GENERIC DRUG SUBSTITUTION

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INTRODUCTION

The only product changes in the pharmaceutical industry until the early 1960s were the development of new and more sophisticated medications. It was in the early 1950s that generic drugs were introduced, but the early 1960s showed a great increase in the number of generic drugs in the marketplace. Many people did not know then what actually made a generic drug different from a brand name drug, but they did know that there was a cost savings of the generic drug over the brand name drug (Carroll, 1986).

Most brand name drugs have been in existence for a number of years and have been regulated by the government. Regulation concerning generic drug substitution was not started until 1961 when formal statutes, both federal and state were enacted (Hamm, 1980). A generic drug could be developed from a prescription drug when the patent had run out on the drug. The time limit for a patent expiration on a prescription drug is 17 years. Once that time has passed, a generic substitute can then be presented to the American Medical Association (AMA) listing its chemical make-up and a suggested generic name for approval. Once the AMA has given its approval, the drug is checked by the United States Food and Drug Administration (FDA) to determine its safety and effectiveness. Since a generic drug is often viewed as a

copycat of a brand name drug, it has been spared much of the testing involved with a completely new drug on the market.

Generic drugs have been making gains in the pharmaceutical industry. It is currently estimated that 15% to 20% of all prescription drugs have generic substitutes (Lavrakas, 1986). In 1978, an FDA report showed that 70 of the most frequently prescribed drugs were available as a generic product (Hamm, 1980). In November of 1985, the FDA approved 169 new generic versions for release in the marketplace (Lavrakas). In a further report by the FDA, it was estimated that by 1990, the top 50 drugs on the market would have generic substitutes (Lavrakas).

As with most medical issues, the subject of generic drug substitution is complicated. It has created mixed signals caused from differences in government reports and medical literature from physicians, pharmacists, and consumers who are familiar with generic drugs (Schwartz, 1985). A ruling by the FDA in 1984, reduced the required testing a company would have to do before marketing a new generic drug product. It will create more problems due to the number of drugs that the FDA will have to approve as patents on older drugs continue to expire and generic drugs are produced.

The controversy regarding generic drugs has developed from a variety of sources. A statement from the Academy of Pharmaceutical Sciences of the American Pharmaceutical Association (APA), said " Drug products from different

sources may differ in quality in several respects. These differences, individually or collectively, may lead to substantial differences in therapeutic effect and/or safety" (1970, p. 109). They went on to say, "differences in the rate and completeness of release of the active ingredient may result in varying therapeutic or adverse effects. This is true of a variety of products whose number is still uncertain, but potentially large" (p. 109). The APA was taking the first step to identify a quality and effectiveness problem of generic drugs.

In 1974, Congress decided to implement a generic substitution program with the goal of saving on health care costs, but wanted to examine the possibility of patient medical problems from such a move. It gathered a group of outstanding scientists and physicians to assess the scientific issues of generic drugs. The Congressional Office of Technology Assessment (OTA) hosted the conference and had scientists and physicians focus on drug bioequivalence. Additionally, the scientists and physicians were to determine whether to endorse the concept of generic substitution. The conference did endorse generic drug substitution, however, the endorsement also warned physicians and pharmacists to exercise caution in prescribing generic drugs due to the lack of bioequivalence, having the same chemical combining capabilities. The OTA report concluded:

Current standards and regulatory practices do not

> insure bioequivalence for drug products. Variations in the bioavailability of drug products have been recognized as responsible for a few therapeutic failures. It is probable that other therapeutic failures (or toxicity) of a similar origin have escaped recognition (1974, p. 1).

After the final OTA report was issued, Consumer Reports (1975) concluded, "the controversy over bioequivalence has at last been put into perspective. Ask your doctor to prescribe a drug by its generic name" (p. 51). Consumer Reports, which is more widely circulated to the general public than the government reports was informing consumers that there were no problems with generic drugs and that to make sure you got the correct generic drug, specify the drug on the prescription. It offered no warnings to the consumer. The FDA wanted to end the controversy by publishing a report in a 1978 issue of the Food and Drug Administration Consumer, stating:

> All drugs, whether they are sold under their brand names or generic names, must meet the same Food and Drug Administration standards for safety, strength, purity, and effectiveness. And all manufacturers, big or small, are subject to Food and Drug Administration inspection and must follow the agency's current good manufacturing practice regulations. That is why the Food and Drug Administration believes that there is no significant difference between generic and brand name

drugs (Hecht, 1978, p. 1).

