HGH Scrutiny Could Bring New Restrictions

Crackdown on off-label use by pro athletes may endanger patients who genuinely need the drug.

BY ALICIA AULT
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WASHINGTON — Congress is taking a tough look at the use of human growth hormone for a wide variety of conditions, which is prompting some concern that payers may react by limiting reimbursement for legitimate purposes.

Insurers are already reluctant to cover scientifically validated uses of HGH, Dr. Richard Hellman of the University of Missouri, Kansas City, said in an interview. The drug can cost $10,000-$20,000 a year. The continuing use for purposes that have little to no evidence of safety and effectiveness may ultimately endanger patients who genuinely need HGH, said Dr. Hellman, president of the American Association of Clinical Endocrinologists.

An Internet search for "HGH" shows that the drug (or an illicit or counterfeit version) is being promoted for a large number of off-label uses.

Although this has been a widely known problem, Congress decided to take a closer look at HGH and other alleged performance-enhancing substances in the wake of the December 2007 report issued by former Sen. George Mitchell that exposed a culture of acceptance for off-label and unproven uses of HGH and anabolic steroids in Major League Baseball.

In mid-February, the House Committee on Oversight and Government Reform held a hearing on what it called "myths and facts" about HGH, vitamin B_{12}, and other substances. The hearing was essentially a warm-up for subsequent panel meetings on the use of such substances in baseball and other professional sports that were scheduled for February, but it touched on issues of interest to physicians.

The hearing was "an opportunity to provide essential and accurate information not just to professional athletes, but to high school kids, senior citizens, baby boomers turning 60, and everyone in between," said Rep. Henry Waxman (D-Calif.), chairman of the oversight committee.

HGH has been touted as an antiaging substance, and increasingly appears to be used by athletes of all ages in the belief that it helps them improve performance and recover from injuries faster.

It has been legitimately studied for injury recovery in the elderly, and also is being investigated as a potential therapy for conditions such as fibromyalgia and chronic fatigue syndrome. But this field of inquiry is relatively new.

All of these uses are illegal. HGH is the sole Food and Drug Administration (FDA) approved product that can only be prescribed for the approved indications. In children, the approved indications are to treat growth hormone deficiency, chronic kidney disease, Turner syndrome, small-for-gestational-age infants who do not catch up to normal range, Prader-Willi syndrome, idiopathic short stature; SHOX gene haploinsufficiency, and Noonan syndrome. In adults, HGH is legal for AIDS-related wasting syndrome, short-bowel syndrome, and growth hormone deficiency.

Distribution of HGH, or possession with intent to distribute, for any off-label use is a felony, punishable with up to 5 years in prison and fines.

"Without question, those attempting to market or distribute HGH claiming it will aid healing, slow or reverse the aging process, assist in weight loss, or cure depression are scamming consumers and breaking the law," warned Rep. Tom Davis (R-Va.), the oversight committee's ranking republican member.

And yet, some estimate that illegal HGH sales far outweigh the sanctioned market. Dr. Thomas Perls told the House committee in February that anti-aging sales amount to $2 billion a year. "I personally have found Web sites of 279 antiaging clinics that advertise HGH treatment, and 26 pharmacies that distribute the drug to these clinics or sometimes directly to users," said Dr. Perls of Boston University. "I have certainly discovered only a fraction of what exists out there," he added.

In a JAMA article in 2005, Dr. Perls said that legal sales of HGH in 2004 amounted to about $622 million annually, for a little more than 200,000 initial and refill prescriptions, according to data from IMS Health, a market research company (JAMA 2005:294;2086-90).

Dr. Alan Rogol, of the University of Virginia, Charlottesville, also expressed dismay at the House hearing at what appears to be the growing misuse of HGH. Off-label use comes with increased risk of side effects such as acromegaly, and increased insulin resistance or diabetes, said Dr. Rogol.

He also said that in many cases, HGH purchasers were getting something other than HGH. The prices being advertised are too low and, "many of these preparations are taken orally and cannot be the protein hormone HGH, for it is not active by this route," said Dr. Rogol, who testified on behalf of the Endocrine Society.

Another potential danger is that many of the illicit sales are of human tissue–derived pituitary growth hormone, which has been removed from the market because it has the potential to contain the pathogen that causes Creutzfeldt-Jakob disease. And yet, some of this type of hormone is still available in Eastern Europe and through the Internet.

"It is my opinion for an adult there are no legitimate off-label uses," Dr. Rogol emphasized in an interview.

But both Dr. Rogol and Dr. Hellman acknowledged that there are no central data on how much HGH is being used illicitly, by either nonphysician or physician prescribers. It's in the public interest to keep a registry or to create some other way to keep track of HGH use, Dr. Hellman said. Physicians legitimately using HGH "should have no problem having their work scrutinized," he said.

Both also said they were open to considering data on new uses of HGH, as long as it came from a validated scientific process.

The Endocrine Society and AACE both have published guidelines on HGH. The Endocrine Society guidelines, published in 2006, only pertained to treating adult growth hormone deficiency (J. Clin. Endocrinol. Metab. 2006; 91:1621-34).

AACE last published guidelines in 2003. That report took a broad look at HGH uses and highlighted concerns that off-label prescribing or abuse could lead to reimbursement issues for legitimate patients (Endocr. Pract. 2003;9:64-76). ■

P4P Demo May Not Work for Small Practices

BY MARY ELLEN SCHNEIDER
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A Medicare demonstration project testing pay for performance among large multispecialty physician groups is yielding good data on care coordination programs but expanding the program to small, single-specialty practices could present challenges, according to an analysis by the Government Accountability Office.

Small practices would have difficulty absorbing the high start-up costs associated with care coordination programs and the hefty price tag for electronic health record adoption and implementation, the GAO found.

The GAO report to Congress analyzed the Physician Group Practice Demonstration project. The demonstration tests an alternative payment approach that combines Medicare fee-for-service payments with incentive payments for achieving cost savings and hitting quality targets.

The demonstration, which began in April 2005, includes 10 multispecialty practices, each with 200 or more physicians. Officials at the Centers for Medicare and Medicaid Services recently added a fourth year to the project, which now is scheduled to end March 31, 2009.

CMS reported the first-year results in July 2007. In the first year, two group practices earned bonus payments of about $7.4 million in total.

But it may be difficult to broaden this approach to other physician practices because of the large size and high revenues of the participating practices, GAO said. All of the demonstration practices had 200 or more physicians, while less than 1% of physician practices in the United States have more than 150 physicians. In fact, about 83% of all physician practices are solo or two-person groups, according to GAO.

The practices weren't just bigger in terms of the number of physicians but also had more support staff and larger annual medical revenues. On average, the demonstration practices had annual medical revenues of $413 million in 2005. By comparison, only about 1% of single-specialty practices in the country have revenues exceeding $50 million a year.

GAO identified three advantages that the participating practices had because of their size: institutional affiliations with an integrated delivery system that gave them greater access to financial capital; past experience with pay-for-performance (P4P) programs; and experience using an electronic health record.

Since most of the participating practices had affiliations with large, integrated delivery systems, they had access to the funds to start or expand quality programs. GAO estimated that on average, each participating practice invested about $489,000 to start or expand its demonstration-related programs and spent about $1.2 million on operating expenses for these programs in the first year.

The practices that participated in the demonstration also had a leg up in terms of electronic health record systems. Eight of the 10 participants had an electronic health record before the project began. By comparison, in 2005, only 24% of physician practices in the United States had a full or partial electronic health record, GAO said.

The majority of the participants in the demonstration also had past experience with pay-for-performance programs either through a private or public-sector organization. ■

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