

By Sheryl Gay Stolberg and  
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## *How Companies Stall Generics and Keep Themselves Healthy*

### **A Bid to Unleash Competition.**

Just two decades ago, companies like Abbot rarely had to worry about generic competition. That changed in 1984, when Congress passed the Drug Price Competition and Patent Term Restoration Act.

The legislation, now known as Hatch-Waxman after its sponsors, Senator Orrin G. Hatch, Republican of Utah, and Representative Waxman, was a balancing act. It came on the heels of a failed attempt by the pharmaceutical industry to persuade Congress to extend the patent life of brand-name drugs.

On the one hand, the law gave the brand companies the patent extensions they coveted--a move that would, in essence, delay generic competition. On the other hand, it eased the regulatory burden on the generics.

Instead of running costly clinical trials to prove their drugs' effectiveness, generic companies would now only have to prove "bioequivalence," that is, that their drugs contained the same key ingredients as the brand, and worked the same way.

The law also offered the generics a bounty: a 180-day competition-free period--in essence, a six-month monopoly--for the first generic drug maker to seek approval

At the same time, the law rewarded the brand companies by giving them patent extensions of up to five years. And there was another, little-noticed benefit for the brands that would also push back the clock on generic competition: once a generic company had requested F.D.A. approval, the brand company

could sue for patent infringement, and the F.D.A. was prohibited from making a decision for 30 months while the courts weighed the issue.

When the law took effect, the generic industry took off, flooding the F.D.A. with approval requests: 800 applications in the first seven months. Then the lawsuits began.

At the center of some of the earliest skirmishes was Albert B. Engelberg, a lawyer and lobbyist who helped write Hatch-Waxman and represented generics manufacturers. In 1988, in one of his first cases, he hit the jackpot.

*"Instead of running costly clinical trials to prove their drugs' effectiveness, generic*

The case involved a popular muscle relaxant, Flexeril, by Merck & Company. Mr. Engelberg recalled that a judge ruled in his favor, enabling his client, a division of Schein Pharmaceuticals, to sell a generic. His fee, a cut of the profits was \$75 million. It was an "unexpected bonanza," he said.

The victory changed the legal dynamic surrounding Hatch-Waxman, Mr. Engelberg said. Not long after, he said, a brand-name drug company offered to settle a case by giving his client cash payments to stay off the market, a tactic similar to the one Abbott would later try with Hytrin. The settlement was kept secret, and Mr. Engelberg would not disclose details. But he said the concept caught him by surprise.

"It never occurred to me that you could settle a case by paying one of your opponents," he said.

Hatch-Waxman, he said, was supposed to give generic companies an incentive to compete, not to take money in exchange for not competing. "It's the evolution," he complained, "of greed versus need." Now, a later, such deals are only starting to come to light. In March, protracted delays in marketing a cheaper alternative for tamoxifen, the breast cancer drug made by AstraZeneca,

for a particular medicine. For a small generic company, that could mean big dollars. When Geneva finally began selling terazosin, court records show, it earned as much as \$11 million a month from the drug, a tidy sum for a company whose total sales in 1997 were about \$25 million a month.

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prompted sharp criticism from Federal District Judge Ricardo M. Urbina for the District of Columbia, who said he found the situation absurd.

Back