

# Through the Looking Glass



**A CAGW Special Report**

## **DAVID v. GOLIATH**

*A New Front in the Ongoing Battle Between Generic and Brand-Name  
Drug Companies*

2000



1301 Connecticut Avenue, NW Suite 400 Washington, D.C. 20036 (202) 467-5300  
Internet Address: [www.cagw.org](http://www.cagw.org)

## Introduction

There's a quiet battle occurring in the states over patient choice and access to generic pharmaceuticals. If this fight is lost, patients, taxpayers and consumers can expect to pay more for their prescription drugs.

Generic pharmaceuticals saved consumers \$8 – \$10 billion in 1994 alone — and that figure represents only drugs sold directly through pharmacies.<sup>1</sup> These savings of healthcare dollars enable insurance companies, managed care companies and patients to acquire other needed health services more easily. But there is a great danger that those savings could be lost if patients, doctors, pharmacists and other healthcare providers do not join together to stop the manipulation of state and federal laws that are raising hurdles to obtaining safe but economical generic drugs.

For example, some brand-name companies spent millions of dollars, during 1997 and 1998, battling over a special category of drugs — narrow therapeutic index (NTI) drugs — in state legislatures. While a brand-name company claims safety reasons and a desire to protect patient health as the reason for all of its activity, a closer look reveals another motive. Either the brand-drug is facing stiff competition for the first time, or the drug has just gone off-patent. What really is going on is a fight to protect the company's monopoly.

This is the latest skirmish in a long history of brand-name drug companies (also called research or innovator drug companies) sparring with generic companies over marketshare. By 2001, brand products with current annual sales of more than \$12 billion will lose patent protection and be vulnerable to generic competition. As "blockbuster" drugs such as Taxol®, Zantac®, Prozac®, Claritin® and others continue to go off patent, the conflict will grow in intensity.

## Background

### What Is a Generic Drug?

According to the Food and Drug Administration (FDA), the federal regulatory agency that oversees the approval process of all pharmaceuticals, a generic drug is a version of a pharmaceutical that is equivalent to the pioneer or brand-name drug. For example, the blood thinning drug Coumadin®, manufactured by Dupont Pharmaceuticals, has a generic version called warfarin sodium. Generic drugs are usually sold under the chemical name of the drug.

Brand-name drug companies invest hundreds of millions of dollars to research and develop a new drug. In exchange for this investment, companies are granted a period of patent protection. But once the drug goes "off-patent," other manufacturers may reproduce and market the generic alternative. The FDA requires the generic version to be bioequivalent. This means the generic drug must have the same active ingredients, be identical in strength, have the same dosage form (tablet, solution, etc.), identical route of administration (mouth, injection), and release the same amount of drug into the body as the brand-name drug. There is one difference: generic drugs tend to be less expensive and can save the patient or insurance company valuable healthcare dollars. The FDA makes it very clear that the less expensive generic drug is not inferior to the brand-name drug.<sup>2</sup> Considering that the FDA is often criticized for being overly cautious, one should consider this admission to be significant.

## **Hatch-Waxman — Revolutionizing the Generic Industry**

In 1984, the Drug Price Competition and Patent Restoration Act, better known as the Hatch-Waxman Act, greatly increased the speed and ease of bringing a generic pharmaceutical to the marketplace. Its goal was to attempt to balance the financial interests of brand-name companies with those of the generic industry. Hatch-Waxman had the following effects:

It created an abbreviated approval process for generic drugs. Before 1984, generic companies were required to prove, independently, the safety and efficacy of their products. But with Hatch-Waxman, a generic company no longer had to duplicate the testing requirements that had already been performed by the brand-name company. Instead, the law allowed the generic company to file an abbreviated new drug application (ANDA) with the FDA that demonstrated the drug's bioequivalence with the brand-name pharmaceutical. Bioequivalence means that the drug's active ingredient is absorbed at the same rate and to the same extent as the brand-name drug. Bioequivalence clinical tests are less costly to perform than safety and efficacy tests, and these savings are passed on to the consumer.

It allowed the ANDA to be filed before the brand-name drug's patent expires. Therefore, the FDA can approve the ANDA immediately after the patent expires, and consumers can get quick access to the generic substitution.

It gave brand-name companies a patent extension, in return for the accelerated approval process for generic drugs. Pharmaceuticals that are in the research phase generally receive a patent before the FDA approves them for marketing. Therefore, a large part of the patent protection time is used up while the drug is in clinical trials and not yet available to the general population. To encourage innovation, and because of the lengthy FDA approval process, Congress provided an extended patent life. The extension equals the sum of all the time the new drug spent in the drug approval process plus half the time the drug spent in clinical testing. However, there are limitations. The extension cannot exceed five years and it cannot allow the period between approval and patent expiration to exceed 14 years. Generally, the average length of patent extension is three years.