The debate continued in 1981 in an address by the deputy director of the Division of Biopharmaceuticals of the Food and Drug Administration, J. Skelly (1981), indicated "perhaps somewhat surprising that only 45 percent of the total manufactured prescription drug products in the marketplace two years ago have been approved for both safety and efficacy." This debate questioned whether a product that was interchangeable with a brand-name product was ever really considered safe.

The controversy over generic drugs continues today. With the growth of generic drugs in the marketplace and the enticement of dollar savings to the consumer, the consumer should become more familiar with generic drugs and the substitution policy affecting these drugs.

The problem presented by this study is that there is a lack of information available on generic drugs and that consumers do not know all they should about generic drug substitution. With the increase of generic drugs available for doctors to prescribe and for pharmacists to dispense and substitute, the consumer must be kept aware of what exactly he or she is receiving. The consumer should be concerned about federal and state generic drug substitution policies that affect the prescribed drug the consumer receives. With the use of a generic drug, a consumer should then know what difference the drug may have in its prescribed performance effects as compared to a brand name drug.

The purpose of this study was to investigate the scientific considerations of prescribing and taking generic drugs and to learn about the federal and state laws that govern generic drug substitution.

Definitions

Bioavailability - percentage of the active ingredient that is released in the body taking into account patient characteristics, formulation of the drug product and the co-administration of other drugs.

Bioequivalence - having the same chemical combining capabilities as a generic drug compared to its brand name equivalent.

Bioinequivalence - not having the same chemical combining capabilities.

Brand name - a class of goods identified by name as the product of a single firm or manufacturer.

Clinical equivalence - a restricted range of variation in bioavailability relative to the norm set by the innovator product.

Generic - common to or characteristic of a whole group or class.

REVIEW OF LITERATURE

Scientific Considerations

The debate regarding generic substitution of drug products is centered around three factors, that of the generic product's quality, its interchangeability with the product prescribed, and the cost of the alternative product. In looking at the scientific issues of generic drug substitution, the areas of quality and interchangeability will be discussed.

The FDA guidelines have maintained the general rule concerning generic drugs that "drug products will be considered therapeutically equivalent except where the agency believes that bioinequivalence exists" (Knapp, 1979, p. 99). In studying these FDA guidelines, Leroy Schwartz, M.D., once head of the FDA, stated "The Food and Drug Administration has decided that certain generic pharmaceutical products can be deemed clinically equivalent to the innovator product though they have been declared bioinequivalent" (1985, p. 41). The emphasis became the difference between clinical equivalence and bioequivalence which have different medical connotations. The FDA actually has a restricted range of variation in bioavailability relative to the brand name product for which the generic drug was derived. The guidelines further stated by Leroy

Schwartz and Culkin (1983) of the FDA are:

> In general, the variability in bioavailability between generics and the reference product, measured as the difference in mean areas under the curve (AUCs), is allowed to extend up to 20 percent for the generic product to be considered clinically equivalent. However, for certain drugs (e.g., trifluoperazines) a 30% allowance is granted, whereas for other drugs (e.g., warfarins) only a 10 difference in mean AUC is permitted.

In examining these guidelines stated by the FDA, it was determined that there was no clinical basis to arrive at these standards (Schwartz, 1985). One study determined that the percent allowances used were arbitrary and also cited studies from Canada to show that the difference in bioavailability was undetectable (Schwartz, and Culkin, 1983). The FDA also stated that because there were no significant complaints of therapeutic failure, that the percentage allowances caused no clinical problems. The main problem can be seen if a patient had one product with a bioavailability of 30% below the standard at one pharmacy, and a refill of the product with a bioavailability of 30% above the standard at another (Lamy, 1984). The patient would therefore have at most a 60% difference in the amount of the active ingredient absorbed from one product to the next (Lamy, 1984).

The tests that were accomplished to measure

bioavailability of certain products were done on young, healthy adults which indicates a problem of whether the generic drugs may be acceptable for the more sensitive patients as the elderly, infants, and children (Levy, 1985). With the large variance in bioavailability for the more frail patient, the question was raised: "Would a physician agree to prescribe a generically equivalent product for an elderly patient if, indeed, equivalency may vary greatly?" (Lamy, 1984, p. 92). If a patient has been stabilized on a certain product, certainly a change to a generic equivalent should not be used. The possibility of an overdose is greater with a large percentage change from one drug to its generic equivalent.

