
Special Agent Alex Davis
Office of Criminal Investigations
U.S. Food & Drug Administration

Sentencing of Food and Drug Offenses
Before the
United States Sentencing Commission

February 13, 2008

Members of the Commission –

Good morning. My name is Alex Davis. I have been employed as a Special Agent with the Office of Criminal Investigations ("OCI"), United States Food and Drug Administration ("FDA") since June 2004. I am assigned to the New Orleans Resident Office, located in Covington, LA. Prior to my current employment, I served as a Special Agent with the United States Secret Service ("USSS") for approximately four years. Prior to my employment with the USSS, I served as a State Trooper with the Louisiana State Police ("LSP") for approximately four years. While employed with LSP, I served for approximately two years as a narcotics agent.

I have participated in numerous investigations involving individuals who have received and distributed controlled substances and human growth hormone (hGH), as well as the seizure of illegal drugs and proceeds from the sale of those illegal drugs. From my experience in investigating controlled substance violations, hGH violations, and violations of other criminal laws, I have executed numerous search warrants, conducted controlled deliveries of illegal drugs, engaged in online investigative techniques, interviewed witnesses, and secured other relevant information using various investigative techniques.

As my FDA colleague, Dr. Perlstein, can tell you, FDA has approved hGH, manufactured by eight different manufacturers, for several indications in children. FDA also has approved some hGH products for adult indications, but these indications are limited. However, the perceived benefits of hGH for uses for which no hGH drug has been approved (hereafter referred to as the "unapproved uses") and the common misconception that such uses are relatively safe, coupled with the relatively low costs of black-market hGH and the ease of obtaining it for unapproved uses, have led to a significant rise in its unlawful distribution.

UNAPPROVED USES OF hGH

I am aware of hGH being distributed primarily for two unapproved uses: (1) to increase athletic performance, and (2) to stop or slow the aging process. Those who

purchase hGH to increase athletic performance will typically use it in conjunction with anabolic steroids and a bodybuilding routine to increase their lean muscle mass, speed, and endurance. Those who purchase hGH for anti-aging purposes use it to lose fat, improve their skin, boost their immune system, improve their memory, and improve their sexual function. Multiple "kits" of hGH are usually purchased for either or both of these unapproved uses. Each kit typically consists of several vials containing hGH in the form of a lyophilized powder mixed with several excipients (inactive ingredients). It is my understanding that, although hGH must be injected for it to be metabolized by the body, the vials always contain hGH in the form of a lyophilized powder until they reach the customer because liquid hGH will quickly lose potency if it is not kept refrigerated. After receiving the vials containing lyophilized hGH powder, the customer reconstitutes the product to the desired potency by adding sterile water or a similar diluent. Once reconstituted, the hGH can then be stored for as long as three weeks in a refrigerated environment. Whether using it for athletic enhancement or anti-aging, hGH is injected into the body either subcutaneously or intramuscularly.

The internet is littered with different recommendations from anonymous sources regarding hGH dosages and durations of use. These anonymous sources almost always discuss hGH dosages in terms of international units ("IUs") of active hGH ingredient (3 IUs of hGH is equal to 1 mg of the active hGH ingredient). Durations of hGH use are often referred to in terms of "cycles." The recommended dosages and cycles contain little, if any, scientific support, and many suggested dosages and cycles seem to be based on purely anecdotal evidence.

The recommendations found on the internet for dosages and cycles fall into general ranges that differ, depending on the intended unapproved use. Those using hGH for athletic performance, including bodybuilding, generally inject from 4 to 10 IUs of reconstituted hGH per day (1.3 to 3.3 mg of the active hGH ingredient) for a cycle of 6 months to a year. Those using hGH for anti-aging purposes generally inject from 1 to 3 IUs of reconstituted hGH per day (0.33 to 1 mg of the active hGH ingredient) for a cycle of a year, or, in some cases, indefinitely.

For both unapproved uses, hGH is typically injected seven days a week. However, in an attempt to conserve the drug, it is not uncommon for hGH users to inject

it for five consecutive days, followed by two days without use, and then repeat the rotation.

hGH TRAFFICKING

All of the hGH that is promoted to stop or slow the aging process or to increase athletic performance is unapproved product, which is primarily manufactured and distributed by foreign drug sources. The internet has made it very easy for anyone to obtain hGH from one of the numerous foreign sources. All of the hGH schemes that I have encountered use websites or internet discussion boards to facilitate the illegal distributions.

