

## How a Drug Maker Tries to Outwit Generics

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President-elect Barack Obama has vowed to reduce prescription-drug costs, but the pricing moves by one pharmaceutical company show why that could be difficult.



Twice this year, Cephalon Inc. has sharply raised the price of its narcolepsy drug Provigil. The drug is now 28% more expensive than it was in March and 74% more expensive than four years ago, according to DestinationRx, a pharmaceutical software and data provider. The Frazer, Pa., company has said in investor presentations that it plans to continue to raise the price.

The Provigil price increases -- the drug's average wholesale price is now \$8.71 a tablet -- are an extreme example of a common tactic pharmaceutical companies employ in the U.S. to boost profits and steer patients away from cheaper generics.

It works like this: Knowing that Provigil will face generic competition in 2012 as its patent nears expiration, Cephalon is planning to launch a longer-acting version of the drug called Nuvigil next year. To convert

patients from Provigil to Nuvigil, Cephalon has suggested in investor presentations it will price Nuvigil lower than the sharply increased price of Provigil.

By the time copycat versions of Provigil hit the market the company is banking that most Provigil users will have switched to the less-expensive Nuvigil, which is patent-protected until 2023. In the meantime, Cephalon will have maximized its Provigil revenue with the repeated price hikes.

"You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil," Chip Merritt, Cephalon's vice president of investor relations, told a Sept. 5 health-care conference, according to a transcript of the meeting.

Cephalon acknowledges regularly increasing the price of its drugs, based on where in their lifecycles they are, market forces, its research-and-development costs and other factors. Before increases in March and August, it said it had rarely raised the price of Provigil, which was launched in 1999. "For the longest time, we were taking no or small price increases for Provigil," a Cephalon spokeswoman said.

Cephalon also acknowledged that its officials have publicly discussed pricing Nuvigil and Provigil to steer patients toward Nuvigil, but the company said it hasn't made any final decision about prices or Nuvigil's launch date.

Patients with health insurance who take the drug for its officially sanctioned uses of narcolepsy, obstructive sleep apnea and shift-work sleep disorder won't likely see the price increases directly, though they are eventually passed on to them through higher health-plan premiums.

Those who take the drug for other, "off label" reasons may face a direct hit since insurers often won't pay for it. Sheila Gibson, an Army retiree in Utah who has been taking Provigil for the symptoms of Parkinson's disease, says she has stopped taking the drug because she can't afford the \$564.65 a monthly refill now costs.

"I'm the one suffering for their greed," said Ms. Gibson, 63 years old, who has asked Cephalon and her insurer for help to no avail.

Cephalon said it provides assistance to a "couple thousand patients" who can't afford Provigil, but said the program reached capacity this year and it wasn't able to accept all applicants. It plans to expand the program next year.

Unlike Ms. Gibson, a large proportion of Provigil users take it as a "lifestyle drug" to help them stay awake during work or leisure activities, according to analysts who follow the company. As a result, a large proportion of Provigil's sales are off label.

In September, Cephalon agreed to plead guilty to one misdemeanor count of violating the U.S. Food, Drug and Cosmetic Act and to pay \$444 million to settle federal and state allegations that it promoted Provigil and two other drugs for off-label uses.

Cephalon promotes Provigil as the "first in a new class" of wakefulness drugs. Provigil's global sales reached \$707 million in the nine months ended Sept. 30, accounting for almost half of Cephalon's \$1.43 billion in sales.

Some health plans have refused to pay for certain costly medicines altogether. Health plans are also experimenting with less punitive measures, such as imposing higher co-payments for certain drugs or asking members to try a cheaper alternative first. Some insurers require a call from a doctor before they will authorize a prescription for a pricey drug to be filled.

Yet insurers say the tools at their disposal to rein in drug prices are limited, noting that many employers choose plans without tiered co-pays or other price-limiting mechanisms, that patients sometimes threaten to leave plans that restrict popular drugs, and that some drugs simply have no cheaper alternative.

Provigil's price increase over the past four years has been almost four times steeper than the 4% compound annual growth rate of the average drug price during that period, according to a DestinationRx analysis of 2,570 brand-name drugs.

Some health-plan managers say it will likely be too costly for them to keep patients on Provigil once Nuvigil is introduced in 2009 because cheaper generic versions of Provigil will still be more than two years off.

"It's really hard to take a higher price now for a lower price in the future when the future is very far away," said Edmund Pezalla, national medical director for Aetna Pharmacy Management.

During his campaign, Mr. Obama promised to lower drug costs by, among other things, allowing the importation of cheaper medicines from other developed countries and increasing the use of generic drugs in public programs like Medicare.

One approach often threatened by Democrats -- allowing Medicare to negotiate prices with drug makers -- would help control rising costs, drug-pricing specialists said. But fully preventing tactics like Cephalon's would be difficult short of outright regulation of drug prices. Many other countries control drug prices, but most U.S. regulators and legislators have opposed such moves.

"It's not going to be easy to fix this type of problem," said John Rother, AARP's executive vice president for policy and strategy.