

REPORT OF

The Attorney General's Steroids Study Group

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State of New Jersey
Office of the Attorney General

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Summary

Recent reporting done by the *Newark Star-Ledger* suggests that some members of law enforcement have sought anabolic steroids, human growth hormone (“HGH”) and/or Human Chorionic Gonadotropin (“HCG”) for purposes of muscle enhancing and/or “lifestyle” improvement. While we caution against extrapolating the actions of those discussed in the newspaper to all law enforcement, the story identified a number of issues, including:

- Suspicious, and potentially illegal actions of a now-deceased doctor, Dr. Joseph Colao, in prescribing, to at least 248 public safety employees (primarily police officers, fire fighters, sheriff’s deputies and correctional officers), a variety of substances, including anabolic steroids, HGH, and HCG.
- Allegations that certain individuals seeking prescriptions for these medications did not have a legitimate medical need for them and utilized their public health benefits to have the medication improperly covered, resulting in the expenditure of significant public funds to pay the costs of these prescriptions.
- Failure to prosecute cases of purported fraud by public safety personnel who were suspected of acquiring steroids and other substances improperly, including a case involving roughly a dozen Trenton police officers who received steroids and HGH over the Internet but were never prosecuted.
- Lawsuits that have been filed against public safety officers who were also clients of Dr. Colao’s and who may have violated the civil rights of individuals through excessive force or police brutality potentially attributable to so-called “steroid rage” – a phenomenon tied to side effects of steroid usage that results in impaired judgment and an inability to control one’s temper.
- The absence, at least until very recently, of health insurer scrutiny of prescription claims filed by officers receiving steroids, HGH, HCG, or other substances potentially improperly prescribed.
- The State Board of Medical Examiners (“SBME”) insufficient regulatory pursuit of physicians for improperly prescribing steroids or growth hormone during the past 5 years and a nearly 6 year delay in the implementation of a prescription drug monitoring program.

Taken together, this reporting revealed potential criminal conduct on the part of Dr. Colao (who is now deceased), public safety officers (if they knowingly obtained prescriptions improperly), and the risk of civil liability based on lawsuits filed by citizens who allege they were the victims of police brutality. Moreover, the articles indicate that there may be a small, but burgeoning industry of doctors known to law enforcement

personnel who will prescribe steroids¹ and other growth hormones based on bogus diagnoses. Filling these prescriptions places a significant burden on health plans and is a substantial expense to programs like the State Health Benefits Plan, which is self-insured and pays claims out of collected tax dollars.

As the authors note, in 2007, Jersey City spent more on treatments associated with growth hormone deficiency, which, according to the American Association of Clinical Endocrinologists (“AACE”) afflicts only 1 in 100,000 people nationwide, than it did “on any other medical condition, including high cholesterol, high blood pressure or diabetes” Finally, the reporting strongly suggests that there has been an absence of any focused investigation of doctors prescribing these medications and thus, insufficient development of evidence that would support disciplinary or prosecutorial action against doctors or patients suspected of either fraudulently prescribing or receiving steroids or growth hormone.

In response to this report, you formed a Study Group to look into, among other things, steroid use in law enforcement, the cost to the public where public health benefits were used to acquire these substances, the role of doctors in prescribing these medications and recommendations for strengthening monitoring, testing and prosecution of individuals either prescribing, dispensing or improperly acquiring these substances.

Within the State Legislature, several lawmakers have spoken publicly about the *Star-Ledger* story. Deputy Assembly Speaker John McKeon (27th District) requested a criminal probe based on this reporting; Senator Loretta Weinberg (37th District) stated that she would introduce legislation making it harder for police and firefighters to “fraudulently obtain the drugs with the aid of doctors”; and Senator Weinberg, along with Senator Richard Codey (27th District), announced her intent to hold hearings on this issue.

On January 10, 2011, Deputy Assembly Speaker McKeon introduced two legislative proposals. A3737 would require police officers who are prescribed steroids or HGH to report such a prescription within five days to a designated physician and to have a fitness for duty examination. AR136 is a resolution encouraging the Attorney General to add steroids and other “designer drugs” to the list of drugs tested for under the Attorney General’s Drug Policy. On the same day, Assemblyman Herb Conaway (7th District) introduced A3698, which would require the Director of the Division of Consumer Affairs to include HGH as a prescription tracked in its prescription monitoring program.² A3698 passed the Assembly 78-0 and has been referred to the state Senate for its consideration.

¹ For the purposes of this memo, we are using the term “steroid” to refer to the sex hormone class of steroids which have anabolic and androgenic effects as opposed to the corticosteroid class of hormones.

² As more fully discussed below, the New Jersey Prescription Monitoring Program, when it comes online later this year, will track the prescription of all controlled substances filled by registered pharmacies in the State of New Jersey and out-of-state pharmacies that are registered in the system.

Discussion

I. Background on Anabolic Steroids, HGH and HCG

Anabolic Steroids

Anabolic steroids are defined by the Drug Enforcement Administration (“DEA”) as “synthetically produced variants of the naturally occurring male hormone testosterone.” The term “steroid” is used to define the class of drugs that provide both an androgenic (characterized by promotion of virility, enhancement of male secondary sex characteristics) and anabolic (characterized by cell and bone growth and the development of muscle mass) effect in its users.³ All steroids at issue here have both an anabolic and androgenic effect on the body; however, the effect ratio of steroids differs depending on the substance. For example, testosterone has a 1:1 anabolic to androgenic effect ratio. By contrast, stanozolol has a 30:1 anabolic to androgenic effect, making its use for the purposes of muscle growth far more potent than testosterone or other steroids with closer (i.e., 3:1 or lower) anabolic to androgenic ratios.

Anabolic steroids do have valid medical uses and are typically prescribed for hypogonadism (low testosterone), decreased muscle mass due to chronic diseases like HIV/AIDS and cancer. They are also properly prescribed to males incapable of producing sufficient testosterone due to pituitary malfunction or loss of their testes. In cases where individuals are illicitly acquiring steroids, they are overwhelmingly being abused for the purpose of increasing muscle mass, strength training and other activities associated with weight lifting, body building and physical enhancement. When prescribed appropriately, doctors typically incorporate regular monitoring of testosterone levels during treatment, including follow-up examinations within 3-6 months of initial prescription, prostate examination and dexamethasone scanning to assess bone density. These follow-up tests are rarely if ever utilized where patients are improperly using steroids. Moreover, an initial diagnosis of legitimate testosterone deficiency should be predicated on the combination of symptoms, physical exam and blood testing of hormone levels. Diagnosis should not be made simply based on blood test results that are merely indicative of traditional declines in testosterone levels as men age.

The DEA has noted that abusers may take dosages of anywhere between 1 and 100 times a normal therapeutic use, take multiple steroids simultaneously (termed “stacking”) and stay in steroid cycles of between 6 and 16 weeks of high dosage followed by a dormant period of low or no dosing.⁴ Because steroid abuse typically involves dosing at levels far beyond therapeutic use, can involve taking multiple steroids at one time (something that is rarely, if ever, prescribed as part of normal treatment) and may also incorporate illicit forms of steroids, the health risks are substantial. They include liver disorders, prostate

³ It should be noted that “testosterone” and “stanozolol,” which were referenced in the *Newark Star-Ledger* article, are steroids and classified as Schedule III substances. See 21 U.S.C. § 802(41)(A)(xliv) (xlvi).

