Unaffordable prescription drugs: the real legacy of the Hatch-Waxman Act

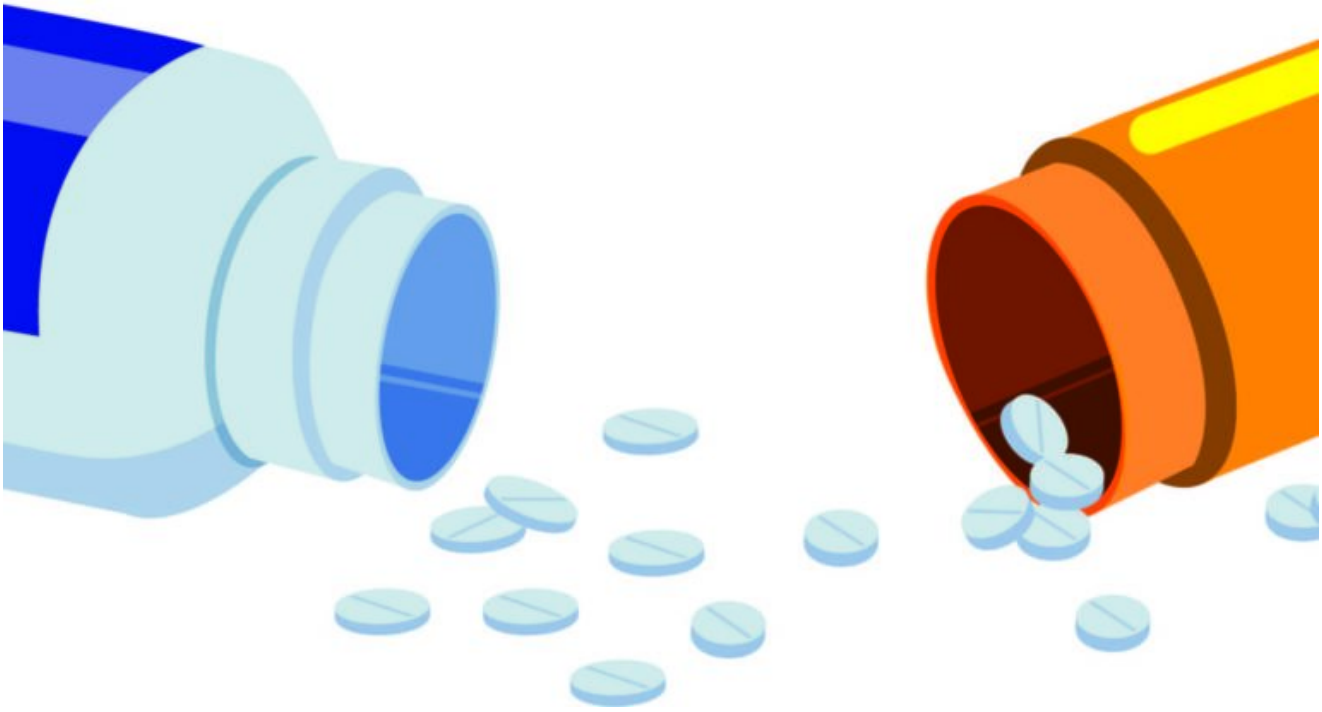
statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/

December 16, 2020

First Opinion

By Alfred Engelberg Dec. 16, 2020

Reprints



Adobe

How is it possible to have a prescription drug price crisis when 90% of prescriptions are filled with generic drugs that cost, on average, $1 a day? The answer: The remaining 10% of prescriptions have an average cost of $20 a day and account for 80% of all prescription drug spending.

High prices for branded medicines are one consequence of the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act, the same law that made low-cost generic drugs widely available. To pass that law, Congress yielded to demands from the powerful pharma lobby for longer and stronger monopolies for new drugs. This payoff to an already highly profitable industry has wiped out the savings that the widespread use of generic drugs should have produced.

Policymakers need to understand the historical background leading to the enactment of Hatch-Waxman and the impact that extra monopolies have had on prescription drug prices over the last 36 years as they consider policy changes that will make medicines more affordable.

It's a history I know well, having been in the middle of the negotiations as counsel to the Generic Pharmaceutical Industry Association (GPIA), and having followed the impact of the act ever since.