It delayed generic competition in other ways. For example, drug companies must wait five years after a new chemical entity drug is approved before they can file applications to sell generic versions. This assists companies that have no patent protection or a little time left on their patents. Another provision delays the marketing of a generic drug by three years when a new drug application is approved that requires new clinical tests, such as for a new dosage form or an over-the-counter (OTC) version, of an already marketed drug.<sup>3</sup>

### **Other Patent Extensions**

Since Hatch-Waxman, other laws have been passed that allow brand-name companies to have a longer period of exclusivity. The Uruguay Round Agreements Act (URAA) passed in 1994, extended the length of patent life for all inventions. Now, the patent length is 20 years from the date the patent application is filed, rather than 17 years from the date the patent is granted. According to the Congressional Budget Office, that change has had a very small impact on the average "effective" patent life — the time between FDA approval and patent expiration -- for all drugs patented after June 1995. Most of those drugs have not yet entered the market.<sup>4</sup>

## **A New Game: Limiting Access to Generic Narrow Therapeutic Index Drugs**

Since implementation of Hatch-Waxman, the generic industry has grown exponentially. Today, generic drugs account for between 45 to 50 percent of all prescriptions dispensed in the United States. Managed care organizations and insurance companies take advantage of the dollar savings, for example, by having low copayments to encourage the use of generic drugs. In light of this, it was natural for brand-name companies to find ways to protect their marketshare. One way was to provide huge discounts to managed care companies so that the brand-name drug was included in the managed care company's formulary — the list of drugs covered under the insurance plan. This is market competition at work.

But, some drug companies have undertaken efforts either to extend patent life or to protect marketshare by gaming the system and lobbying legislatures to pass laws that restrict access to generics. Sometimes the brand-name company goes to Congress and lobbies successfully for a patent extension.<sup>5</sup> At other times, the major pharmaceutical companies can act like Trojan Horses.

In 1997, some drug companies attempted to use a small portion of their profits to provide additional funding for the National Institutes of Health and biomedical research in the fiscal year 1998 Labor, Health and Human Services Appropriations Bill. On the face of it, the proposal sounded laudable — increased funding for valuable medical research without tapping the Treasury. But in exchange for providing three percent of their profits, the companies would get an extended patent life of up to 10 years on their products.<sup>6</sup> Considering that drug companies can make millions of dollars a day on some of their "blockbuster" drugs, the cost to them would have been minuscule, while the cost to consumers and taxpayers would have been enormous.

In 1997, Citizens Against Government Waste (CAGW) uncovered a story about the politics involved in the approval process for generic versions of Premarin®, a hormone replacement drug used for the treatment of menopause. The drug's manufacturer, Wyeth-Ayerst, used political pressure — including attending one of the infamous White House coffee klatches and contributing \$50,000 to the Democratic National Committee — as part of its effort to stop the FDA from approving any generic version of its popular and profitable drug.<sup>7</sup>

Not all of the political activity directed toward protecting marketshare occurs in Washington, D.C. Starting in 1997, some brand-name pharmaceuticals began state-by-state campaigns to limit access to generic pharmaceuticals, specifically NTI drugs. An NTI drug has a small therapeutic range — if too little is taken, the drug doesn't provide the desired effect, but if too much is taken, it can cause serious harm. Typical NTI drugs are those used for high blood pressure, contraception, epilepsy, and asthma.

One company's motive, Dupont Pharmaceuticals, for spending so much time and money to limit access to NTI generic drugs appears to be because its "blood-thinning" drug Coumadin® is facing its first serious competition in years. In July 1997, Barr Laboratories, a drug manufacturer located in New York, introduced warfarin sodium, the generic version of Coumadin®, to the market. Coumadin® alone brings in approximately \$535 million a year, or \$1.4 million a day, for Dupont Pharmaceuticals, so it was obviously in the company's best interest to spend lots of money to stop the generic version. However, it is not in the consumer's or taxpayers' best interest because many people need blood-thinning drugs, particularly the elderly. Furthermore, many states have health plans that offer pharmaceuticals either free or at low cost to low-income

citizens. Many of these plans rely on generics to keep their costs down while at the same time providing quality pharmaceuticals to those who need them.

The modus operandi is pretty typical across the country. Claiming safety concerns, brand-name companies find a friendly politician in the state legislature and get him or her to introduce legislation that in some way makes it more difficult for consumers to obtain access to a generic NTI drug. The legislation usually establishes a list of NTI drugs requiring special treatment. Although the actual language will vary from state to state, pharmacists, doctors and patients will usually be forced to go through all sorts of checks and double checks before a pharmacy can dispense the generic version of a drug on the NTI list. For example, the pharmacist might be required to speak with the physician or get written notice that dispensing the generic is allowed, even though the prescription indicated a generic substitution was permitted. In such cases, it is likely that the generic version will hardly ever be dispensed because pharmacists and doctors are too busy to jump through the regulatory hoops.