The question of use of generic substitutions on infants and children in regard to bioavailability is greatly in question. The American Academy of Pediatrics stated that "few drug products have been appropriately studied for bioavailability in infants and children" (1976, p. 275). Studies of differences in a drug product's bioavailability may be greatly enlarged when considering infants' and children's large differences in drug absorption, distribution, and excretion.

Three areas where doctors have felt that generic substitution is not acceptable is that of psychotropic (mental) disorders, cardiovascular, and metabolic drugs. The Task Force on Bioavailability and Bioequivalence of the American College of Neuropsychopharmacology (1979) stated:

> It would be most undesirable to use multi-source psychotropic drug products interchangeably without establishment of their bioequivalency. It is our belief that without such Federal requirements there may, in fact, be bioinequivalency among these psychotropic drugs occurring either now or in the near future due to the repeal of antisubstitution laws in over two thirds of the states in this country (p. 3).

The Task Force continued to address problems of determining if a mental disorder could be properly treated if a drug could hinder or disguise a reliable report from a patient since a substituted drug may not perform as well on the patient as the brand-name drug would.

The scientific issues are weighed against generic drugs in looking at the quality and interchangeability of brand-name drugs to generic drugs. It is indicated that further research and testing be accomplished on generic drugs to ensure their bioavailability as compared to brand name drugs.

Federal Laws Concerning Generic Drug Substitution

Generic drugs have existed since early prescription drug days, but were not regulated until 1961 when the regulation of generic drugs came in the form of federal and state laws which allowed substitution of generic drugs for brand name drugs. Before these laws were passed, brand name drugs could not be substituted with generic drugs. As part

of the 1961 laws, the federal government approved that a pharmacist could substitute a generic drug for a brand name drug with the permission of the prescriber or buyer. This statute started the development of a market of generic drugs which has grown ever since.

Since the 1961 statute allowing generic drug substitution, the federal government has made little change in its regulation of generic drugs (Hamm, 1980). The federal agency that has the final approving authority of any drug including generic drugs is the Food and Drug Administration (FDA). For approval of a drug, it must be proven to be both safe and effective. The term "safe" is relative, as no drug is totally safe for all people, and a physician must decide whether the benefits of a specific drug outweigh the dangers it may pose to the patient. Before a new drug can enter the market, scientific studies must be accomplished, first on animals, then on humans. Through these studies, it is determined whether the drug is safe and effective for general use. The FDA oversees much of the scientific research on drugs and once a manufacturer believes a drug is both safe and effective, it asks the FDA if the drug can be marketed. The FDA usually reviews the results of the research and decides if the drug can be placed in general use or whether more study is needed.

Generic drug testing is quite different from introducing a brand name product to the market. In the 1960s when generic drugs were becoming more common, and generic

drug substitution was increasing, the FDA was demanding the same tests for generic drugs as were required for new brand name drugs. Since the number of generic drugs were increasing with the deregulation of their use and the consumer demanding the lower priced drugs, the FDA was over tasked to approve the drugs. Eventually, the FDA gave in and eliminated much of the testing required for approval of a generic drug into the marketplace.

In September of 1984, Congress passed a step to decrease the time that the FDA had to process and approve a generic drug (Lavrakas, 1986). This was called the Drug Price Competition and Patent Term Restoration Act. It was passed mainly due to concerns about getting generic substitutes into the marketplace to consumers, namely government benefit recipients, a savings on prescription drugs. It mandated the FDA to process and approve new generic drug applications within 180 days. It greatly simplified the procedures for generic drug approval.

New procedures which the FDA developed, required a manufacturer to do certain things before granting approval of a generic drug (Lavrakas, 1986). The FDA told the manufacturer that instead of the lengthy clinical tests it normally would run, it would require the manufacturer to prove that the product was therapeutically equivalent to a brand name product. The FDA then stated that it would approve a generic drug for public sale if it met the following criteria:

1. Used the same active ingredients.
2. Have identical dosage strength.
3. Be of the same dosage form (tablet, solution).
4. Be administered by the same route (mouth, injection).
5. Be used for the same illness.
6. Is bioequivalent (destination in the body in the same amount and time).

Once these items were proven to the FDA, a test on 20 to 30 normal patients would be tried. In comparison, a new drug must be tested on at least 40 times more patients which is a better sampling to ensure the safety of the drug. This simplified process is the current approval process for a generic drug.

