



COLLINS, McDONALD & GANN, P.C.
ATTORNEYS AT LAW

MARC C. GANN*
ROBERT A. McDONALD
RICHARD D. COLLINS*

DANIEL W. RUSSO
MICHAEL J. DiMAGGIO

**Also Member MD Bar*

**Also Member PA, MA, TX and D.C. Bars*

138 MINEOLA BOULEVARD • MINEOLA, NY 11501
TEL: (516) 294-0300 • FAX: (516) 294-0477
info@cmgesq.com • www.cmgesq.com
New York City Office By Appointment

Of Counsel
ALAN H. FELDSTEIN[‡]
15250 Ventura Blvd. • 3rd Floor
Sherman Oaks, CA 91403
Tel: (818) 377-2831
Fax: (818) 377-2861

‡Member CA Bar Only

Testimony to the United States Sentencing Commission

Re: Formulating a Guideline for Human Growth Hormone

February 13, 2008

Rick Collins, Esquire

Once again it is my honor to offer my commentary to the Commission. The non-medical use of human growth hormone (HGH) continues to receive intense media coverage, as well as new attention from Congress. In fact, the House Committee on Oversight and Government Reform held a hearing on the substance on February 12. HGH is one of today's hot topics. Hopefully, the Mitchell Report and the ongoing Roger Clemens investigation will not create an atmosphere which inhibits rational discourse in Washington. Looking back generally on past drug policy changes, drug policy is best made under calm and thoughtful conditions, not when media headlines are at their most sensational.

Without question, the illicit trafficking of prescription drugs including HGH presents societal problems and enforcement challenges. It is my privilege to weigh in on how sentencing in such matters might be altered or enhanced. My comments are respectfully offered based upon my experiences in dealing with HGH criminal matters and representing individuals accused of HGH possession or distribution. I have previously provided my curriculum vitae for the Commission's reference and testified before the Commission on behalf of the National Association of Criminal Defense Lawyers. I hope that my experience in dealing with these cases and with the community of users will be helpful to this Commission on the issue of whether to formulate a specific guideline to address HGH crimes, and if so, how to ensure its fairness.

Legal Status of HGH

Human growth hormone (HGH or hGH) is a natural hormone produced in the human body by the pituitary gland. It consists of a sequence of 191 amino acids. It is not a steroid. It is available as a synthetically produced drug in the form of a lyophilized powder. Typically, the powder is mixed with Bacteriostatic Water by the user to create a solution for injection. Daily dosing is utilized as HGH has a very short life span in the body (cleared from the body with a half life of only 20 to 30 minutes). It is most frequently injected subcutaneously (under the skin) using a small insulin needle. In its usable form it may be measured in International Units (IU's), although this measurement only applies when the powder has been mixed. Webster's defines IU as: a quantity of a biologic (such as a vitamin) that produces a particular biological effect agreed upon as an international standard. Therefore, the milligram (mg) weight is the appropriate quantification for the powder form of the drug (the form in which it is trafficked). When mixed, 1 mg is equivalent to 2.7 IU's (or, for shorthand purpose, about 3 IU's).

Currently, standard urinalysis cannot detect the exogenous use of this hormone and, as such, its use appears to have increased in prevalence among drug-tested athletes. It is also popular among strength athletes and bodybuilders who typically administer it in conjunction with anabolic steroids. It is also reportedly popular among aging Baby Boomers with diminished ("deficient") endogenous levels (recent news reports have focused on movie stars and pop singers using the drug to "stay in shape"); however, HGH may not lawfully be prescribed for sports performance, bodybuilding, "anti-aging" or other non-medical purposes under federal law. Prolonged use of excessive dosages can lead to significant side effects. Examples of some brand names are Genotropin®, Humatrope®, Nutropin®, Protropin®, Saizen®, Serostim® and Somatotropin®. HGH is available by prescription only; it is not a controlled substance under federal law. However, a specific federal law (21 U.S.C. § 333(e)) prohibits the distribution or possession with the intent to distribute human growth hormone for use in humans other than for the treatment of a disease or other recognized medical condition. Violations may be punishable by imprisonment of up to 5 years (10 years if to a person under 18 years). Some states have classified HGH as a controlled substance [see Appendix chart] despite a lack of evidence of psychoactive effect. In fact, the medical consensus at this time is that HGH has no psychoactive effect whatsoever.