⁴ See *Steroid Abuse in Today’s Society*, U.S. Department of Justice, Drug Enforcement Administration – Office of Diversion Control, www.deadiversion.usdoj.gov/pubs/brochures/steroids/professionals.

cancer, enlargement of the heart, stroke, and sexual dysfunction, among many other adverse side effects.

Regulation

Pursuant to the Anabolic Steroids Control Act of 1990,⁵ anabolic steroids were added to Schedule III of the Controlled Substances Act⁶ and are defined as “any drug or hormonal substance chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids and dehydroepiandrosterone).” 21 U.S.C. § 802(41)(A). The statute then lists 49 separate chemical substances that are considered anabolic steroids. 21 U.S.C. § 802(41)(A)(i)-(xlix). Under federal law, possession or sale of anabolic steroids without a valid prescription is illegal and simple possession of illegally obtained steroids is subject to a maximum penalty of a year in prison and a minimum \$1,000 fine for a first offense. 21 U.S.C. § 844(a). A first offense for trafficking steroids is punishable by up to 5 years in federal prison and a fine of up to \$250,000.⁷ For second offenses, the prison time and fine can double.⁸

New Jersey has adopted by reference the federal Schedule I-V Lists of Controlled Dangerous Substances. N.J.S.A. 24:21-3(c); N.J.A.C. 13:45H-10.1. While the current version of New Jersey’s statute does not specifically include anabolic steroids on the list printed in the statute at N.J.S.A. 24:21-7, N.J.S.A. 24:21-7(b) provides that the list in the statute is subject to any revision and republishing pursuant to N.J.S.A. 24:21-3(d). The Director of the Division of Consumer Affairs recently updated and re-published the list, now found at N.J.A.C. 13:45H-10.1. That regulation specifically adopts the federal schedule, along with any changes thereto. As such, anabolic steroids are listed on both the federal and the New Jersey Schedules. Under our criminal code, prosecution is permitted for possession of a Schedule III CDS⁹ and/or for manufacturing, distributing or dispensing a Schedule III CDS.¹⁰

The SBME has promulgated both general regulations regarding the prescription and dispensing of drugs and specific regulations addressing the prescription and dispensing of anabolic steroids and HGH. *See* N.J.A.C. 13:35-7.1A; N.J.A.C. 13:35-7.9. Generally, no prescription drug can be given unless, among other things, it is given after “an appropriate history and physical examination” and is “based upon the examination and all diagnostic and laboratory tests consistent with good medical care.” N.J.A.C. 13:35-7.1A(a)(1)(2).

SBME has a clear enforcement provision regarding the prescription, administration and dispensing of drugs, including steroids and HGH. N.J.A.C. 13:35-7.10. Violations of

⁵ 21 U.S.C. § 801 *et seq.*

⁶ A Schedule III controlled substance is one that has less potential for abuse than a Schedule I or II substance, has an accepted medical use but that abuse of the drug or substance “may lead to moderate or low physical dependence or high psychological dependence.” 21 U.S.C. § 812(b)(3).

⁷ www.justice.gov/dea/agency/penalties.htm.

⁸ Id.

⁹ N.J.S.A. 2C:35-10, a third-degree crime subject to potential prison time and a fine of up to \$35,000.

¹⁰ N.J.S.A. 2C:35-5, a third-degree crime subject to potential prison time and a fine of up to \$25,000.

SBME regulations can result in suspension or revocation of a doctor's license to practice medicine for a variety of reasons, including distributing or dispensing a controlled dangerous substance "in an indiscriminate manner, or not in good faith, or without good cause,"¹¹ for "gross or repeated malpractice, neglect, or incompetence,"¹² for "professional misconduct,"¹³ or for failing "to comply with the provisions of an Act of regulation administered by the Board."¹⁴ Finally, medical licensees have an obligation, upon the issuance of a subpoena by either the SBME or the Office of the Attorney General, to produce medical treatment records of their patients.¹⁵

With regard to steroids and HGH specifically, the SBME prohibits the prescription, ordering, dispensing, administering, selling or transfer of anabolic steroids or HGH "for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight." N.J.A.C. 13:35-7.9(a). Moreover, the regulations specifically preclude as a "valid medical purpose" the use of these substances for "body building, muscle enhancement, or increasing muscle bulk or strength ... by a person in good health for the intended purpose of improving performance in any form of exercise, sport or game." Id.

Under SBME regulations, doctors are also required to prepare and maintain a medical record when steroids or HGH are prescribed that reflects the specific substance prescribed, the diagnosis justifying the prescription, and the purpose for which the drug is being prescribed. N.J.A.C. 13:35-7.9(b). Finally, the SBME lists a number of steroids and HGH that are subject to this regulation.¹⁶

Steroid Rage

With regard to "steroid rage," research is equivocal regarding the prevalence of this phenomenon. Generally speaking, "steroid (or 'roid') rage" is a term of art used to describe elevated levels of aggression and violence exhibited by individuals abusing steroids. Because steroids are essentially synthetic forms of testosterone, utilizing these substances results in a significant elevation of male hormones and, particularly in younger men, can lead to violent outbursts and uncontrolled anger. Two types of studies have been conducted to determine the prevalence of steroid abuse: (1) studies where subjects receive a defined quantity of steroids and whose behavioral changes are compared to a control group that receives a placebo;¹⁷ and (2) studies where users self-reported changes in mood and behavior.¹⁸

¹¹ N.J.S.A. 45:1-21(m).

¹² N.J.S.A. 45:1-21(c) and (d).

¹³ N.J.S.A. 45:1-21(e).

¹⁴ N.J.S.A. 45:1-21(h).

¹⁵ N.J.A.C. 13:35-6.5(d)(1).

¹⁶ The regulation notes that the list is "not exhaustive or exclusive," but "includes many of the generic and brand-name anabolic steroids and human growth hormones subject to this section." N.J.A.C. 13:35-7.9(c).

¹⁷ See Pope, H., Kouri, E, and Hudson, J., *Effects of Supraphysiologic Doses of Testosterone on Mood and Aggression in Normal Men*, Archive of General Psychiatry, Vol. 57 p. 133-140 (Feb. 2000), Tricker, R., Casaburi, R. et al., *The Effects of Supraphysiological Doses of Testosterone on Angry Behavior in Healthy Eugonadal Men*, Journal of Endocrinology and Metabolism, Vol. 81 No. 10, p. 3754-58 (1996).

¹⁸ See, e.g., Strauss, R., Liggett, M., and Laeese, R., *Anabolic Steroid Use Perceived Effects on Weight-Trained Men*, Physician Sports Medicine, Volume 11, p. 86-96 (1983); Strauss, R., Liggett, M., and

Each type of study has its benefits and drawbacks. The former allows for controlled dosing of specific substances over defined periods; however, the tests may not accurately depict the amount, quantity (no “stacking” is done) or type(s) of steroid(s) users may actually use, which tend to be higher. Conversely, the latter has few if any controls as the subjects are not uniform in their use, dosage or type of steroids utilized, but may be more likely to accurately depict usage among abusers. In addition, self-reporting on one’s own behavioral changes may not be particularly reliable.

