Established 1992

Adult Human Growth Hormone Replacement Therapy Is Safe and Efficacious When Conducted in Accordance with Clinical Guidelines

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Hormone replacement therapy (HRT) is the replacement of physiological levels of hormones that decline as a result of a specific disease state. While the use of hormones in aging patients to replenish their levels to a youthful physiologic state is considered as "off label use," it is the position of the A4M that such use, when conducted by qualified physicians trained in the practice of treating age-related hormonal declines, constitutes a legitimate and important medical application. The A4M strongly supports the continued right of physicians to engage in legitimate and appropriate "off label" medical prescribing without interference from non-medical regulatory bodies.

Human Growth Hormone (HGH) deficiency in adults is recognized by a cluster of cardinal clinical features, namely: increased weight and body fat mass; decreased lean body mass; decreased exercise capacity; decreased muscle mass and strength; reduced cardiac performance; reduced bone density and increased fracture rate; poor sleep; and impaired sense of well being. Because HGH sets the pace for all the other anti-aging hormones such as estrogen, testosterone, DHEA, and melatonin, there has been an increasing interest in adult growth hormone replacement therapy (GHRT). Hundreds of controlled research studies conducted over the course of the past fifteen years document the safety and efficacy of adult GHRT. It is incumbent upon physicians administering adult GHRT to secure their supply of HGH only from a reliable, safe, approved pharmaceutical supplier.

On July 5, 1990, an article by Dr. Daniel Rudman and colleagues at the Medical College of Wisconsin appearing in the *New England Journal of Medicine* established one of the most important milestones in the history of clinical anti-aging medicine. Rudman's article documented the world's first clinical trial of human growth hormone replacement in elderly men. Comparing the effects of six months' of HGH injections on twelve men, ages 61 to 81, with an age-matched control group, the researchers showed clear benefits to the therapy. Men administered HGH gained an average of 8.8% in lean body mass and lost 14% in fat (without diet or exercise), improved their skin texture and tone, and increased their bone density. In language rarely used in conservative medical journals, the researchers wrote: "The effects of six months of human growth hormone on lean body mass and adipose-tissue mass were equivalent in magnitude to the changes incurred during 10 to 20 years of aging." [Rudman D, Feller AG, Nagraj HS, Lalitha PY, Goldberg AF, Schlenker RA, Cohn L, Rudman IW, Mattson DE. "Effects of human growth hormone in men over 60 years old," N Engl J Med, 1990 Jul 5:323(1):1-6.]

In April 2002, Dr. Murray and colleagues (The Christie Hospital, Manchester, UK) administered low-dose GH regimen administered to 67 growth-hormone deficient (GHD) adults. Significant improvements in total cholesterol, LDL, triglycerides, and ratio of total cholesterol to HDL were seen. The researchers commented that "Growth hormone deficiency in adult life is associated with a number of adverse biological changes … . Most of these changes can be reversed by growth hormone replacement therapy." [Murray RD, Wieringa GE, Lissett CA, Darzy KH, Smethurst LE, Shalet SM. Low-dose GH replacement improves the adverse lipid profile associated with the adult GH deficiency syndrome. Clin Endocrinol (Oxf). 2002 Apr;56(4):525-32.]

In June 2002, Dr. Ezzat and colleagues from the University of Toronto (Ontario, Canada) administered HGH to 67 men and 48 women found to be growth hormone deficient. After a six-month treatment period, lean body mass increased by an average of 2.1 kg, decrease in fat mass of 2.8 kg, and of 2.1 kg, greatly improved left ventricular systolic function, and significantly restored ejection fraction ("approaching normalcy"). GH treatment was well tolerated, with adverse events primarily related to effects on fluid balance. In both men and women, the researchers found "No apparent relationship between IGF-I levels and the occurrence or severity of adverse events. GH replacement therapy in adults demonstrated beneficial effects on lean body mass composition … [and] … cardiac function improvement." [Ezzat S, Fear S, Gaillard RC, Gayle C, Landy H, Marcovitz S, Mattioni T, Nussey S, Rees A, Svanberg E. Gender-specific responses of lean body composition and non-gender-specific cardiac function improvement after GH replacement in GH-deficient adults. *J Clin Endocrinol Metab*. 2002 Jun;87(6):2725-33.]

While adult GHRT may cause transient blood sugar elevation during the course of treatment, short-term blood sugar elevation is not equivalent to diabetic disease. Properly supervised and administered, adult GHRT does not lead to the diabetic state and/or to pancreatic damage. Diabetes is a permanent physiological condition, and a symptomatic rise in blood sugar as may result from adult GHRT has not been clinically shown to cause diabetes in any scientific study or reported in the 100,000+ patients currently on this therapy worldwide. The A4M is unaware of any peer-reviewed published scientific paper implicating adult GHRT with the onset of a permanent diabetic state. In the anti-aging clinical setting, adult GHRT employs doses of HGH at 1/3 to 1/2 that used in the pediatric setting for the treatment of dwarfism. The attenuated low-dose therapies have been proven effective in twelve years of application by physician members of the A4M.

Of all of the hormones in-use for adult replacement, HGH has the most extensive history of rigorous scientific trials and practical clinical application. "The usefulness of GH treatment in adults who have completed their statural growth is based on the roles of GH in: increasing bone density; increasing lean tissue; decreasing adipose tissue; bolstering cardiac contractility; improving mood and motivation; increasing exercise capacity." [AACE Guidelines for Growth Hormone Use, Endocrine Practice 4(3):165-173]. Many clinical studies have demonstrated the value of HGH replacement in healthy adults, associated with negligible side effects, when acquired from a reliable, safe, approved pharmaceutical supplier and administered judiciously by a qualified physician.