It may be worth noting that on March 14, 2007, Senator Charles Schumer (D-NY) introduced a bill (S. 877) to classify HGH as a Schedule III controlled substance, "thus equating it with anabolic steroids in the eyes of the law" (Senator Schumer's press release is available at <http://schumer.senate.gov/SchumerWebsite/pressroom/record.cfm?id=289392>). The bill is pending. Despite a highly significant question as to whether this hormone meets the statutory scheduling criteria of 21 USC § 811(c) or § 812(b)(3)(C), it appears possible given the current climate regarding sports doping that HGH will be classified as a federally controlled substance at some point in the not so distant future. The Commission may or may not want to factor this into its deliberations as to whether the time is yet ripe for a Guidelines amendment.

HGH Prosecutions in Federal Courts

Federal prosecutions have targeted mostly HGH traffickers, although on rare occasions personal users have been prosecuted in U.S. District Courts. For example, in one case the Defendant was a 40 year old non-competing fitness enthusiast with no criminal history of any kind. He ordered HGH for his personal use over the Internet from China, paying \$1,650 in advance. The package arrived mislabeled as a "toy/gift." The package was searched by U.S. Customs and found to contain 50 vials of a Chinese HGH product. It was then delivered under law enforcement surveillance, and the Defendant's residence was searched upon his acceptance of the delivery. He was arrested and prosecuted in the U.S. District Court for the Western District of Washington State. The Government conceded that there was no evidence that the Defendant was "distributing the drug to other body-builders." Nevertheless, the Government would not agree to a deferred prosecution or non-criminal resolution. Defendant entered a guilty plea under 21 U.S.C. § 331(a) and 333(a)(1), Introducing a Misbranded Drug into Interstate Commerce. Under the Plea Agreement: "The parties estimate and agree that the base offense level in this case pursuant to Section 2N2.1 of the Federal Sentencing Guidelines is level 6." With Acceptance of responsibility under § 3E1.1, the adjusted level was 4. Defendant was sentenced to a one year probationary term and a \$5,000 fine.

Probably the most highly publicized HGH case in the federal court system was the case against physician James M. Shortt of South Carolina. Dr. Shortt had been the team doctor for the NFL Carolina Panthers and he catered to athletes nationwide. He was prosecuted in a 43-count indictment charging him with participating in a seven-year conspiracy to distribute and dispense anabolic steroids and human growth hormone solely to aid athletic performance. He entered a guilty plea to a conspiracy count. The Presentence Report recommended a sentencing offense level of 6, with a two-level enhancement for special skill and a two-level reduction for Acceptance of Responsibility. As a Category I offender, his adjusted level of 6 placed him in a zero to six month sentencing range. The Presentence Report noted the absence of a guideline specific to 21 U.S.C. § 333(e). In the absence of an explicit guideline, the Probation Officer determined the offense level for distribution by reference to the "amount paid by the user for the substance." Dr. Shortt was sentenced to 12 months and 1 day – a variance with the zero to 6 month guideline. One basis for the non-guideline sentence (among seven bases) was the absence of a guideline on HGH. The court cited: "The end result is there is no penalty imposed at all because of the use of prescriptions for the human growth hormone." The case went up on appeal with the Defendant arguing his sentence was unreasonable. The sentence was affirmed by the Fourth Circuit [485 F.3d 243; 2007 US App. LEXIS 11019].

Dr. Shortt's case presents a departure from one element that plays a tremendous part in most steroid and HGH cases: the Internet. Most trafficking of these substances involves mass marketing using computers. The drugs are shipped by mail; mail fraud typically occurs. The money is "laundered" by various methods to shield it from detection. However, the Shortt case does present a familiar scenario in one respect: anabolic steroids and growth hormone are often used together by non-medical users.