In one controlled study, researchers found that instances of mania and aggression went up among a group of subjects during periods where those subjects received testosterone injections; however, this collective rise in mania and aggression was largely attributable to a small subset of the study group (8 out of 50 members). The majority of the participants (42 out of 50) exhibited minimal psychiatric effects.¹⁹ Another study stated that it “failed to detect any significant effects of testosterone treatment on mood or the subsets of angry behavior”²⁰ Of particular significance was the fact that subjects who received steroids were given “the highest dose used in any clinical trial designed to examine the effect of testosterone on body composition or behavior.”²¹

Comparatively, in studies that rely on self-reporting, incidences of aggression and rage are more commonplace. For example, in a study of 24 steroid users and 14 non-users, self-reporting among the steroid users of verbal and/or physical fights with their girlfriend/spouse was “significantly higher” than among non-users.²² In another study of 32 men who were using steroids while weight training, 56 percent reported “increased irritability and aggression.”²³ Yet another report, utilizing structured clinical interviews of 88 athletes who admitted using steroids, revealed that 23 percent “reported major mood syndromes – mania, hypomania, or major depression – in association with steroid use.”²⁴ These individuals also experienced mood disorders in greater numbers during steroid cycles than when steroids were not being used.²⁵

In short, conflicting evidence exists regarding steroid rage – controlled studies where subjects are administered measured doses that may not accurately reflect amounts taken by abusers have failed to show a medically significant difference in the behavioral patterns of steroid users and non-users; studies that rely on self-reporting among a group

Laaese, R., *Anabolic Steroid Use Perceived Effects on Weight-Trained Women Athletes*, Journal of the American Medical Association, Vol. 253, p. 2871-73 (1985).

¹⁹ See fn. 17, *supra*, Pope, H., Kouri, E., and Hudson, J., *Effects of Supraphysiologic Doses of Testosterone on Mood and Aggression in Normal Men* at p. 133.

²⁰ See fn. 18, *supra*, Tricker, R., Casaburi, R. *et al.*, *The Effects of Supraphysiological Doses of Testosterone on Angry Behavior in Healthy Eugonadal Men*, at p. 3756.

²¹ Id.

²² See Choi, P. and Pope, H., *Violence Towards Women and Illicit Androgenic-Anabolic Steroid Use*, Annals of Clinical Psychiatry, Volume 6, No. 1, p. 21-25 (1994).

²³ See fn. 18, *supra*, Strauss, R., Liggett, M., and Laaese, R., *Anabolic Steroid Use Perceived Effects on Weight-Trained Men*, Physician Sports Medicine.

²⁴ See Pope, H. and Katz, D., *Psychiatric and Medical Effects of Anabolic-Androgenic Steroid Use, A Controlled Study of 160 Athletes*, Archives of General Psychiatry, Vol. 51 No. 5, p. 375-82 (May 1994).

²⁵ Id.

of individuals not taking uniform amounts of these substances appear to show a much stronger correlation between steroid abuse and negative emotions.²⁶

Testing

Testing for anabolic steroids can be done by drawing blood or taking urine samples.²⁷ The basic test to determine whether a person is abusing steroids gauges the ratio of testosterone to epitestosterone in the body. One obstacle to medical testing for steroid use is the magnitude of the ratio that would clearly indicate an abnormality in this ratio. As an example, there is general agreement that an epitestosterone to testosterone level of 10:1 or even as low as 8:1 is a clear indicator of steroid abuse; however, ratios in the 5:1 or 4:1 range are more equivocal. As more fully discussed below, the state outsources its steroid testing to Aegis Laboratory, a nationally-recognized company in the field of steroid testing.

Steroid testing can be effectuated with little difficulty; however, and as an example, as opposed to testing for the substances in the Attorney General's Drug Testing Policy, which can be screened quickly with a high level of accuracy, steroid testing is more time and labor intensive, in addition to being more costly. Whereas a basic screening for the substances under the Drug Testing Policy costs \$35, Aegis charges the state \$250 for each specimen it tests for steroids.

Human Growth Hormone

HGH is a naturally occurring hormone secreted from the pituitary glands and plays an important role in body growth. In 1985, researchers were able to manufacture a synthetic form of HGH which stimulates the production of insulin like growth factor ("IGF-1"), resulting in the secretion of hormones that promote bone growth and also play a key role in muscle and organ growth. In recent years, HGH has been utilized by bodybuilders and athletes who seek to reduce body fat and increase skeletal muscle mass and by adults interested in arresting the effects of aging, such as reduced muscle mass, libido, energy, and other indicators of old age.

Unlike steroids, HGH use is not thought to be connected to overt aggressiveness and its casual usage among middle-aged men for "lifestyle" improvement as opposed to primary use among body builders, bouncers, weight lifters and others, reflects an important distinction between the two substances.

Regulation

HGH is not restricted pursuant to the Controlled Substances Act; rather, it is regulated by the Food and Drug Administration ("FDA"). Under federal statute, it is a felony, punishable by up to five years in prison, to possess and distribute with the intent to

²⁶ As the DEA notes, "anger, hostility, aggression and/or violent behavior occurs in *some* but not *all* anabolic steroid users." www.deadiverson.usdoj.gov/pubs/brochures/steroids/professionals.

²⁷ Case law limits law enforcement drug testing to the analysis of urine samples.

distribute HGH “for any use ... other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services” 21 U.S.C. § 333(e)(1).²⁸ Among the limited purposes the FDA has approved HGH for are, in children, those suffering from poor development or growth due to Turner’s Syndrome, Prader-Willi Syndrome, chronic renal insufficiency, for children born at low gestational weights and for idiopathic (having no known cause) short stature. In adults, the uses are even more limited. HGH is only approved in adults for three general purposes: (1) to counter the effects of HIV/AIDS wasting syndrome (approved effective 1996); (2) for short bowel syndrome (a condition where nutrients are not digested due to intestinal disease) (approved effective December 2003); and (3) for adult growth hormone deficiency, either alone or in association with hormone deficiency due to pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma (approved effective August 1996). It is for this third purpose that the overwhelming majority of improper diagnoses and prescriptions appear to be utilized.

As noted above, the SBME strictly limits the prescription and dispensing of HGH and prohibits its prescription “for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight.” N.J.A.C. 13:35-7.9(a). The SBME specifically references somatrem and somatropin, the generic names for HGH, on its list of substances subject to this regulation. *See* N.J.A.C. 13:35-7.9(c). Thus, improper prescription and dispensing of HGH is subject to the SBME’s enforcement provisions and can result in suspension or revocation of a doctor’s license to practice medicine. N.J.A.C. 13:35-7.10.

