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**Drug's price up more than \$21,000; The hike for H.P. Acthar, which treats a rare childhood disorder, has sparked debate over prescription costs.**

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There's one drug most doctors turn to first when babies have catastrophic seizures: a natural hormone sold under the name H.P. Acthar. It's the gold standard to stop seizures that can ruin a child's chance for a normal life.

On Aug. 27, the lone maker of that drug raised the price from \$1,650 a vial to more than \$23,000 a vial, sending the price for an average patient to \$100,000 or more.

The 13-fold increase stunned some caregivers and seemed to crystallize their frustrations over drug pricing.

"It's an obscene increase. I could almost see doubling or tripling the price but [14] times seems ridiculous," said Sarah Erush, clinical manager of pharmacy at the Children's Hospital of Philadelphia.

Robert R. Clancy, a neurologist who directs the hospital's Pediatric Regional Epilepsy Program, said: "Everyone understands it's a business and they need to have a fair profit. But to go from \$1,600 to \$23,000 strikes me as old-fashioned greed."

The maker, Questcor Pharmaceuticals Inc. of Union City, Calif., said it had no choice. The company, which has been losing nearly \$1 million a month, receives more than 90 percent of its revenue from Acthar. It had \$12.8 million in total revenue last year.

"We had to take this kind of a pricing increase to ensure that Acthar remains available," said Steve Cartt, Questcor's executive vice president for corporate development. "The company was in a bad situation."

Cartt said the firm had revamped a patient-assistance program to make more Acthar available at no cost to help uninsured parents, and it has started two co-pay assistance programs.

But the price increase has already caused at least one insurer to put in a more stringent pre-authorization process. Experts say it is likely that many patients will find it harder to get this drug.

The increase is an extreme example of how drugs are priced in the United States: There is no regulation of drug prices. Companies can charge what the market will bear, and commercial insurers, who cover most employees' prescriptions, often follow Medicare's lead in covering drugs.

Prescription drugs are "a legal monopoly. We expect monopolists to behave like monopolists," said Mark V. Pauly, a health economist at the Wharton School. "The argument is the higher profits will stimulate further beneficial research."

Large spikes in drug prices are not uncommon, especially when the potential market is small.

In 2006, Ovation Pharmaceuticals Inc. raised the price of indomethacin, an injected anti-inflammatory drug often used in premature babies, from \$100 to \$1,875 for three vials, prompting howls of protest. "This is a rather astounding increase in price for a drug that has a stable niche market and requires no advertising," said Alan H. Jobe, a doctor at Cincinnati Children's Hospital, in the journal *Pediatrics*.

Ovation spokeswoman Sally Benjamin Young said the drug, which privately held Ovation acquired from Merck & Co. Inc. in 2006, had had few price adjustments since it was introduced in 1985. The increase was needed to support better testing, packaging and manufacturing, and to ensure a more stable supply, she said.

Experts say it is not uncommon for new drugs, especially for those that treat rare diseases, to cost more than \$100,000 a year. The high price is needed, economists say, so the firm can be encouraged to enter the field.

What sets apart Acthar is that it is an old drug. The compound (Adrenocorticotrophic hormone) was first synthesized in the 1940s by Armour & Co., the canned-meat firm, which harvested it from pigs' pituitary glands.

The drug, used for years to treat Infantile Spasms, was made by Rhone-Poulenc Rorer Inc. and then by its successor, Aventis. It was never a big seller, and the former owner nearly stopped making it in the mid-1990s - only to see it brought back after a storm of pediatricians complained that there was no substitute.

Questcor bought the rights to the drug in 2001. The company sought formal approval for Infantile Spasms from the Food and Drug Administration, but it issued a "non-approvable" letter in May. The agency did not think the existing clinical trials were good enough, Cartt said, adding that the firm is exploring what kind of tests the FDA will need.

Even without formal FDA approval, Acthar remains the drug of choice for babies with Infantile Spasms. It is the most likely drug to end the seizures, which, if not stopped, make the chances of normal development remote at best.

Acthar is also one of several drugs that helps with sudden flare-ups in multiple sclerosis patients, though its use is small.

Several economists said the firm, whose shares closed at 75 cents yesterday, up 12 cents on the American Stock Exchange, needs to find a balance on price. "From the company's point of view, if the company charged too high a price, nobody would buy it," said William Comanor, director of the UCLA program on Pharmaceutical Economics and Policy. "And if they charge too low a price, they'd be leaving a lot of money on the table."

On the other hand, the drugmaker will have to show it merits a rich price. Acthar is "one of the most expensive drugs on the market," said Frank Lichtenberg, a business professor at Columbia University. "This raises the question: Are the clinical benefits commensurate with that extremely high cost? The burden will be on the company to demonstrate this will extend life, it will improve quality of life, and it will reduce other medical expenditures."

**Cartt, the firm's vice president, said Questcor first tried to expand use where the drug had labeled indications, such as multiple sclerosis, and failed.**

It then hired consultants and came up with a price to sustain the company without turning off insurers.

Cartt estimated that only about 1,000 to 1,500 children a year need Acthar. (An additional 100 children use Acthar for an even rarer neurological condition called Opsoclonus-Myoclonus.)

The average insurer "may see one or two of these cases" a year, Cartt said. "It's just insignificant. Even at the current pricing, it doesn't show up."

So far the company's plan appears to be working, Cartt said. "We're seeing greater than 90 percent insurance coverage at the new pricing," he said. Some state Medicaid programs have balked, he said, but big insurers, such as WellPoint Inc., United HealthCare and Kaiser Permanente, are covering it.

Darryl Richard, a United HealthCare spokesman, confirmed that the insurer is covering Acthar at the higher cost. But he said the insurer was requiring a new pre-authorization process to make sure the drug is used only when necessary.

Clancy, the Children's Hospital neurologist, said the new restrictions did not surprise him. "When insurers start getting these massive bills, their filter is going to be set very tight," he said. "It's a very vulnerable population. Time is of the essence."

"This is just another obstacle for us. If a child does fall through the cracks, that has a lifelong impact."

Families of the affected children also "are up in arms. It's highly unusual to have such an old drug have a huge price increase," said Maria Hardin, vice president of patient services for the National Organization for Rare Disorders in Danbury, Conn.

The group represents patients with rare diseases and runs Questcor's patient-assistance program.

Of 6,000 rare diseases, only one third have any kind of therapy, she noted.

"We're thrilled when these companies develop drugs, but not when they crunch the numbers" and come up with stiff increases, Hardin said.

Mike and Laurel Schwartz of Flourtown are living in the new world of Acthar. Their 3-year-old daughter Reegan was having catastrophic seizures - little jerks that lasted a fraction of a second. She had tried three other drugs without success.

Schwartz was expecting the worst with Acthar, but his insurer, Aetna Inc., approved the drug in part, he thinks, because it was the fourth one.

Schwartz, who works in manufacturing for a major pharmaceutical company, knows Questcor needs to modernize its processes. But he added, "I was pretty shocked at the price increase just because there's got to be some form of corporate responsibility."

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