They are frequently trafficked together as well. Therefore, formulating a unit basis for HGH would permit quantities of HGH to be added to quantities of anabolic steroids to increase the total drug volume for sentencing purposes.

In practice so far, most HGH prosecutions have turned to money-based counts for punishment. A perusal of public court records reveals various cases in which the defendants were sentenced based on loss estimates. For example, in a case in the Northern District of Iowa the Defendant was involved in a conspiracy to distribute a large volume of counterfeited HGH over the Internet. He was charged with Conspiracy to Distribute Growth Hormone and a substantive count. He pled guilty to the conspiracy in violation of 18 U.S.C. § 371. The Probation Office determined that "the total amount of loss resulting from the defendant's fraudulent activities is estimated to be \$450,000." Therefore, "Pursuant to USSG § 2B1.1(b)(1)(H), defendant's base offense level for each of the offenses defendant conspired to commit was increased by 14 levels." Defendant also got a two-level enhancement for creating a reckless risk of bodily injury to his customers. He was sentenced to 24 months imprisonment, 3 years supervised release, and \$100 assessment. The sentence was appealed and affirmed [141 Fed. Appx. 503; 2005 U.S. App. LEXIS 16440].

In a related Iowa case, the Defendant was charged with a variety of counts including Distribution of Anabolic Steroids, Conspiracy to Distribute Human Growth Hormone, Introducing and Delivering for Introduction into Interstate Commerce Misbranded Drugs, and Money Laundering. The total offense level was 24, yielding a range of 51 to 63 months. The Defendant was sentenced to a 31 month term of imprisonment based on § 5K1.1 motion.

In a different matter, the Defendant received 100 boxes ("kits") of HGH in the summer of 2002. He kept 10 for his own use and distributed the other 90 to bodybuilders he knew. It was later determined that the products were counterfeit; they had been manufactured illicitly and contained no actual HGH. However, neither the Defendant nor his customers suffered ill effects from the products. The Defendant was arrested for distributing HGH in violation of § 333(e) and prosecuted in San Diego. His Base Offense Level under § 2N2.1 was 6. The amount of loss (based on what he sold the kits for) under § 2B1.1(b)(1)(D) added 6 levels. Two points were added for number of victims [§ 2B1.1(b)(2)(A)] and two points reduced for Acceptance [§ 3E1.1] leaving an Adjusted Offense level of 12 (range of 10 to 16 months custody). Defendant was sentenced to 10 months, split between federal prison and home confinement.

Patterns of Illicit Use

Most individuals who self-administer HGH inject the drug subcutaneously once each day for five to seven days (it is not uncommon to skip administration two days each week). The purpose in using the drug non-medically is often to increase muscle hypertrophy and shed body fat (although some non-athlete users seek other "anti-aging" effects). Many users report that HGH is extremely effective, especially for the purpose of decreasing abdominal fat. Most non-medical users stay on HGH for long periods of time, as the results (especially muscle gains) reportedly take much longer to

see than is the case with steroids. Non-medical HGH users seeking to build dramatic muscle size almost always use HGH in conjunction with anabolic steroids, as it is believed that HGH has limited benefits for that purpose without steroids. Men and women who use HGH non-medically in order to primarily decrease body fat often use it alone, and in lesser doses.

The fact that prolonged excessive use of HGH is associated with significant adverse effects is well-known by the community of users. The standard dosing among illicit users, based on my substantial personal interaction with this community and with other professionals familiar with the subject, is 1mg (about 2.7 IU's, or, for shorthand purposes, 3 IU's), give or take a little. A minority of heavier users more interested in hypertrophy than fat loss may use 1.5mg to 2mg daily (about 4 to 5 IU's) and a small minority may use even more. To put this in perspective, it should be compared to medical dosing. The popular brand Serostim® by Serono is available in both single dose and multiple dose administration. The single dose vials are either 5mg or 6mg (about 14 or 16 IU's). Serono recommends [see www.serostim.com] that HIV-wasting patients (over 121 pounds) start with 6mg daily dosing (that's six times more than most much heavier weightlifters use). The package insert for Serostim® cites favorable studies administering 4mg (approximately 12 IU's) to HIV-wasting patients. It is further my understanding that for short-statured children the dosing is 1mg to 1.5mg daily – even though these pediatric patients may weigh only a quarter of the typical adult non-medical user.