Medical Uses and Abuses

According to the Journal of Clinical Endocrinology and Metabolism (“JCEM”), “as defined by strict hormonal criteria, idiopathic (no known cause) growth hormone deficiency (“GHD”) is very rare.”²⁹ Indeed, it has been noted that the total incidence of GHD in the general adult population is approximately 50,000, with roughly 6,000 new cases yearly.³⁰ That fact notwithstanding, because idiopathic GHD has ambiguous symptoms, including “decreased lean body mass, increased visceral fat and subcutaneous fat, decreased bone mass, and hyperlipidemia (high cholesterol),”³¹ as well as “decreased energy and quality of life,”³² it has been the diagnosis utilized to justify the improper

²⁸ Although prescription for HGH is limited in this way, the U.S. Attorney Civil Resource Manual indicates that if evidence of a physician-patient relationship exists, prosecution of illegal distribution of HGH based on 21 U.S.C. § 333 in the treatment of disease or other medical conditions not recognized by the Secretary of Health and Human Services may be problematic.

²⁹ Molitch, Clemmons, *et al.*, *Evaluation and Treatment of Adult Growth Hormone Deficiency: An Endocrine Society Clinical Practice Guideline*, Journal of Clinical and Endocrinology and Metabolism, Vol. 91, No. 5 p. 1621-1634 (2006).

³⁰ Owens, Balfour *et al.*, *Clinical Presentation and Diagnosis: Growth Hormone Deficiency in Adults*, The American Journal of Managed Care, Vol. 10, Number 13, October 1, 2004. A separate study referenced in the *Newark Star-Ledger* series reporting GHD as occurring in 1 in 100,000 adults was conducted in Denmark, not the United States. *See* Stochholm, Gravholt *et al.*, *Incidence of GH Deficiency – A Nationwide Study*, European Journal of Endocrinology, July 2006.

³¹ *See* fn. 23 *supra*.

³² *See* fn. 24 *supra*.

prescribing of HGH to those seeking nothing more than anti-aging benefits. HGH is properly prescribed after fairly aggressive blood testing in patients to confirm cases meet the “strict hormonal criteria” for a diagnosis.

As both the *Star-Ledger* and a cursory search of other newspaper articles and websites confirm, HGH is advertised as an anti-aging medication.³³ Practitioners in this burgeoning field, which includes the American Academy of Anti-Aging Medicine (“A4M”), a professional group of more than 22,000 doctors nationwide, believe that HGH and other substances are appropriately prescribed to combat the effects of aging and can extend lifespan.³⁴ An influential article published in the *New England Journal of Medicine* in 1990 is oft-cited by HGH proponents to illustrate the benefits of hormone-replacement treatment.³⁵ In this study, 12 healthy men between the ages of 61-81 with low IGF-1 relative to men ages 20-40 received growth hormone injections over a six-month time period. At the end of the study, these men had increased their lean body (muscle) mass, on average, by nearly 9 percent and reduced their body fat, on average, by nearly 15 percent.³⁶

While this study has been cited in nearly 200 subsequent articles, its reliability was called into question in 2003.³⁷ The 1990 study, for example, dosed individuals with twice the typical amount of HGH prescribed to adult men, was not double blind, which is the generally accepted medical practice, did not measure muscle strength, endurance or improvement in quality of life and was based on measuring IGF-1 of elderly individuals against those levels in much younger men.³⁸ Conversely, subsequent double-blind, placebo-controlled studies on elderly men and women showed “no change in muscle strength or maximal oxygen uptake during exercise.”³⁹ Moreover, a second study that incorporated strength training in addition to either growth hormone or a placebo showed that “growth hormone did not result in any further improvement.”⁴⁰ These findings are consistent with the most recent American Association of Clinical Endocrinologists’ guideline for prescribing HGH:

[N]o data are available to suggest that GH [growth hormone] has beneficial effects in treating age and age-related conditions and the enhancement of sporting performance; therefore, we do not recommend

³³ See, e.g., Mattingly, D. and Estrada, I., HGH in Forefront to Remain Young, *articles.cnn.com*, January 24, 2008, Garreau, J., Holding Back the Years: Scientists Say Extended Youth May Be Near, *The Washington Post*, October 19, 2002.

³⁴ <http://www.worldhealth.net/about-a4m>.

³⁵ Rudman, D. et al., *Effects of Human Growth Hormone in Men Over 60 Years Old*, *New England Journal of Medicine*, July 5, 1990.

³⁶ Id.

³⁷ Vance, M.L., *Can Growth Hormone Prevent Aging?*, *New England Journal of Medicine*, February 27, 2003.

³⁸ Id.

³⁹ Id.

⁴⁰ Id.

the prescription of GH to patients for any reason other than the well-defined approved uses of the drug.⁴¹

Because symptoms of GHD can be vague, if doctors opt to test an individual's blood to confirm a diagnosis of idiopathic GHD, JCEM advises using one of two tests – either the Insulin Tolerance Test (“ITT”) or the GHRH-arginine Test. Both tests stimulate hormone production to measure the body's ability to produce same. In the ITT, patients are dosed with insulin and then have blood samples taken 6 times over the course of two hours to measure hormone production. In the GHRH-arginine test, the process is similar, but instead of using insulin, this test utilizes GHRH (a natural hormone that stimulates the release of growth hormone) produced in the brain, and arginine, an amino acid that also stimulates hormone production. While the ITT is considered the “gold standard” for GHD screening,⁴² with an accuracy rate of more than 96 percent, the GHRH test is considered an acceptable alternative, with an accuracy rate of above 90 percent.⁴³ While these tests have high accuracy rates, because of their intrusiveness and time intensive nature, it is unlikely they are utilized in meaningful ways by treating physicians.

Testing

The World Anti-Doping Agency (“WADA”), an independent agency that conducts testing for, among others, the International Olympic Committee, began blood testing for HGH during the 2004 Athens Olympics. In the hundreds of thousands of samples WADA-accredited laboratories tested in 2009, however, only 1 came back positive for HGH. This is likely due to the fact that HGH is metabolized and excreted by the body very quickly. Dr. Anthony Butch, who leads one of the two WADA-accredited laboratories in the United States, advised us that testing for HGH should occur within 24-36 hours after usage; otherwise, a test is unlikely to come back positive even if the person in question is using HGH.

HGH testing is expensive. Dr. Butch advised that testing a single blood sample would cost about \$1,400 and that even if “batch” samples of more than 15 were analyzed at one time, testing each sample would cost about \$130. This would not include follow-up testing that is typically done when an initial sample comes back positive. In addition to the exorbitant cost, because HGH is metabolized by the body quickly and can be rendered undetectable as quickly as 24-36 hours after dosing, effective testing can only be accomplished if done randomly without prior notice or immediately upon receiving information that the individual has very recently (*i.e.*, within the past day or two) used HGH.

⁴¹ American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update.

⁴² Id.

⁴³ Id.

Human Chorionic Gonadotropin

HCG is a hormone naturally produced in the early stages of pregnancy during the formation of the placenta, helping to ensure the stability of the embryo post-conception and in the early stages of gestation. Indeed, most home pregnancy tests rely on detection of HCG as a means of confirming pregnancy. HCG is also a marker for certain tumors, including those formed in the placenta, ovaries, and testes and during ectopic pregnancies.⁴⁴ HCG can be obtained by extracting it from the urine of pregnant women or it can be produced synthetically by recombinant DNA technology.⁴⁵ HCG's primary usage is to induce fertility in women who are having difficulty conceiving children.