Before Hatch-Waxman

In the pre-Hatch-Waxman era, the Food and Drug Administration's generic drug approval process required independent proof that a new generic drug was safe and effective. The process was so costly that few generic medicines were approved, and most branded medicines enjoyed perpetual monopolies. Since 1970, FDA regulations have included an Abbreviated New Drug Application (ANDA) process for approving generic drugs that only required applicants to prove that a drug was chemically and biologically the same as a previously approved drug. But the abbreviated application could only be used for generic versions of drugs that had been approved before 1962, when the law only required proof that a drug was safe and did not require proof that it was effective.

Manufacturers of brand-name drugs feared that their perpetual monopolies would come to an end if the ANDA was used to approve all generic drugs especially since the Federal Trade Commission had recommended that all states adopt laws mandating generic substitution on prescriptions written for branded medicines. To offset that possibility, they asked Congress for longer monopolies for new drugs.

By 1979, legislation had been introduced to extend the life of pharmaceutical patents by up to seven years. The pharmaceutical industry argued that patents claiming a new drug were entitled to longer life to compensate for the time lost in obtaining FDA approval before a new drug could be sold. There was no legal basis for that claim. A patent does not create an affirmative right to sell a patented product at all let alone for the life of the patent. It only grants the right to exclude others from doing so. Whether a patented product is ever sold, for how long, and under what circumstances, is governed by a host of commercial factors including laws that protect the health and safety of consumers by limiting or barring the sale of dangerous products. In some industries, like electronics, the pace of innovation is so rapid that a patented product may be obsolete by the time a patent is granted.

The winding road to Hatch-Waxman

Nevertheless, in July 1981, the Senate unanimously passed a bill extending the length of drug patents by up to seven years and the House began hearings on similar legislation. In 1982, I provided the House Committee on Science and Technology's Subcommittee on Investigations and Oversight chaired by Al Gore (D-Tenn.) with a detailed analysis of why longer pharmaceutical patents would be an unprecedented, expensive and unnecessary giveaway. Later than year I predicted in the journal Health Affairs that it "… would substantially increase prescription drug costs to consumers without any assurances whatever that any of the extra revenue derived would be reinvested in pharmaceutical R&D."

Despite such warnings, the House fell just two votes short of the 2/3 majority needed to bypass regular order and enact the Senate bill into law before it adjourned for the 1982 midterm elections. It was clear that longer drug monopolies would be the political price for permitting the abbreviated generic drug approval process.

Henry Waxman a liberal Democrat from California, became chair of the House subcommittee on health in the new Congress. In January 1984, he brought leaders of the brand and generic industries together and hammered out an agreement in principle on a compromise in which the branded industry would get longer monopolies and the generic industry would get the abbreviated generic drug approval process. Critically, brand-name drug manufacturers also received guaranteed exclusivity for 10 years for new drugs launched in the two years preceding the compromise thereby assuring that the new law would not adversely impact their projected earnings.

The legislative process leading to the enactment of Hatch-Waxman, in which I participated as counsel to GPIA, was essentially a congressionally supervised negotiation between the brand and generic drug industries in which each side fought for provisions that would ensure their own long-term profitability. Waxman supervised the initial phase of those negotiations which led to the introduction of an agreed-upon House bill. Conservative Republican Sen. Orrin Hatch of Utah became the sponsor of the Senate version of the House bill and forged the additional compromises required to save the legislation after several major brand name manufacturers sought to back out of their agreement to support the House bill.

The Hatch-Waxman Act was lauded as a victory for consumers by its sponsors who claimed that it would simultaneously make access to medicines more affordable while enhancing the incentives to invest in biomedical research. That boast ignored the fact that in an unrigged

free market, the public was entitled to the benefit of competition from lower cost generic drugs without regard to the existence of patents and without paying for that right by granting longer monopolies to brand name drugs.

Initial benefits

Consumers did initially benefit from the enactment of Hatch-Waxman. The ANDA process led to the rapid approval of a backlog of generic versions of older medicines which increased the use of generics and lowered the overall cost of prescription drugs for many patients. By 1990, about 40% of prescriptions were being filled with generic drugs at an average cost of only 35 cents a day versus a cost of about $1 a day for branded medicines.