Comparison of HGH to Anabolic Steroids

It seems logical and reasonable that drug trafficking cases involving both anabolic steroids and HGH should permit a cumulative effect for sentencing. However, the fact that steroids and HGH are often used or trafficked together does not mean they should be treated equally. It should be noted that in many steroid trafficking cases, non-scheduled prescription drugs other than HGH are also involved. Steroid use is universally noted for its polypharmacy – users administer a wide variety of ancillary medications to maximize positive effects and minimize adverse ones. Steroid traffickers typically offer these non-scheduled drugs for sale in addition to anabolic steroids. However, it would be unreasonable to attempt to treat all these drugs on par with steroids simply because they are also used by the same population. These drugs, like HGH, are currently not counted under § 2D1.1. Therefore, although it may improve steroid/HGH combination case sentencing, it should be recognized that creating a "unit" of HGH won't address the range of other ancillary drugs sometimes involved in such cases, including anastrozole, human chorionic gonadotropin, clomiphene citrate, letrozole, tamoxifen citrate, clenbuterol, Cytomel®, Proscar®, Viagra®, etc.

For the time being, there would seem to be little scientific evidence to support exact sentencing parity between anabolic steroids and HGH. The fact that anabolic steroids are Schedule III has little instructive benefit as to what controlled substance category, if any, HGH should be placed in by Congress (or treated by the Guidelines for sentencing purposes). Certainly, raising the base offense level for HGH trafficking higher than the base offense level for steroid trafficking would be disproportionate. There are

two paramount concerns over non-medical anabolic steroid use: the psychological / psychoactive effects and the use of excessive dosages beyond what would ever be prescribed in a medical context. Neither applies to HGH.

The psychoactive effects of steroid use among a small group of illicit users (unduly sensationalized as "roid rage" by the media, according to psychiatric steroid researcher Harrison Pope, MD and epidemiologist Dr. Charles Yesalis) appear to be *absent* among HGH users. Nothing in the literature supports enhanced aggression, psychosis, hypomania, or any other psychoactive effects. Further, no data suggest that the discontinuation of HGH has any depressive effect on mood. Comparing steroids to HGH in terms of possible psychoactive effects is comparing apples to oranges.

Regarding dosages, it is widely recognized that non-medical anabolic steroid users take 10 to 100 times the medical dosage, potentially magnifying the side effects. That's the problem with most drugs of abuse or misuse: people take more than they should. HGH is a strange if not unique drug in that its non-medical users typically administer only a *small fraction* of the dosages approved for medical use. Since the adverse effects of most drugs, HGH included, are generally dose-related, it is unknown what effect this disparity may have upon the potential adverse effects of HGH to non-medical users (it may explain why, anecdotally, few illicit HGH users report serious side effects). Ironically, one might speculate that the potential for serious side effects associated with "prolonged" and "excessive" use may be greater for some medical patients, such as AIDS patients, than for non-medical "abusers." While some may debate whether it's fair to compare HGH dosing for AIDS patients to HGH dosing by illicit users, the fact remains that AIDS patients are prescribed much more HGH than most illicit users self-administer.

Obviously, unsupervised prescription drug use is a legitimate concern to government regulators, and to society as a whole. That applies to HGH, of course. But one of the specific difficulties in stemming illicit HGH use is that the community of non-medical users compares its use – fairly or not, simplistically or not – to HGH use within the pediatric and AIDS communities. Merits of the debate aside, they reject the idea that a drug that is accepted as safe and approved to prescribe to children and AIDS patients in high dosages would be toxic to robust and healthy athletes at lower dosages.

