

TESTIMONY

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Topic:

"Myths and Facts About Human Growth
Hormone, B-12, and Other Substances"

**The Mission of the
The Endocrine Society** is to
advance excellence in endocrinology
and promote its essential role as an
integrative force in scientific
research and medical practice.

Statement of Alan D. Rogol, M.D., Ph.D.
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Mr. Chairman and members of the committee, I am pleased that the committee has taken the time to examine this issue as hormone abuse & misuse have long been a concern to The Endocrine Society and its membership. The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing over 14,000 members worldwide. We are dedicated to quality research, patient care, and education.

One of the remarkable roles of the endocrine system is the regulation of growth and development throughout our bodies. This work is directed by the pituitary gland — perhaps the most important “master gland” of the endocrine system. A small oval-shaped organ at the base of the brain, the pituitary gland releases a variety of hormones into the blood stream. One of these is growth hormone called *somatotropin*. Once in the blood, growth hormone travels to bone, muscle, and other tissues where it has many effects.

The hypothalamus, a small structure located at the base of the brain just above the pituitary, controls the release of growth hormone by the pituitary gland. In children, for example, growth hormone stimulates linear growth, or height. It is also important for the development of muscle and bone, and the distribution of body fat throughout the body. In adults, growth hormone affects energy, muscle strength, bone health, and psychological well being. Having either too much or too little growth hormone can cause health problems.

Allow me first to outline the clinical role of growth hormone. Growth hormone is administered to promote linear growth in short children. The FDA-approved indications for administering growth hormone are as follows:

- Growth hormone-deficiency
- Chronic kidney disease
- Turner syndrome
- Small for gestational age infants who fail to catch-up to the normal growth percentiles
- Prader-Willi syndrome
- Idiopathic short stature
- SHOX gene haploinsufficiency
- Noonan syndrome

The most common efficacy outcome for the use of growth hormone is increase in linear growth. Growth hormone therapy employing replacement doses and modestly high doses is quite safe. Very large data bases have noted only minimal increases in scoliosis and slipped capital femoral epiphysis, both likely due to rapid growth and can occur with any therapy that promotes rapid growth, or even normal puberty.

The single serious side effect is increased intracranial pressure and visual disturbance which usually occurs in the first month of therapy as the kidney is re-learning how to handle salt and water. Stopping growth hormone therapy for a few days and then beginning again at half-dose is usually all that is necessary to combat these side effects.

Growth hormone is also administered by physicians to promote psychological wellbeing and alter body composition in adults with:

- Growth hormone deficiency
- Muscle wasting due to HIV/AIDS

Now I want to address the off-label uses of growth hormone. Off-label use usually occurs in adults in two main spheres, the anti-aging market and the body image or athletic market.

It should be noted that off-label use comes with increased risk. One risk factor is that most off label users are usually unaware of the correct doses (at least for athletes) and one can only assume that the doses administered to athletes must be much greater than those used for the legitimate uses noted above. As I'm sure you are aware increased dosages often mean increased risk(s).

With increased doses one might get into the range of acromegaly—a serious disease that results from too much growth hormone in the body. In a child with growth potential this might cause gigantism, but I am unaware of anyone being able to take these doses (and pay for them) in the athletic sphere. It should be noted that acromegaly is a serious disease with weak muscle and very significant heart disease.

Perhaps the most insidious off-label use is by athletes who are told they are receiving “growth hormone”, but may actually be receiving a different substance(s). Growth hormone is an injectable medication. Magazines and the internet are replete with advertisements for “growth hormone.” Many of these preparations are taken orally and cannot be the protein hormone hGH, for it is not active by this route. Most likely they may contain amino acids, which do release growth hormone, but usually only in much larger doses given intravenously.

In fact, the amino acid arginine (or ornithine) is administered as a test for growth hormone sufficiency. Most of the releasers are water soluble compounds and are excreted in the urine with the main side effect of having expensive urine. Some of the compounds purported to be growth hormone have many ingredients including anabolic steroid hormones or steroid precursors in unknown quantities and the entire preparation of unknown purity and with multiple safety concerns. Longer term use of this anabolic agent may promote tumor growth.

In addition, the vast majority of clinically administered growth hormone is made by recombinant DNA techniques and thus not from human tissue. Growth hormone made from human tissue has largely been removed from the market because of the rare, but fatal disease, Creutzfeldt-Jakob disease. Some of the growth hormone now available clandestinely is of human origin and may carry this biological agent.

Also worth noting is that, as with any injectable, one is at risk for diseases of shared needles: Hepatitis and HIV/AIDS both of which are serious and may be fatal.

In summary, there are a number of FDA-approved uses of growth hormone in children and adults. These do not include anti-aging or “improvement” in athletic performance. The larger the doses of growth hormone administered the more like moderate and serious side effects may occur.