HCG is regulated by the FDA and is not a substance listed on the federal Controlled Substances Act. The FDA has approved HCG for three basic purposes: (1) to induce ovulation in women;⁴⁶ (2) to treat prepubertal cryptorchidism (failure of the testes to descend); and (3) selected cases of hypogonadatropic hypogonadism⁴⁷ secondary to pituitary deficiencies in men.

For our purposes, it is important to note that HCG does not provide the specific muscle-building or anti-aging benefits that anabolic steroids and HGH provide. Rather, HCG acts as a "masking" agent that is typically used by individuals completing a "cycle" of steroid usage to elevate testosterone levels that become depleted once steroids are no longer being taken. The presence of HCG in men, therefore, is ordinarily indicative of steroid abuse and as such, is banned by major athletic organizations including the International Olympic Committee, the National Football League and Major League Baseball.

Of the three main substances at issue, HCG is in a way the easiest to categorize, as it is not a substance that is typically used in isolation by men or prescribed by doctors for anything other than severe hormonal issues tied to very specific ailments. Rather, it is used almost exclusively as an add-on to steroid use and for the purpose of elevating reduced testosterone levels.

Regulation

As noted, HCG is regulated by the FDA and has been approved for treating only a few conditions. Dispensing HCG, or any other prescription drug without a valid prescription by a licensed practitioner is deemed by statute to be an act which causes the drug to be "misbranded" while held for sale. *See* 21 U.S.C. § 353(b)(1)(B)(iii).

⁴⁴ Handelsman, D, *The Rationale for Banning Human Chorionic Gonadotropin and Estrogen Blockers in Sport*, *The Journal of Clinical Endocrinology and Metabolism*, Vol. 91 (2006).

⁴⁵ Recombinant DNA is created by taking two forms of DNA that do not normally occur together and merging them through gene splicing.

⁴⁶ http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/017692s018lbl.pdf.

⁴⁷ Hypogonadatropic hypogonadism is generally defined as the absence or decreased function of the male testes or female ovaries. It is considered a secondary form of hypogonadism associated with a problem with the pituitary or hypothalamus glands and is generally associated with pubescent boys and infertile men. <http://health.nytimes.com/health/guides/disease/hypogonadatropic-hypogonadism/overview.html>.

At the state level, as a prescription drug, HCG is subject to the same restrictions and limitations on its usage as any other drug that is prescribed by a doctor. In this way, doctors would be subject to sanction under any/all of the SBME's enforcement mechanisms. See N.J.A.C. 13:35-7.10.

Medical Uses and Abuses

HCG is primarily prescribed as a treatment for female infertility. Prescription use in males appears limited to severe instances of medical abnormality, such as delayed onset of puberty and where the testes do not descend properly from the body. On a somewhat unrelated note, the main "off label" use for HCG is for weight loss. People such as "infomercial" personality Kevin Trudeau pitch HCG as a supplement to a calorie-restricted diet in books such as "*The Weight Loss Cure They Don't Want You To Know About*" and "naturopath" doctors encourage similar use.⁴⁸ For example, the FDA requires a specific warning label for HCG that notes, "HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity."

As a masking agent for steroids, HCG has gained prominence in recent years when two well known athletes, Manny Ramirez (Major League Baseball) and Brian Cushing (National Football League), both received suspensions due to drug tests that revealed elevated levels of HCG in their systems.⁴⁹ HCG is favored by steroid users because HCG stimulates the production of testosterone, allowing steroid users to avoid the severe drop-off in this hormone as they complete a steroid cycle. For longer-term abusers of steroids who experience suppression of the pituitary gland, and thus, a reduction in their ability to naturally produce testosterone, HCG can temporarily stem this problem, although such treatment does not abate long-term pituitary damage.⁵⁰

Testing

As mentioned previously, the most common testing device for HCG is a home pregnancy test. More generally, basic urine and/or blood testing can be used to measure HCG levels in a person's body.

⁴⁸ See Alltucker, K., *HCG Diet Popular in Valley, But Could Be Risky*, The Arizona Republic, October 24, 2010.

⁴⁹ See Weir, T., *Report: NFL's Brian Cushing Suspended For Same Drug Manny Ramirez Used*, USA Today, May 11, 2010.

⁵⁰ See Drakeley, A *et al.*, *Duration of Azoospermia Following Anabolic Steroids*, Fertility & Sterility, Vol. 81 p. 226 (2004).

II. How Are These Substances Distributed and What Is Their Connection to Law Enforcement

Publicly Reported Information

It is difficult to extrapolate how pervasive the problem of anabolic steroid and/or HGH use is among law enforcement based solely on the *Star-Ledger* reporting. The report indicated that a substantial number of the 248 patients under Dr. Colao's care held law enforcement positions in Hudson County⁵¹ with smaller numbers, typically less than 10, coming from a wide range of law enforcement agencies and fire departments in other parts of the state. It is also important to note that the reporting done by the *Star-Ledger* focused solely on instances where law enforcement personnel were seeking reimbursement from their health benefit plan for the cost of these prescriptions. The prevalence of steroid and/or HGH use by individuals who acquire these medications illicitly or pay out of pocket was beyond the scope of the investigation.

As the *Star-Ledger* noted, even after Dr. Colao's death, other "wellness" and "anti-aging" centers exist and treat people with HGH. One doctor interviewed, Dr. Henry Balzani, openly treated patients with testosterone and HGH out of a clinic in Clifton.⁵² Dr. Balzani, however, did not accept insurance and required people to pay out of pocket, often in amounts of between \$6,000 and \$12,000 per year. The *Star-Ledger* noted that this was due in part to the fact that insurers are becoming more vigilant in flagging HGH and testosterone prescriptions for potential fraud.⁵³ Similarly, Dr. Colao's former office manager, Victor Biancamano, is the registered officer of Total Life Rejuvenation, an anti-aging company with offices in New Jersey, New York and Florida.⁵⁴ Finally, although not reported in the *Star-Ledger*, a cursory examination of a recent issue of NJ COPS magazine included two full-page advertisements for "wellness" centers marketing hormone replacement treatment.⁵⁵

How are these substances being distributed?

All three categories of substances require a doctor's prescription. Research conducted by our office indicates that symptoms for which these substances are prescribed are, in many cases, generic enough that a doctor uninterested in following more rigorous medical protocols to confirm a diagnosis of, for example, low testosterone levels or adult growth hormone deficiency, could plausibly justify the prescription of steroids or HGH. A screening exam from Abbott Laboratories, a large pharmaceutical company that markets testosterone treatment, identifies such symptoms as "lack of energy," "a decrease in your enjoyment of life," "falling asleep after dinner," and "decrease in libido," as potential indicators of low testosterone.⁵⁶ Such indicators are so vague that they can be used as a

⁵¹ 107 patients worked for some component of law enforcement or a fire department in Hudson County.

⁵² According to the Division of Consumer Affairs, Dr. Balzani is no longer in business.