Quantification Alternatives

If a "unit" for HGH is to be set, how should it compare to steroids? Should it be tied to Schedule III, or to a lower category like Schedule IV or V? As stated earlier, just because the same folks may use both drugs illicitly doesn't automatically justify equal treatment. If HGH is to be quantified as a controlled substance for sentencing purposes, one option for the Commission might be to treat it under a lesser Schedule category to more appropriately distinguish it from steroids. Alternatively, the two drugs could be distinguished through the "unit" quantification process.

In any event, if a "unit" is to be created, what should it be? For example, should it be based on IU's or milligrams? It would most reasonably be set on a milligram (mg)

basis. Nobody can hold a piece of lyophilized HGH powder in hand and announce how many IU's it is. The quantification of drugs units under the USSG is based on the metric system. Drugs are converted to grams of marijuana. Hallucinogens, stimulants and even marijuana cigarettes are ascribed "typical weights per unit" in grams or milligrams. HGH can only be weighed in milligrams. Neither mass nor weight is measured in IU's. While the revised anabolic steroid guideline uses an oral pill/tablet and liquid milliliter basis for some steroids, it also incorporates a milligram unit equivalency base of 25mg for raw powders and other atypical steroid forms. The simplest option might be to apply the same 25mg standard used for steroids to HGH. While a 25mg weight for a unit of HGH might be too large to provide adequate deterrence in sentencing, a weight based on some mg standard would be rational, assuming the Commission is inclined to quantify this substance.

Under a 10mg = HGH unit formula, 1,000 HGH kits would add up to be 7,000 bottles at .6 units (6mg) each. That's 4,200 units (each kit would be 4.2 units.) Under § 2D1.1, that's a level 12 if HGH is Schedule III. Now add 2 levels for the use of the computer to mass market under § 2D1.1(b)(6) and you have Level 14. Reduce by two points for Acceptance [§ 3E1.1] and you have an Adjusted Offense level of 12 (range of 10 to 16 months custody). If the formulation of an explicit guideline for HGH is to make quantification simpler in combination cases and to permit enhanced punishment for combined steroids and HGH, this formula would appear to meet those goals.

Final Thoughts

Lastly, I should point out a curious anomaly in the law regarding steroids and HGH. As controlled substances, anabolic steroids may be prescribed "off label" like any other drugs, as long as it is for a legitimate medical purpose and within the usual course of professional practice [21 C.F.R. § 1306.04(a)]. Under the current statute specific to HGH [21 U.S.C. § 333(e)], it would seem that physicians are restricted from any off-label prescribing of HGH even for legitimate medical purposes and in the usual course of practice. Whether this restriction is of benefit or detriment to the public is open to debate. While nothing in the Congressional history of the HGH statute suggests that Congress ever intended to restrict HGH prescribing more than steroids and all other Schedule II through V controlled substances, which is the current FDA and DOJ interpretation. Therefore, the Commission should recognize that combining that interpretation of the statute with sentencing under § 2D1.1 would create a situation wherein HGH will be the most highly restricted prescription drug to be sentenced under the entire Controlled Substances Act. It might seem that if the Commission decides to treat HGH as a controlled substance, so should Congress, thereby repealing § 333(e) and freeing physicians to prescribe off-label as with other controlled substances.

I hope these comments are of some assistance to the Commission.

