

# Researchers seek to focus attention upon the distributors of human growth hormone

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A great deal of attention has been paid to the use of growth hormone (hGH) by elite athletes and a few vocal entertainers. But underlying this tip of the iceberg is a \$2 billion dollar a year business, likely involving hundreds of thousands of regular people, and promoted by anti-aging and age-management clinics and compounding pharmacies who aggressively market and sell growth hormone with the claim that it has anti-aging or athletic enhancing properties.

Since their previous article in the *Journal of the American Medical Association (JAMA)* in 2005 on the clinical and legal aspects of growth hormone for anti-aging, in which researchers from Boston University School of Medicine, Boston Medical Center and the University of Illinois at Chicago alerted the medical community and lay public to the deceptive mass marketing and illegal distribution of growth hormone for anti-aging and athletic enhancement, the authors provide new evidence demonstrating that these deceptive and dangerous activities have grown worse.

Remarks Dr. Thomas Perls, Director of the New England Centenarian Study and an associate professor of Medicine at Boston University School of Medicine, who has monitored the anti-aging industry for over the past ten years, "despite the overwhelming evidence that the risks and dangers of growth hormone far outweigh the clinically demonstrated insignificant benefit in normally aging individuals, the prescribing, distribution and sale of hGH for alleged anti-aging aesthetic and athletic enhancement has dramatically grown over the past few years. Clearly,

the coordinated and aggressive marketing campaigns of the anti-aging and age-management industries are highly and most unfortunately effective."

Clinical evidence does support the therapeutic use of hGH for children and adults with appropriate clinical indications. However, these cases are disease specific and rare. Furthermore, any effectiveness that is demonstrated in the rare medical conditions approved for hGH distribution cannot be translated into effectiveness among healthy aging adults, a deceptive assertion often made by proponents of hGH use for a wide range of panacea-like benefits.

In January, 2007, the FDA issued an alert emphasizing that prescribing and distributing hGH for anti-aging and body building is illegal. A number of high-profile government investigations such as Operations Raw Deal, Phony Pharm and Which Doctor have attempted to make a dent in the illegal distribution of hGH and anabolic steroids for unapproved uses such as anti-aging or aesthetic reasons. As stated on the Albany County District Attorney's website, in the case of Operation Which Doctor, numerous governmental agencies are "working together to take down a nationwide distribution ring of anabolic steroids, Human Growth Hormones and other controlled substances, by targeting the ring's dirty doctors, its distributors that pose as clinics, and ultimately the ring's supplier Signature Pharmacy."

Contrary to published claims, neither long-term safety nor health benefits have been demonstrated in normally aging individuals taking hGH. A review of clinical studies among healthy, normally aging individuals found that hGH supplementation does not significantly increase muscle strength or aerobic exercise capacity. However, documented adverse effects include soft tissue edema, arthralgias (joint pains), carpal tunnel-like syndrome, gynecomastia (enlarged breasts) and insulin resistance with an elevated risk of developing diabetes.

Increasingly more and more animal and laboratory studies suggest an increased cancer risk.

The authors suggest that several measures need to be taken to address the inappropriate distribution and use of hGH. Among their recommendations:

- The public must be accurately informed by physicians and scientists who do not have a vested interest in hGH, about health risks, fraudulent marketing and illegal distribution of this drug.
- Organizations that promote or indirectly profit from the medically inappropriate and illegal distribution of hGH that have been accredited by the Accreditation Council for Continuing Medical Education (ACCME) to offer American Medical Association Physician Recognition Award (PRA) category 1 CME credits or other categories of CME credit should, at a minimum, have their accreditation revoked.
- U.S. manufacturers of hGH must be more effective in, and held accountable for, controlling the distribution of the drug to companies providing the drug for illegal uses.
- Congressional hearings and media attention surrounding hGH should focus less on athletes and prominent entertainers who are also victims of deceptive marketing and pushing of hGH, and much more on the distributors who are violating federal and state laws by making the drug available for non-approved uses.
- Senators Schumer and Grassley and Representative Steven Lynch deserve the public's support of their intention to strengthen and enhance the law regarding the illegal distribution of hGH. 'Strengthening the law' should entail stiffer financial and imprisonment penalties for illegally prescribing and/or distributing growth hormone for purported anti-aging,

age management, aesthetic enhancement, and body building uses. Enhancing the law should include the addition of sermorlin (growth hormone releasing hormone [GHRH]) and mecasermin (insulin-like growth factor I [IGF-1]) and their analogues. GHRH (which stimulates the release of endogenous hGH) and IGF-I (which mediates many of the effects of hGH) result in hGH-like effects, and, therefore, the potential for their inappropriate use as purported anti-aging and performance enhancement therapies clearly exists.

Perl adds: "In my capacity as a reviewer of medical records seized from anti-aging clinics by the DEA, I almost never see hGH provided in isolation. It is usually a part of a complex cocktail of one or more anabolic steroids, human chorionic gonadotropin (specifically for men to decrease the obvious signs of steroid abuse such as small testicles and enlarged breasts), thyroid hormone, DHEA and other drugs. Additional drugs such as blood pressure medicines, diuretics and insulin may be given to treat the side effects of the basic cocktail."

Source: Boston University

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