⁵³ Brittain, A. and Mueller, M., *Booming Anti-Aging Business Relies on Risky Mix of Steroids, Growth Hormone*, *Newark Star-Ledger*, December 14, 2010.

⁵⁴ *Id.*

⁵⁵ See NJ COPS, November 2010.

⁵⁶ www.isitlowt.com.

basis to prescribe these substances in a large variety of cases without the rigorous testing required.

Notwithstanding the diagnostic issues surrounding the prescription of steroids, HGH and/or HCG, it should be noted that even in situations where one or more of these medications are prescribed, the quantity (dosage) and duration (length of prescription and/or refilling of same) would be obvious indicators for abuse. While legitimate steroid and/or HGH prescriptions are typically done at low doses and tied specifically to a person's body weight, those who abuse these substances tend to take them in high doses or take multiple medications ("stacking").

Perception from the Ground

The Study Group found that officers have a number of different ways of getting information regarding steroids and HGH and acquiring same, including: (1) publications such as NJ COPS magazine and other federal or state periodicals that advertise hormone replacement treatment and "wellness centers" that provide such treatment;⁵⁷ (2) mail ordering using an alias; (3) internet message boards dedicated to steroids and/or HGH or police/fire personnel; (4) conventions and conferences; (5) references from doctors directing law enforcement to out-of-state pharmacies; (6) overseas mail order; and (7) gyms. While some departments do conduct random testing, the Study Group learned that in at least one location where random testing is utilized, more than two years have passed since officers were last tested.

III. Government's Legal and Financial Burden

What are the Legal Liability Risks for Government?

The *Star-Ledger* reported that in at least one case in Trenton, the city settled a lawsuit for \$500,000 brought by a man who alleged that two officers (one of whom received steroids and HGH through the mail) severely beat him because he refused to stay in his home while the officers conducted an investigation outside.⁵⁸ A second case in Jersey City involving two officers accused of participating in a "roid rage" fueled beating is in binding arbitration after the charges against the citizen for resisting arrest were dropped.⁵⁹ In total, the *Star-Ledger* uncovered five cases alleging either brutality or civil rights violations by law enforcement personnel who were treated by Dr. Colao.⁶⁰

A more recent investigation was not criminal in nature *per se*, but rather, was in regards to drug testing mandated by the Jersey City Police Department ("JCPD") against a number of its officers who were suspected of acquiring steroids at Lowen's Pharmacy,

⁵⁷ See fn. 55 *supra*.

⁵⁸ Brittain, A. and Mueller, M., *N.J. Taxpayers Get Bill for Millions in Steroid, Growth Hormone Prescriptions for Cops, Firefighters*, Newark Star-Ledger, December 13, 2010.

⁵⁹ Brittain, A. and Mueller, M., *N.J. Doctor Supplied Steroids to Hundreds of Law Enforcement Officers, Firefighters*, Newark Star-Ledger, December 12, 2010.

⁶⁰ Id.

the same pharmacy that was implicated in the Dr. Colao investigation. The initial investigation was led by the New York Police Department (“NYPD”) based on tips they received that Lowen’s was using “foreign, federally unapproved components of drugs” that may have been used to fill steroid prescriptions. Kramer v. City of Jersey City, 2010 U.S. Dist. LEXIS 56449 *7 (D.N.J. June 3, 2010). The NYPD investigation turned up the names of more than 50 JCPD officers who were prescribed steroids. Id. This information was passed along from a captain in the NYPD to JCPD Chief of Police Thomas Comey. Comey, concerned that elevated steroid levels are linked to aggressive behavior, required the officers to be drug tested and to provide a list of all medications they had taken in the past 60 days. Id. at *8-9. Those officers whose testosterone levels were deemed too high to be fit for duty were placed on restricted duty until subsequent testing showed their testosterone range was within an acceptable range. Id.

The officers sued, claiming various violations of their constitutional and civil rights. In an unpublished decision, their case was dismissed. While the matter focused primarily on the question of immunity from suit, the underlying discussion confirmed several important legal concepts. For example, the court found that reasonable suspicion existed to require the testing and that no federal law was violated where Chief Comey, acting on a tip from a fellow law enforcement official, required the drug testing and then placed those whose testosterone levels were elevated, on restricted duty. Id. at *15. The court further confirmed that law enforcement officers have a lowered expectation of privacy based on the sensitivity of their positions and, balancing the need for the government to ensure that those who they permit to carry firearms and enforce the law are not inhibited by drugs or alcohol, provides the needed authority to drug test such individuals. Id. at *19; *see also* Carroll v. City of Warminster, 233 F.3d 208, 211 (3d Cir. 2000).

Moreover, the court rejected the officers’ contention that the testing was improper because steroids are not listed on the Attorney General’s Drug Testing Policy. Id. at *21-22. The court reasoned that the government’s “compelling interest in assuring that police officers are medically fit for duty is not proscribed because of the AG Policy.” Id. at 22. Further, the court found that merely because a state policy does not mention a substance does not create the permissible limit of what the government can test for because “any drug impairment that affects a police officer’s abilities is a significant concern.” Id. In short, the court upheld the drug testing conducted by the JCPD and dismissed the case.⁶¹

There is limited case law involving attempts to hold municipalities liable for civil rights violations where an officer engaged in civil rights violations stemming, at least in part, from steroid abuse. In one case from Tennessee, a federal district court rejected a Monell⁶² claim against the City of Shelbyville where a plaintiff attempted to sue that municipality on the theory that it did not adequately drug test its officers to determine

⁶¹ It is important to note that the Court did not reach the question of whether random testing of officers would be permissible as the case before the Court involved testing based on individualized suspicion. *See* Kramer, 2010 U.S. Dist. LEXIS 56449 at *17.

⁶² Under Monell v. Department of Social Services of New York, 436 U.S. 658 (1978), plaintiffs can sue municipalities for civil rights violations of their employees if the action in question stemmed from an “official policy or custom.” *See* Monell, 436 U.S. at 691, Schneider v. Simonini, 163 N.J. 336, 370-71 (2001).

which of those officers had a propensity for violence based on their use of steroids. Pamplin v. City of Shelbyville, 2006 U.S. Dist. LEXIS 21276 (E.D. Tenn. Apr. 17, 2006). This failure, according to the plaintiff, resulted in excessive force being used by an officer, resulting in injury to the litigant. The Court dismissed the claim, reasoning that (1) the officer was treated for steroid abuse after the incident; (2) that a random drug testing policy was in effect and the officer had not failed a test; and (3) there was no evidence that the officer's supervisors knew or had reason to know of the officer's drug abuse or that he presented a threat to the public. Id. at *7.