Appendix: State Scheduling of Steroids and HGH

STATE	STEROIDS (SCHEDULE III UNLESS OTHERWISE NOTED)	HGH
ALABAMA	FELONY	NOT SCHEDULED
ALASKA	FELONY (SCHEDULE V)	NOT SCHEDULED
ARIZONA	FELONY	NOT SCHEDULED
ARKANSAS	MISD.	NOT SCHEDULED
CALIFORNIA	MISD.	NOT SCHEDULED
COLORADO	"USE" IS MISD. BUT "POSS" IS FELONY!	SCHEDULED
CONNECTICUT	MISD.	NOT SCHEDULED
D.C.	MISD.	NOT SCHEDULED
DELAWARE	MISD.	NOT SCHEDULED
FLORIDA	FELONY	NOT SCHEDULED
GEORGIA	FELONY	NOT SCHEDULED
HAWAII	MISD, IF LESS THAN 25 TABS	NOT SCHEDULED
IDAHO	MISD	SCHEDULED
ILLINOIS	MISD	NOT SCHEDULED, NON-MEDICAL DISTRIBUTION OF hGH IS CRIMINALIZED
INDIANA	FELONY, BUT COURT MAY ENTER JUDGMENT OF CONVICTION AS A MISDEMEANOR FOR 1 ST OFFENSE	NOT SCHEDULED
IOWA	MISD.	NOT SCHEDULED
KANSAS	MISD.	NOT SCHEDULED
KENTUCKY	MISD.	NOT SCHEDULED
LOUISIANA	FELONY, WITH UP TO 5 YEARS W/ OR W/O HARD LABOR	NOT SCHEDULED
MAINE	CLASS E CRIME, ESSENTIALLY A MISD.	ALL PRESCRIPTION DRUGS
MARYLAND	"MISD.," BUT UP TO 4 YEARS IN JAIL!!!	NOT SCHEDULED
MASSACHUSETTS	MISD.	ALL PRESCRIPTION DRUGS
MICHIGAN	"USE" IS MISD. BUT "POSS" IS FELONY!	NOT SCHEDULED
MINNESOTA	FELONY, UP TO 5 YEARS ON FIRST OFFENSE (SCHEDULE IV)	SCHEDULED
MISSISSIPPI	MISD. IF LESS THAN 50 GRAMS OR 100 DOSAGE UNITS AS DEFINED BY	NOT SCHEDULED

	STATE LAW	
MISSOURI	FELONY, SUSP'D IMP. (UP TO 7 YEARS)	NOT SCHEDULED
MONTANA	MISD. 6 MONTHS, 1 ST OFFENSE (EXCEPTION TO OTHER DRUGS – MORE LENIENT FOR AAS)	NOT SCHEDULED
NEBRASKA	FELONY	NOT SCHEDULED
NEVADA	FELONY, BUT SUSP'D SENTENCE AUTH'D	NOT SCHEDULED
NEW HAMPSHIRE	FELONY	NOT SCHEDULED
NEW JERSEY	FELONY	NOT SCHEDULED
NEW MEXICO	MISD.	NOT SCHEDULED
NEW YORK	MISD. (SCHEDULE II)	NOT SCHEDULED
NORTH CAROLINA	MISD., UNLESS OVER 100 TABS OR DOSAGE UNITS	NOT SCHEDULED
NORTH DAKOTA	FELONY	NOT SCHEDULED
OHIO	MISD., IF UNDER 200 TABS, 16 GRAMS OR 16 ML	NOT SCHEDULED
OKLAHOMA	MISD.	NOT SCHEDULED
OREGON	MISD.	SCHEDULED
PENNSYLVANIA	MISD.	NOT SCHEDULED
PUERTO RICO	NOT SCHEDULED	NOT SCHEDULED
RHODE ISLAND	FELONY	SCHEDULED
SOUTH CAROLINA	MISD., UP TO 100 DOSAGE UNITS	NOT SCHEDULED
SOUTH DAKOTA	FELONY	NOT SCHEDULED
TENNESSEE	MISD.	NOT SCHEDULED
TEXAS	MISD. IF UNDER 28 GRAMS BY AGGREGATE WEIGHT	NOT SCHEDULED
UTAH	MISD.	NOT SCHEDULED
VERMONT	NOT SCHEDULED	NOT SCHEDULED
VIRGINIA	MISD.	NOT SCHEDULED
WASHINGTON	FELONY	NOT SCHEDULED
WEST VIRGINIA	MISD.	SCHEDULED
WISCONSIN	MISD.	NOT SCHEDULED
WYOMING	MISD. IF NOT OVER 3 GRAMS IN PILLS OR 3/10 GRAM OF LIQUID	NOT SCHEDULED