The website distribution scheme is very simple. A foreign source of hGH will use one or more websites that allow anyone in the United States to place and order to buy hGH and have it delivered from a foreign source directly to his or her door.

The other popular distribution method involves U.S.-based distributors who obtain hGH from foreign sources and use internet discussion boards to advertise their ability to distribute the drug. There are over one hundred bodybuilding internet discussion boards that are used as a communication hub linking hGH distributors to customers located throughout the world. Typically, the distributor gains the trust of a discussion board operator and requests permission to advertise hGH on the internet discussion board. If permission is granted, the discussion board operator, for a monetary fee or some other method of payment, allows the distributor to advertise on a private forum that only certain discussion-board members can access. It is on this private section of the discussion board that the distributor anonymously advertises his products, the dosages, the prices, the time it takes for the customer to receive an order, and the method of payment. The customer simply sends an encrypted email to the distributor requesting a specific amount of hGH and awaits a response for payment instructions. The use of encrypted emails is employed by hGH distributors and their customers in an effort to evade law enforcement. Upon receiving payment for the drug, the distributor ships the package containing hGH to the customer.

hGH distributors using internet websites and internet discussion boards usually use similar operating procedures to complete hGH transactions. In an attempt to avoid U.S. law enforcement, these distributors often base their website server in a foreign country (usually one that is known not to fully cooperate with U.S. law enforcement). The distributors do not require identification and do not verify the customers' ages when conducting a transaction. The hGH purchased from a website or internet discussion board is almost always significantly cheaper than FDA-approved hGH. Currency for these drug transactions is usually sent in the form of cash in the mail or by Western Union.

If hGH is received directly from the foreign drug source, the customer is charged less to account for the risk that the international package may be stopped by U.S. Customs and Boarder Protection ("CBP") and a further law enforcement action might be taken. These packages typically contain false declarations to avoid seizure by CBP. However, if a falsely declared package containing hGH is seized by CBP upon entry into the United States, the customer, whose name and address is on the package, will usually receive a letter that warns him or her of the seizure. By simply sending a copy of this warning letter to their hGH source, the source will usually re-ship another package of hGH to the customer, free of charge.

To avoid being caught by CBP, many transactions include an intermediary, or "remailer." Under this scheme, the customer pays an additional amount of money to avoid receiving an international package that must pass through CBP. Instead of mailing the package containing hGH directly to the customer, the drug source mails a package to a different individual in the United States, a remailer. The remailer then sends the package though the domestic mail to the customer.

STEROIDS AND OTHER DRUG TRAFFICKING

Anabolic Steroids, which, of course, are controlled substances, are distributed in much the same manner as hGH -- that is, imported from a foreign source and sold over the internet, either through a website or a bodybuilding internet discussion board. As I already noted, hGH is often used in conjunction with steroids and a bodybuilding routine

to increase athletic performance. Therefore, those who are distributing steroids are very often the same individuals who are distributing hGH, and many of the websites and bodybuilding internet discussion boards that offer hGH for sale will also offer steroids for sale. The websites and internet discussion boards will also offer for sale various prescription drugs -- without a prescription -- that purportedly counteract the negative effects of hGH and steroids.

Controlled substances such as cocaine, however, are typically not offered for sale on websites and internet discussion boards that sell hGH. There are a few reasons for this. First, controlled substances like cocaine are usually distributed through a hierarchical structure, rather than over the internet. Also, because distributors using a website or internet discussion board to sell hGH, steroids, and the prescription drugs that counteract the negative effects of hGH and steroids can create a lucrative illegal drug business over time, they seek to avoid what they perceive as the extra scrutiny from law enforcement and to avoid the higher penalties that are associated with selling "recreational drugs" such as cocaine. For the same reasons, operators of bodybuilding internet discussion boards strictly forbid discussions of "recreational drugs" such as cocaine.

Thank you for the opportunity to speak this morning. I'm happy to answer any questions that you might have.

Special Agent Alex Davis
Food and Drug Administration
Office of Criminal Investigations