In another case, a federal district court threw out civil rights claims filed by plaintiffs based on allegations of steroid use by a police officer. Coury v. Helmer, 2009 U.S. Dist. LEXIS 85092 (W.D.Okla. September 17, 2009). In Coury, a complaint against the city of Oklahoma City, the local Fraternal Order of Police and an officer of the Oklahoma City Police Department was dismissed as to the plaintiffs' argument that the City, by failing to implement a steroid drug testing program when, according to plaintiffs, use of steroids was known in the department, resulted in a deprivation of the plaintiffs' civil rights. Id. at *10. The plaintiffs claimed that the officer, who was alleged to be using steroids, acted in an aggressive manner toward one of the plaintiffs, "handcuffed him too tightly, physically manhandled him, and placed him in the back of a patrol car." Id. at *4. The court did not think there was sufficient evidence to meet the evidentiary burden for plaintiffs to overcome the defendants' motion to dismiss; however, the court allowed the case to proceed as to the plaintiffs' state-law claim for assault against the officer. Id. at *10, *14-*15.

Testing

Current Procedures for Testing – Attorney General Policy Guideline

The Attorney General's Law Enforcement Drug Testing Policy ("Drug Testing Policy") was initially enacted in October 1986 and was most recently revised in June 2001. The policy permits drug testing of veteran law enforcement officers under one of three conditions: (1) where reasonable suspicion exists to believe that the officer is using illegal drugs; (2) as part of a random drug test where all officers have an equal chance of being selected to be screened; and (3) as part of a regularly scheduled and announced medical exam or a fitness for duty exam. The current policy screens for:

- Amphetamines/methamphetamine
- Barbiturates (sedatives)
- Benzodiazepine (anxiety, anti-depressants, sleep aids)
- Cannabinoids (Marijuana)
- Cocaine
- Methadone
- Phencyclidine (PCP)
- Opiates (Morphine, Codeine, etc.)

Urine specimens are not screened for steroids; however, as to New Jersey State Police, the “unauthorized” use of steroids is prohibited. In addition, the policy does not preclude local law enforcement from testing for anabolic steroids and indeed, some do test for steroids as part of their random drug testing program. The primary purpose of the Drug Testing Policy was to establish uniform criteria for the collection and analysis of specimens collected for drug testing by law enforcement agencies. In addition, the Drug Testing Policy mandated uniform discipline (*i.e.*, termination) for officers who tested positive. The policy provided officers accused of testing positive with due process rights and required that a database be created that contains the names of all officers who test positive under the policy. The Drug Testing Policy covers all law enforcement personnel under the Attorney General’s purview – state, county and municipal law enforcement agencies. The Policy does not cover other public safety officers such as corrections officers, firefighters or public transit workers. While a decision to conduct random drug testing is considered a managerial prerogative not subject to collective bargaining, the method of random selection may be subject to collective bargaining.

All testing of drugs referenced in the Drug Testing Policy is conducted by the State Toxicology Laboratory. As the sole facility for law enforcement drug testing, the State Toxicology Laboratory has been responsible for analyzing specimens submitted to it for the eight substances outlined above, reporting the results of its analysis to individual law enforcement agencies, providing testimony in support of its results at disciplinary hearing and providing expert services as requested. The lab charges a fee of \$35 for each specimen tested.

Every positive test result at the Toxicology Lab is examined by a medical review officer who compares the test result with medical information, including the prescription disclosure information officers submit when they are tested. A report is generated for each specimen tested. Negative results indicate that no controlled dangerous substances were detected. Positive test results indicate whether the test result was consistent with the information submitted by the officer. When the prescription(s) disclosed by the officer explains the test result, the police department is advised to verify the prescription. When there is no information provided to explain the test result, it is presumed that the officer is illegally using the drug and the officer’s agency is advised of that fact.

The lab does not test for steroids; rather, when a specimen needs to be screened for steroids, it is sent to Aegis Laboratory. Aegis charges \$250 per specimen with additional fees levied if other services (*e.g.*, discovery, expert testimony, etc.) are needed. The annual cap on services Aegis can charge in any one year is approximately \$40,000.

Municipal Drug Testing

There are some police departments in New Jersey that have instituted drug testing for steroids. The Study Group contacted one of those departments to ascertain the manner in which it tests its officers. The Study Group was advised that this department added steroids to its random drug testing policy due to the department’s concern over the increased availability of anabolic steroids and other growth hormones in recent years.

The random screening for steroids is done in concert with random testing for substances referenced in the Drug Testing Policy and the sampling is conducted at the Chief of Police's discretion, with no pre-determined date/month and with officers being selected at random via a software program. The tests are conducted at different points during the year. While the police department noted that testing for steroids resulted in a "modest" additional cost to its budget, it was the department's belief that the benefits far outweigh the nominal additional expenditure associated with the expanded testing protocol.

Prosecution

Prosecuting individuals who have received medication through a licensed practitioner presents certain challenges. For example, in the Kramer case discussed above, the lead plaintiffs argued that they "suffered from various medical conditions that required them to seek medical treatment." Kramer, 2010 U.S. Dist. LEXIS 56449 at *5. These conditions included erectile dysfunction, hypogonadism, impotence and fatigue. Id. The response from officers interviewed as part of the *Star-Ledger* report was similar – that is, if a doctor was prescribing the medication and the insurer approved payment for it, the officers did not think they did anything wrong.

The Office of Insurance Fraud Prosecutor ("OIFP") can prosecute individuals for health care claims fraud pursuant to N.J.S.A. 2C:21-4.2. Prosecuting individuals for health care claims fraud requires that the state prove beyond a reasonable doubt that the person: (1) knowingly; (2) made a false, fictitious, fraudulent or misleading statement; (3) which is material; and (4) which is submitted for payment or reimbursement for health care services. Fraud can be committed by any party to the health care transaction or by an accessory to the transaction.

OIFP prosecutions can include situations where doctors submit bogus insurance claims, where prescriptions are done outside the norms of good faith, where patients misrepresent their medical conditions or where pharmacies submit bogus claims or where pharmacy employees engage in fraudulent activity. In addition, OIFP works with Medco, our pharmacy benefits manager, when Medco identifies potential incidences of fraud in the system.

How are other governmental entities addressing this issue?

Steroid use among law enforcement personnel is an issue that other governmental entities have examined in recent years, typically in response to direct reports of criminality or investigations that indicated either usage or trafficking of steroids, and to a lesser extent, HGH, within the public safety sector. For example, during the course of an FBI investigation into a cocaine distribution ring in Boston, it was discovered that one of the defendants (who was a police officer) was also a steroid user. That fact led to an expansion of the investigation, which culminated in eleven Boston police officers being disciplined, including seven officers who used steroids. Further, BPD modified its drug testing program, which previously only tested for steroids during police academy, to make those who test positive for drugs as officers be subject to testing for their entire

career⁶³ and began training supervisors to spot signs of substance abuse, particularly steroids.

