Have Prescription Drug Brand Names Become Generic?

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In 2012, 84% of the nearly 4 billion prescriptions written in the United States were filled with a generic drug, and a generic version of a drug, when available, was dispensed 95% of the time.[1] Although the vast majority of those prescriptions were written using the brand name,[2] a lower-cost generic was dispensed under state laws which permit or require such substitution.

Generic substitution laws have saved consumers more than $1 trillion in just the last 10 years. But substitution often confuses patients because they are not familiar with the generic name of the drug that appears on the prescription bottle, and because the generic pills may have a different color or shape than the branded version to which they are accustomed. Despite efforts by the American Medical Association and others to adopt prescription labeling guidelines designed to minimize such confusion, medication errors due to confusing names or appearances, as well as failures by patients to take their medicine because of uncertainty about whether the right medicine was dispensed, are continuing problems that disrupt compliance and may lead to health problems that reduce the benefit of generic substitution.[3,4]

If all bioequivalent brand and generic versions of the same medicine had only 1 name and 1 appearance from the day that medicine is first marketed until the day it is discontinued, patients could get the economic benefit of generic substitution without the confusion caused by a bewildering array of names and appearances for the same medicine. That result has been unattainable because pharmaceutical companies claim that the names and appearances they give to their drugs are protected under trademark laws, which give them exclusive rights. That may no longer be true. In recent years, courts have held that the color, size, and shape of a medicine are functional features that cannot be exclusively monopolized as trademarks.[5] And a compelling argument exists that state laws requiring generic substitution on a prescription written using the brand name have not only undercut the market for the brand but have also "genericized" the brand name itself. "Genericide" occurs when a name associated with a product that initially served a trademark function—ie, served to identify a product made by a particular manufacturer—becomes the common name for identifying the product itself. Aspirin, cellophane, escalator, shredded wheat, and thermos are examples of generic names for products that were once famous trademarks.

Over 90 years ago, a federal court held that "Aspirin," a Bayer trademark, had become the generic name for that product. The central question posed by the court in reaching that conclusion was: "What do the buyers understand by the word for whose use the parties are contending?" If they only understand the word as describing the kind of goods sold, and not the producer of those goods, then it cannot be said that when competitors use the word to describe their product they are taking away customers.[6]

In the "Shredded Wheat" case, that product had been known by that name for a long time, during which it was produced by only 1 manufacturer under a patent. The Supreme Court held that there can be no trademark rights which survive the patent unless the primary significance of the name in the mind of the public is the producer and not the product itself.[7] Otherwise, a perpetual monopoly over the common name of a product would improperly create a perpetual monopoly over the

Take-Away Points

- As a result of state substitution laws, most prescriptions are filled with a generic drug even though the brand name is used on the prescription.
- Brand names have become the common name by which people refer to their medicine and no longer function as trademarks that identify a particular producer of the medicine.
- The use of a single name and appearance for all approved bioequivalent versions of the same medicine would enhance the safety and efficacy of medications by reassuring patients that they are always receiving the same medication to which they are accustomed.

product itself. State laws requiring generic substitution result from the implementation of a public policy that was based on the same logic applied in the Shredded Wheat decision. In 1979, a Federal Trade Commission (FTC) study of competition in the sale of prescription drugs concluded "…that the forces of competition do not work well in a market where the consumer who pays does not choose and the physician who chooses does not pay."[8] The FTC found that physicians became accustomed to writing prescriptions by brand name during the period a drug is exclusively sold by its innovator, and they continued to prescribe by brand name even after generic versions of a drug became available, because neither they nor their patients were familiar with the generic name. Until the 1970s, state laws regarding unfair competition prohibited pharmacists from dispensing a generic version of a drug on a prescription written for the brand name, thereby creating a perpetual monopoly for brand name medicines. The FTC successfully urged states to repeal those anti-substitution laws and replace them with laws requiring pharmacists to disregard the brand name written on a prescription and to substitute a lower-cost, FDA-approved bioequivalent generic drug unless the physician affirmatively insisted that the prescription be dispensed as written.

The substitution of a different product when a brand name is requested violates federal trademark and unfair competition laws. When you order a "Coke," a waiter is not likely to substitute Pepsi without asking your permission, because the Coca-Cola Company sues restaurants for trademark infringement when they fail to do so. Substitution of a generic medicine on a prescription written for a brand name has occurred billions of times over the last several decades without any legal objection by pharmaceutical trademark owners. Today, although the vast majority of prescriptions are written using the brand name, those prescriptions are almost always filled with a generic version of the product. Beyond question, the primary significance of a prescription drug brand name, once generic competition begins, is to describe the medicine to be dispensed and not its producer. Just as in the Aspirin and Shredded Wheat cases, prescription drug brand names cease to function as trademarks once the same medicine is available from more than 1 manufacturer.

Brand name manufacturers have actually aided genericide by marketing "authorized generic" versions of their medicines. An "authorized generic" is produced under the innovator's original FDA drug approval; is identical to the branded product in pill shape, color, and size; is distributed under its generic name; and is packaged to hide the identity of the original manufacturer by listing a subsidiary or licensee as the distributor. Authorized generics are promoted as having a marketing advantage over other generics because patients feel reassured that they are getting the same medicine when it is identical in appearance to the brand name product to which they have become accustomed. By cannibalizing the market for prescriptions written for their branded products in this manner, pharmaceutical innovators have undermined any legitimate claim that either the name or the appearance of these medicines continue to function as legitimate trademarks.

It would not be surprising if public interest groups concerned with enhancing patient safety and compliance in taking medications began to bring actions aimed at canceling the trademark registrations for pharmaceutical brand names on the grounds that those names have become generic. Rather than resist these challenges, pharmaceutical innovators should consider whether a new approach to drug names might be less confusing for consumers and also more profitable for them. Bayer has maintained a large share of the aspirin market for decades by using the Bayer name to identify the original version of aspirin. The use of a corporate name in association with a generic name for a medicine would create a clear brand identity shared by the medicine and its original producer, which would permanently distinguish the original product from later generic versions. That would enable patients to choose between competing bioequivalent medicines, all of which have the same name and appearance, on price and real or perceived differences in quality just as they now do when purchasing over-the-counter medicines. State laws requiring or permitting substitution of a lower-cost generic medicine would be unaffected, and insurance companies would be

free to continue to limit reimbursement for brand name products when an FDA-approved bioequivalent generic version of the medicine is available. But patients would have much greater certainty that they were getting the right medication regardless of its source and more clarity about the source of the medicine.

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Author Disclosures: Mr Engelberg is an intellectual property lawyer who was a principal negotiator of the Drug Price Competition and Patent Term Restoration Act of 1984, which led to a growth in the use of generic drugs. He has no current relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

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