With the new approval process enacted, the Head of the Food and Drug Administration's Division of Generic Drugs, Dr. Marvin Seife, stated "These [brand name and generic drugs] are interchangeable; they are mirror images of each other" (Lavrakas, p. 12). Shortly thereafter, several pharmaceutical manufacturers asked for more extensive tests on generic drug versions due to concerns they had on the safety of some generic drugs. The FDA responded by saying that the concerns were "scientifically groundless."

The FDA continued to be put to the test in approving new generic drugs, and in November of 1985, set a record of approving 169 new generic versions. At the same time, it had 500 Abbreviated New Drug Applications (ANDA) pending

approval. It was estimated that by 1990, the top 50 drugs would have generics (Lavrakas, 1986).

The federal government has made few changes to the statutes governing generic drug substitution, but by deregulating substitution, manufacturers have found a larger market to exploit. The FDA has an enormous responsibility in approving both brand name and generic drugs for public use. Its changed approach to approving generic drugs has been questioned by even the manufacturers themselves and should be questioned by the government and consumer also. The market for generic drugs will continue to grow and challenge the government for effective regulations concerning their safety and control.

Oklahoma Laws On Generic Drug Substitution

State regulation of generic drug substitution started with the enactment of federal legislation allowing generic drug substitution in 1961. The current regulation on pharmacy practice is called the Oklahoma State Laws Pertaining to the Practice of Pharmacy, dated 1972, and published by the Oklahoma State Board of Pharmacy. Some revisions have been made in the laws concerning pharmaceutical practice, but the area of generic drug substitution has not been changed since 1961.

The Oklahoma state laws governing the practice of pharmacy in the state include a section specifically for generic drug substitution. The Oklahoma State law pertaining

to generic drugs, states:

> It shall be unlawful for any pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, to substitute or cause to be substituted therefore, without authority of the prescriber or purchaser, any other drug, medicine chemical or pharmaceutical preparation (Oklahoma State Board of Pharmacy, 1972, p. 15).

Very simply, what is needed for a pharmacist to substitute a generic drug is the approval of the prescriber or the purchaser. The prescriber, namely the physician, knows what a person should need in the way of a specific prescription drug and may imprint on the prescription form that the pharmacist must dispense the drug as written. The physician may also note on the prescription form that a substitute drug may be given. If the physician does not state the restrictions, the pharmacist has an option of substituting a generic drug for the brand name drug prescribed. In this case, the consumer's approval is required before the substitution can be made. The problem then is whether a consumer really knows about the substituted drug's safety and effectiveness.

Many pharmacists are willing to substitute generic drugs for brand name drugs, mainly to save the customer some expense. Pharmacists advertise their use in newspapers, the Yellow Pages, and most often in their own stores. Typical

signs include:

Money Saving Generic Drugs

Are Available

For Some Prescriptions

or

Ask Your Pharmacist If

There Is A Generic Drug

Available For Your Prescription

By state law, a pharmacist is required to have reference books on pharmaceutical products. They include a recent copy of the Oklahoma State Laws Pertaining to the Practice of Pharmacy and a Blue Book or Red Book which are books containing tables of drugs which state a drug's properties, recommended dosages, and the standards which determine their strength and purity (Oklahoma State Board of Pharmacy, 1972, p. 16). Optional reference books include combinations of a modern drug encyclopedia, USP N. F. Mercks (a drug manufacturer and referencing drug agent), USD Remington-Emergency Toxicology (a reference for toxic or poisonous drugs), and a medical dictionary on pharmacy compounding and dispensing book. Brand name and generic name drugs are listed in some or all of the references and are cross-referenced for brand names and generic names.

Since the laws offer no guidance in consumer understanding of specific drugs and only stste the approval required for a generic drug substitute, consumers should be sure to know their rights pertaining to the policies of

generic drug substitution. In doing so, a consumer may ask a pharmacist relevant questions pertaining to a specific generic drug's safety and effectiveness.

Concerns Regarding The Future Of Prescribing

With the continued rise in health care costs, there will be increased emphasis on the use of generic substitutes whenever possible. Some states may eventually require substitution and doctors who prescribe a brand name drug to be used, may have to state "medically required" so that a substitute is not given (Schwartz, 1985). A term that is becoming more common when discussing generic drug substitution is that of therapeutic substitution. This implies that a substituted drug would have to have the same general pharmacologic and therapeutic class in combination to that of the drug prescribed. This would broaden the categories of substitute drugs available to be prescribed for specific treatments. The pharmacist would then give the patient whatever product that would correct the problem from the therapeutic class of drugs.

