.)

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