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From the Baltimore Sun

Growth hormone for kids debated

Families, doctors at odds over need for adding height

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Across the country, increasing numbers of very short children are taking human growth hormone in hopes of eventually reaching normal, or near-normal, height. The treatment, which takes years and costs tens of thousands of dollars, will help a significant number of these patients grow at least a few inches taller.

These children and their families say this added height can make a huge difference in quality of life. It can boost kids' self-confidence, help them avoid being teased or bullied, and later make it easier to drive a car.

But some doctors and researchers say that in many cases, growth hormone therapy is unnecessary and wasteful, closer to cosmetic surgery than essential medical care.

In the small world of pediatric endocrinology - the specialty that treats children with hormone problems - the issue has triggered a heated debate.

"It is a messy thing to consider," says Dr. Steven Chernausek, a pediatric endocrinologist at the Cincinnati Children's Hospital Medical Center. "At what point do you cross the line between being a normal short person and being a person with a medical problem? It's fuzzy."

The question has become more confusing over the past three years, ever since the Food and Drug Administration changed the rules governing which categories of short children should be treated with human growth hormone.

Before 2003, the FDA said that doctors should prescribe it only for children who had a growth hormone deficiency. But that summer, the agency expanded eligibility to include very short children who nonetheless had normal levels of the hormone and no known medical cause of their shortness.

These patients have a condition known as idiopathic short stature, or ISS, which is defined by the FDA as being shorter than 99 percent of children of the same age.

Left untreated, boys with the condition are unlikely to grow taller than 5 feet 3 inches, while girls have little chance of being more than 4 feet 11 inches; most would be much shorter. The average height of an American woman is 5 feet 4 inches; for a man, 5 feet 10 inches.

Some doctors were already prescribing growth hormone for children in this category, using the drug "off label;" the FDA ruling gave this approach more credibility.

Although exact numbers are not available, experts say that since the rule change, the number of children with ISS who take growth hormone has increased.

Overall, perhaps 10,000 children diagnosed with ISS now take human growth hormone. About 40,000 other short children - those with growth hormone deficiency or a range of other diseases affecting growth - also use it.

"It's pretty incredible," Stephanie Dietz says of the growth hormone treatments that have helped her 10-year-old daughter, Sara, reach nearly normal height. Five years ago, Sara, who does not have growth hormone deficiency, had basically stopped growing, and was by far the shortest child in her class.

After discussions with the family, Dr. Emily Germain-Lee, a pediatric endocrinologist at Johns Hopkins Hospital, decided to prescribe growth hormone for Sara. Within a month of starting, the child began growing; in the first year alone she sprouted 4 inches.

Sara, who has just finished fourth grade, is now 4 feet 1 inch and is on a pace to end up about 5 feet tall by the time she finishes growing. That would put her just two inches shorter than her mother; her father is 5 feet 10 inches.

"If I didn't take growth hormone, I'd be 4 feet tall for the rest of my life," says Sara, who lives with her family in the Woodbine section of Howard County. "I'm catching up. Most of the other kids are only a little bit taller than me."

Six days a week, Sara injects herself with growth hormone - the molecule is broken down by the gastrointestinal tract, and so must be delivered under the skin via a penlike needle. She will continue this regimen until she stops growing, probably between the ages of 15 and 20. Treating children early is crucial. Once growth stops at the end of adolescence, growth hormone can no longer increase height

The effects of growth hormone vary widely. In most patients, it produces additional growth of 1 1/2 to 3 inches. But Germain-Lee says that some patients don't grow at all, while others grow as much as to 5 inches.

Growth hormone therapy can have a range of side effects, including joint pain, headaches and a decrease in the production of thyroid hormone. Germain-Lee says that in general the side effects are rare and, when they do occur, manageable. "As far as drugs go, this is relatively safe," she says.

Some researchers nonetheless suspect that the hormone could increase the risk of certain kinds of cancer by providing a boost to tumor development. However, studies so far have shown only inconclusive results.

Critics of growth hormone therapy for ISS don't dispute that some patients with ISS truly need treatment, or that the drug can increase height. But they argue that some children who don't merit treatment are getting it anyway. Even worse, they say, growth hormone therapy promotes the pernicious idea that being short is a medical condition that requires medical treatment.

"Being short is not a disease," says Dr. Mitch Harman, director of the Kronos Longevity Research Institute in Phoenix, and an expert on growth hormone. "There's really nothing wrong with these kids."

Some pediatric endocrinologists say that since the FDA's ruling, they have seen an increase in the number of parents who want their therapy for their children - even though these potential patients are not particularly short.

"Parents say, 'He's just not tall enough. He has to be on the varsity team,'" says Dr. Adda Grimberg, a pediatric endocrinologist at Children's Hospital of Philadelphia.

Unless these children have an underlying disorder, a growth hormone deficiency or meet the FDA definition of ISS, she turns down these requests. Instead she tells families that the child might benefit from psychological counseling.

"It really diminishes the child to say that height is so important," she says. "You want to teach these kids to have good self-esteem and coping skills."

Parents and children with ISS stress the benefits of treatment. Patricia Costa says her daughter Nicole was constantly teased for being short. When the child began growth hormone injections at the age of 6, she was on track to end up 4 feet 6 inches. Now 21, she is 5 feet 2 inches.

"It makes a big difference in a child's life. It really does," says Costa, executive director of the Human Growth Foundation, a nonprofit organization that tries to increase awareness of growth-related conditions in children and adults.

The group receives funding from pharmaceutical companies that make human growth hormone. Costa, who lives in Glen Head, N.Y., was among those who testified before the FDA in support of the rule change.

Skeptics, however, argue that there is no proof that greater height brings increased happiness. "I doubt that, even in those children who are successfully treated, there is any benefit to quality of life," says Dr. Allan Root, a pediatric endocrinologist at Children's Hospital in South Florida. He and others point to a 2004 study by University of Michigan psychologist David Sandberg that found that shorter children, even those who had been teased, were just as well-adjusted as their taller peers.

The rise of growth hormone therapy has been limited by its cost. A year of treatment can run between $20,000 and $50,000. Many insurance companies refuse to cover treatment of ISS kids. Growth hormone manufacturers have programs to help parents who can't afford treatment.

Some researchers use the current lack of knowledge about ISS as an argument for treatment. Pediatric endocrinologist Dr. Margaret MacGillivray, a professor at the University at Buffalo, suspects that many of these children may have dysfunctional growth hormone receptors, the cells that relay messages from the growth hormone molecule to other tissues, such as muscle and bone.

It is unfair, MacGillivray argues, to withhold growth hormone from children with ISS simply because researchers don't yet understand the condition.

"There is a vast amount of information that we do not yet have," she says. "In the next decade or so, the breadth and depth of our understanding about the growth pathway will be far greater. We will scientifically understand ISS."