Although brand-name companies may argue that these restrictions on NTI drugs are important, claiming there is too much variation in dosage strength between the brand-name product and the generic, it is important to point out what the FDA has said about this very issue. In 1990, the FDA tested more than 400 NTI drug samples and virtually all of them met applicable standards of purity and quality. Only five batches were found not to contain the correct amount of stabilizing ingredient but this posed no health hazard. Health and Human Services Secretary Louis Sullivan stated, "These results should be reassuring to consumers who use generic drugs, since the drugs that were examined are the kind that critics of generics are most likely to claim could cause problems."<sup>8</sup>

Recently, Doctor Stuart Nightingale, associate commissioner for health affairs at the FDA, responded to the campaigns being conducted to limit access to generic NTI drugs in the following statement issued to health professionals across the county:

As you may be aware, certain individuals and groups have appeared recently before state legislatures, state boards of pharmacy, and drug utilization review committees, to express concerns about the interchangeability of certain products they characterize as narrow therapeutic index (NTI) drug products.... For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. For these reasons, FDA approved product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand-name drug product to a generic equivalent, from a generic equivalent to a brand-name product, or from one generic to another when both are deemed equivalent to a brand-name product.<sup>9</sup>

During 1997 – 1998, at least 32 states had some sort of legislation introduced or activity by brand-name lobbyists to restrict access to generic NTI drugs. Thanks to the vigilance of many organizations that educated legislators on the faults of these bills, most of the proposed legislation was either pulled, died in committee or simply didn't pass. Unfortunately, three states — North Carolina, Texas and Virginia — did pass legislation that could restrict access to generic NTI drugs, ultimately driving up costs to consumers. However, the Virginia and Texas Boards of Pharmacy are reviewing the legislation and may find a way to limit the list of drugs that will be affected by the new law.

## What's Next?

CAGW expects that several states will see actions next year by brand-name companies directed toward limiting access to NTI drugs. In their never-ending quest to fight off generic competition, some brand-name companies are employing new tactics to restrict access to other generic drugs. If an NTI list exists within a particular state, the brand-name company will petition the state's pharmacy board to add one of their drugs to the list — usually just as the drug is ready to go off-patent. In many cases, the drug will not even be considered to be an NTI drug.

According to industry sources, another tactic companies use is creating new lists of drugs that need "special" handling, called "critical care" drugs. Drug companies are seeking help from politicians in Washington and the state legislatures to restrict access to generic drugs that might fall into this phony new category, once again forcing taxpayers and consumers to pay more for their pharmaceuticals than is necessary.

Citizens, taxpayers, doctors, pharmacists and other healthcare providers need to remain vigilant against these tactics and let brand-name companies know that these attempts to block access to generic pharmaceuticals will not be tolerated.

## Conclusion

CAGW understands the important role research pharmaceutical companies play in discovering new therapies that cure or control serious diseases. Brand-name companies deserve to make a decent return on their investments. But competition is good for research and it is also good for the consumer. The Congressional Budget Office had this to say about the marketplace for pharmaceuticals and the growth of the generic industry since the passage of Hatch-Waxman in 1984:

Between 1983 and 1995, investment in R&D as a percentage of pharmaceutical sales by brand-name companies increased from 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion (in current dollars). Overall, then, the changes that have occurred since 1984 appear to be favoring investment in drug development.<sup>10</sup>

It appears to CAGW that the generic industry has not harmed the research pharmaceutical industry. Efforts to stifle generic competition must be opposed. When competition is ensured, the real winners will be the American taxpayer — and the patient.

## ENDNOTES

1: Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," Washington, D.C., July 1998, p. ix.

2: Food and Drug Administration, "New Drug Development in the United States," An FDA Consumer Special Report, January 1995, pp. 52-57.

3: Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, pp. xiii-xiv.

4: Ibid., p. 42.

- 5: "Drug Makers Guard Patents Lawsuits, Other Delaying Tactics Make It Tough for Generics to Break Brand-Name Grip," Pittsburgh Post-Gazette, March 8, 1998, p. E4.
- 6: Inside Washington's FDA Week, Vol. 3, No. 42, October 17, 1997, pp. 1, 14.
- 7: See: "Premarin, Politics and the Public Health," CAGW Looking Glass Report, 1997.
- 8: Mike Shaffer, "Narrow Therapeutic Range Generic Drugs," FDA Press Release, September 12, 1990.
- 9: Associate Commissioner Stuart L. Nightingale, "Dear Colleague Letter," Office of Health Affairs, Food and Drug Administration, Rockville, MD, January 28, 1998.
- 10: Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, p. xv.