Another concern regarding the future of medical treatment involves the pharmacist prescribing medication for primary care. The patient would see a pharmacist for a primary care diagnosis and have a prescription ordered as a remedy. If it was more serious, obviously a physician would have to become involved.

The concept of therapeutic substitution could be a

reality. With the continued concern for generic substitution, Koch-Weber (1974) summed up generic substitution, warning:

> Once the effective and safe dose of any one drug product has been established in a given patient, substitution of alternative products with markedly different bioavailability could be catastrophic, particularly when it occurs without the physician's knowledge. Under present circumstances, free substitution of another drug product of different bioavailability for that prescribed by the physician could expose a patient to serious risks of intoxication due to greater absorption of the active drug or to therapeutic failure because of bioavailability (p. 236).

It appears that generic substitution involves some questions and problems for physicians, pharmacists, and the consumer. We are faced with more serious problems that generic substitution now may be replaced with therapeutic substitution or prescribing by pharmacists.

SUMMARY AND CONCLUSIONS

Changes in the pharmaceutical industry have been great with the capability of developing new and improved prescription drugs. Generic drugs have been taking a greater share of the prescription drug industry with the patent expiration on aging drugs. With the increasing prescription and use of generic drugs, consumers should become more familiar with generic drugs and the substitution policy of these drugs.

A key concern for today's consumer is to save money. This includes saving on medical expenses which have increased at alarming rates. Generic drugs have offered consumers some savings, and these saving have been the key to the success of generic drugs. A cost savings is very important to consumers, but safety should remain the overall concern to the consumer of prescription drugs. Many consumers are not completely aware of the controversy surrounding their use and substitution.

The scientific considerations of quality and interchangeability of a prescribed product indicate that not all generic drugs are bioequivalent to their brand name counterpart as defined by the FDA. The bioavailability of a generic drug can have a substantial deviation from its brand name drug which can significantly affect its therapeutic

affects. Identifying specific high risk groups that can be greatly affected by the deviation of bioavailability between a brand name and generic drug, indicate potential problems with established therapeutic effects as stated by the FDA.

The federal and state laws which govern the substitution of generic drugs are centered around a cost savings for the consumer also. They do not consider testing that is required on a new drug about to enter the marketplace. Generic drugs are tested quite differently than a new brand name drug. The federal government has made few changes to the approval process of generic drugs and have continued in its simplified process of approval. State laws concerning generic drugs have not changed since created in 1961, and lend little guidance to a consumer on generic drug substitution.

Scientific considerations and current federal and state laws regarding generic drugs and the substitution of these drugs indicate that there are potential problems in the generic drug industry, some actions need to take place. The key issue of safety in the drug industry can not be ignored. The place to start is to better define the parameters for a generic drug to be considered bioequivalent to a brand name drug and thus eliminate any concerns of quality or interchangeability. Once these parameters are established, the FDA can then evaluate those drugs that do not meet specifications as stated, and then begin the testing of these products as they normally would if it was a new

prescription drug entering the market. The FDA would have to uphold the standards through strict regulations. The problem that may occur and hold up this process is political. Pharmaceutical companies have strong lobbies which would have to be contended with while the new legislation of generic drug testing was started. Having to interrupt the multimillion dollar drug industry while new testing and evaluations on drugs were going on could cause problems. The issue to consider again however, is the individual consumer who deserves a safe and effective prescription drug.

An issue that the consumer can take upon individually is to get to know more about the drug industry, especially, the generic drug industry. Questioning your physician and pharmacist on the particular drugs prescribed is a start. Ask your medical professionals if they know about generic substitutes to your prescribed drug to see if it is as safe and effective as the brand name drug. If there are any questions on a generic drug, know the answers before accepting the generic substitute.

With emphasis of saving money, it is important for consumers to buy wisely. In many cases, it is easy for a consumer to make the right decisions, but the purchasing of all products continues to get more complex every day. When it comes to health products, greater concern must be taken and the area of prescription drugs is where a good consumer must study and evaluate the options. Generic drugs are an

answer to high priced brand name drugs, but considerations must be taken to ensure they are as safe and effective as their brand name counterparts.

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