Related:

The industry that cries wolf: pharma and innovation

The enactment of Hatch-Waxman also happened to coincide with a golden era in scientific discoveries related to the physiological site of action of many chronic conditions. That led to the introduction of new medicines to treat high cholesterol, high blood pressure, diabetes, depression, and gastric reflux, to name a few. Between 1984 and 2009, sales of branded pharmaceuticals soared from $20 billion to $250 billion largely as a result of the introduction of blockbuster drugs such as Tenormin, Lipitor, Zantac, Nexium, and dozens more. Each of these blockbusters treated a chronic condition and were prescribed for millions of patients. These drugs were expensive, often costing more than $1,000 per patient per year, and per capita expenditures for prescription drugs significantly increased. But the increase was driven by increases in the annual number of prescriptions being dispensed — not by aggressive price increases.

In 2006, the Medicare Part D prescription drug benefit went into effect and provided senior citizens with financial relief from the increased use and cost of prescription drugs to treat chronic conditions. In its early years, the government's cost for Part D was surprisingly lower than expected because of increased use of low-cost generic drugs. That reinforced the belief that Hatch-Waxman had achieved a balance between encouraging innovation and making prescription medicines more affordable.

Extending patent protection and price hikes

Against this background, in 2010 a Democrat-controlled Congress extended the extra monopoly philosophy of Hatch-Waxman to biologic drugs by enacting the Biologics Price Competition and Innovation Act (BPCIA) as part of the Affordable Care Act. It established a pathway for approving generic biologic (biosimilar) drugs while giving branded manufacturers 12 years of guaranteed market exclusivity, even if no patents existed and by creating the so-called "patent dance" which allowed patent owners to delay competition by asserting claims of potential patent infringement without regard to their merit.

A generation of rapid revenue growth for branded pharmaceuticals began to subside beginning around 2009 as a result of what was known as the patent cliff. Between 2009 and 2017, patent expirations on blockbuster drugs resulted in the loss of $185 billion of brand-name sales to low-cost generic competition. It was not possible for pharmaceutical manufacturers to replace that revenue by introducing new medicines, because most new medicines were specialty drugs that were useful for relatively small patient populations, compared to the millions of people being treated with each blockbuster drug. Although these specialty drugs were often launched at prices that were 10 times or more than the price of the old blockbuster drugs, they produced less revenue. The increased use of generic drugs because of the patent cliff should have resulted in a significant drop in total consumer and government spending on prescription medicines. It did not.

Related:

Strap on your parachutes, pharma faces a mini patent cliff

To make up the lost revenue from patent expirations, manufacturers of branded drugs aggressively increased the prices of their remaining drug monopolies, often more than once a year and by as much as 10% or more annually. The industry's revenue growth from yearly price increases between 2009 and 2013 was far greater than the revenues from new product introductions. That ceased to be true thereafter only because of the introduction of the hepatitis C drug, Solvaldi, at the staggering price of $89,000/patient. But for the period 2008-17, the IQVIA annual reports on pharmaceutical sales show cumulative price increases totaling $187 billion. In short, the loss of revenues resulting from patent expirations was completely offset by price increases.

Branded drug manufacturers also aggressively sought to make their monopolies longer. They exploited loopholes in Hatch-Waxman such as paying to delay generic competition and denying access to samples required to make legitimate generic copies. They also exploited flaws in the patent laws by creating patent thickets — the practice of acquiring additional patents of dubious merit claiming minor aspects of conventional drug formulation and manufacturing that are used to delay competition after the basic patent claiming a new drug expires.

Published economic data shows the shocking extent to which price gouging rather than innovation has driven pharmaceutical revenues over the last decade. Between 2010 and 2018, the percentage of prescriptions filled with a generic drug rose from 77% to 90% and the number of prescriptions filled with a branded medicine dropped by more than 50%, from 910 scrips to 425 million. Nevertheless, revenues for invoiced sales of branded prescriptions rose by 60% and produced $140 billion in revenue growth. As a result of high launch prices and aggressive price increases, spending on the 20 largest selling branded drugs in 2018 was greater than the total sales of all generic drugs: $109 billion versus $103 billion. Five of the 12 largest-selling branded drugs have already enjoyed at least 20 years of monopoly protection

and three others have enjoyed 15 years or more. Between 2012 and 2017, four of those drugs had cumulative price increases of more than 100%: Lyrica, 166%; Enbrel, 155%; Humira, 144%; and Lantus, 114%.

If Medicare Part D had limited price increases to the rate of inflation instead of prohibiting the government from negotiating drug prices, annual expenditures on branded prescription drugs would be at least $100 billion lower today. Instead, brand-name manufacturers have so perverted the intent of Hatch-Waxman that the savings generated by the greater use of low-cost generic drugs each year have been offset by price increases on branded medicines.

The true legacy of Hatch-Waxman

Higher drug prices and less innovation is the true legacy of Hatch-Waxman, the Biologics Price Competition and Innovation Act, and other such laws enacted over the last 40 years which put extraordinary monopoly power in the hands of pharmaceutical manufacturers. As I predicted in 1982, experience has proven that longer monopolies produce higher dug prices but do not guarantee greater investment in innovation. The claim that Hatch-Waxman was a victory for consumers is demolished by the fact that low-cost generic drugs now fill 90% of all prescriptions in the U.S. but U.S. citizens still spend two to three times as much per capita on prescription drugs as the citizens of other developed countries. Why? Because no other developed nation allows pharmaceutical manufacturers to abuse their monopoly power by price gouging.

The reality is that the extraordinary monopoly power granted to pharmaceutical manufacturers in the U.S. has allowed them to grow their revenues and profits by raising prices to offset their loss of market share to generic competition rather than by innovating. In fact, the government's own study shows that the large pharmaceutical companies no longer engage in basic biomedical research to discover new drugs but instead rely on academic medical centers that are supported by government grants.

I believe that repealing these special monopolies for new drugs is in the best interest of the American people. The pharmaceutical industry is not entitled to any greater patent or other monopoly rights than the Constitution provides to any other industry. Eliminating the special

monopoly privileges for pharmaceuticals will shorten their monopolies, limit the industry's ability to generate revenues from price increases, and make the industry's profits more dependent on innovation.

In addition to eliminating extra monopolies granted by the government, changes are needed to both the patent laws and the FDA new drug approval process to ensure that generic competition begins on the day the patent claiming a new drug expires. There are at least three ways to reduce or eliminate the patent thickets that allow monopolies to last longer than that. First, fix a broken patent system that grants drug manufacturers dozens of additional patents for minor changes because patent examiners lack the tools or experience required to understand that these changes do not meet the requirements for a valid patent. To do that, the Patent Office procedures which allow competitors to challenge the issuance of such patents must be strengthened and the presumption that a patent is valid simply because it was granted must be repealed.

Second, the FDA must preserve the ability of generic manufacturers to copy a new drug, as originally approved. Drug makers often supplement their original submission to make minor changes to an approved drug that have no significant effect on either its safety or efficacy but serve to bring the drug under the protective umbrella of the patent thicket. FDA regulations should be modified to prevent non-essential changes to a drug that serve to delay generic competition.

Third, the patent law should be amended to prevent courts from granting injunctions for infringement of patents claiming minor changes to a drug after the patents claiming the drug itself or its medical use have expired. The Supreme Court has held that an injunction for patent infringement is discretionary and should not be granted when it would do a disservice to the public interest. Congress can make a legislative determination that it is not in the public interest to enjoin generic competition after the patent claiming a new drug or its medical use expires — at least in those instances where an injunction is sought due to the existence of a secondary patent claiming subject matter that is not material to the safety or efficacy of a drug as originally approved.

Unfortunately, modifying Hatch-Waxman or other laws to shorten drug monopolies won't lower the price of any drug now being sold or prevent price increases on those drugs. Congress must take immediate action to roll back the price gouging that these monopolies have enabled. Pending legislation would provide relief by limiting the price of a drug to no more than 120% of the amount being charged in other developed countries and limiting annual drug price increases to the rate of inflation. The pharmaceutical industry argues that the imposition of such price controls offends free-market principles. But there is no free market for prescription drugs.

Brand-name drug manufacturers destroyed the free market by successfully lobbying for the laws that created extra monopolies for drugs and by wrongfully prolonging those monopolies through manipulation of the patent system and the FDA new drug approval process.

Congress has both the right and the obligation to regulate this broken market to protect consumers from price gouging.

Alfred Engelberg was patent counsel to the Generic Pharmaceutical Industry Association from 1980 until his retirement in 1995. In his private practice, he successfully challenged the validity of many pharmaceutical patents. He is now a philanthropist and focuses on efforts to make health care and medicines more affordable.

About the Author Reprints

Alfred Engelberg

Tags

drug pricing