In New York City, in the wake of a police scandal that police officers were involved in purchasing steroids through illegal sources, random drug testing of the entire 36,000 member New York Police Department began in 2008 at a cost of roughly \$1 million per year.⁶⁴ Similarly, the Phoenix Police Department instituted one of the first steroid testing programs in 2005 after several incidents either directly or indirectly involving officers accused of abusing anabolic steroids. The PPD now tests all applicants for steroids and randomly tests its officers, but in doing so, tripled its drug testing costs.⁶⁵ Other large police departments that test for steroids include Dallas and Albuquerque; however, at least one other big city department, Portland, recently decided against randomly testing for steroids due to cost concerns and instead modified its drug testing procedure to allow for individualized steroid testing when a reasonable suspicion exists that an officer is using the substances.⁶⁶

In the military, the uniform branches have similar policies with regard to steroid testing. In the Army, random drug testing is not done for steroids, but can be done when a commander has “probable cause” to suspect abuse.⁶⁷ Information provided by the U.S. Army indicated, however, that in 2008, while more than 450,000 soldiers were drug tested, only about 300 of them were tested for steroid use.⁶⁸ In the Navy and Marine Corps, only a commander within the Navy’s Personnel Command can request that a steroid test be performed.⁶⁹ In the Air Force, random steroid testing of all cadets and civilian employees at the Air Force Academy in Colorado began in 2004 and, in addition, for active duty members, the Air Force can screen for steroids in a manner similar to the other branches of the military.⁷⁰

Some states have also passed laws specifically targeting the illegal prescription or dispensing of steroids and/or growth hormone.⁷¹ For example, in Rhode Island, it is a misdemeanor, punishable by up to six months in prison and/or a fine of \$1,000 for a medical practitioner to “prescribe, order, distribute, supply or sell an anabolic or human

⁶³ It should be noted that the Boston Police Department only tests its recruits for steroids, not its officers.

⁶⁴ *The Associated Press*, [NYPD to Test for Steroid Abuse](#), April 9, 2008.

⁶⁵ [Humphrey, K. et al.](#), *Anabolic Steroid Use and Abuse by Police Officers: Policy and Prevention*, [The Police Chief](#), Vol. LXXV, No. 6, June 2008.

⁶⁶ [Bernstein, M.](#), *Portland Police Contract Includes Random Drug Testing, But Delays Testing for Steroids*, [Oregon Live](#), February 2, 2011.

⁶⁷ [Bernton, H.](#), *Steroid Use in the Army on the Rise*, [Seattle Times](#), November 22, 2010.

⁶⁸ [Id.](#)

⁶⁹ [Giordono, J.](#), *Despite Better Tests, Some Drug Users Slipping Through Gaps in the System*, [Stars and Stripes](#) (Pacific Edition), July 17, 2003.

⁷⁰ [Jacobson, T.](#), *Air Force’s Random Checks for Steroids Are Unusual*, [Colorado Springs Gazette](#), July 22, 2004.

⁷¹ While this discussion relates to states that have specific laws on their books dealing with steroids or growth hormone, steroids are a federal Schedule III CDS and, as of 1999, at least 22 states had adopted the federal CDS standard as part of their criminal code. Therefore, states, including New Jersey, without specific laws related to illegal steroid prescription, sale or distribution have felony penalties based on their classification of steroids as a Schedule III CDS.

growth hormone” for the purpose of “enhancing performance in an exercise, sport, or game, or hormonal manipulation intended to increase muscle mass, strength or weight without a medical necessity.”⁷² In Louisiana, anabolic steroids cannot be prescribed for “bodybuilding, muscle enhancement, or increasing muscle bulk or strength.” The statute subjects those convicted of illegal manufacture or distribution with up to ten years at hard labor or a fine of up to \$15,000⁷³ (or both) and those convicted of illegal possession with up to five years at hard labor or a \$5,000 fine (or both). Other states that have specifically criminalized the improper prescription or dispensing of steroids or HGH by medical practitioners include Ohio,⁷⁴ Oklahoma⁷⁵ and Delaware.⁷⁶

Financial Costs to Government

Medco has provided us with data regarding the anabolic steroid, HGH and HCG prescriptions it filled in 2010. The total cost to the state benefit plan for anabolic steroids and HGH was \$11,275,944.82. Of that amount, \$6,345,157.96 was spent on a total of 6,012 patients who were prescribed steroids at an average cost of \$1,055.41 per person, and \$4,930,786.86 on a total of 210 patients who were prescribed HGH at an average cost of \$23,479.93 per patient. Member costs totaled \$1,643,734.15, with the patients receiving HGH having average out of pocket expenses of \$4,877.88, and patients receiving steroids having average out of pocket expenses of \$103.22.

For calendar year 2010, payment for prescriptions of steroids ranked 45th among the 172 subcategories of prescriptions filled by Medco. Payment for prescriptions of HGH ranked 53rd. With regard to HCG, disaggregating that data was made more difficult because of its primary use as a fertility treatment; however, we were advised that of 713 people who were prescribed HCG in 2010, 89, or slightly more than 12 percent, were men. Utilizing those figures, we estimate that of the \$129,468.87 spent on HCG prescriptions (\$102,529.12 paid by the plan, \$26,939.75 paid by patients), approximately \$12,303.49, or \$139.81 per patient in plan costs are attributable to men who were prescribed HCG, and \$3,232.77, or \$37.15 per patient in out-of-pocket expenses were incurred.

The *Star-Ledger* report confirms that the cost of filling steroid, HGH and HCG prescriptions through self-financed prescription plans is significant. The *Star-Ledger* cited several specific figures in its reporting, most prominently, the fact that in 2007, Jersey City spent more on treatments associated with growth hormone deficiency than it did “on any other medical condition, including high cholesterol, high blood pressure or diabetes.”⁷⁷ Moreover, the *Star-Ledger* was provided documents from a lawsuit related to a purported incident of “roid rage” by a Jersey City Police Officer which showed that while treatment for growth hormone deficiency was the number one ailment for which

⁷² R.I. Gen. Law § 21-28:401(e) (2011).

⁷³ La. Rev. Stat. Title 40 § 968 (2011).

⁷⁴ Or. Stat. Ann. 2925.06 (2011).

⁷⁵ 63 Okl. St. § 2-312.1 (2011).

⁷⁶ 16 De. C. § 4752 (2011).

⁷⁷ See fn. 53 *supra*.

the city's prescription drug manager filled prescriptions in 2007, the same ailment ranked 43rd among the drug manager's other governmental clients.⁷⁸ The total cost in Jersey City for growth hormone deficiency skyrocketed from \$255,000 in 2006 (itself a high number) to \$677,000 in 2007, when Dr. Colao's practice was at its height.

Additional figures referenced by the *Star-Ledger* show that reimbursement was provided for nearly \$300,000 in steroids and HGH received by a small group of Trenton police officers between 2002 and 2004 and slightly more than \$7,000 for one officer who received steroids, HGH and HCG in a roughly eight month time period in 2007.⁷⁹ The *Star-Ledger* conducted follow-up reporting with prescription drug plan managers who confirmed that oversight of the dispensing of these medications has increased in recent years due to a greater awareness of the propensity of people in general to seek out these medications and to have the costs covered by their prescription drug plans. As the *Star-Ledger* noted, Horizon Blue Cross/Blue Shield and Medco have both become more aggressive in challenging the information given them by providers before signing off on prescriptions for steroids and/or HGH.

IV. Recommendations

Our recommendations take into account several important factors. First, steroids, HGH and HCG are legal compounds subject to regulation and criminal prosecution where they are improperly dispensed, prescribed, possessed or used. We are mindful of the fact that not every person who is prescribed one of these medications is committing a crime and indeed, we want to ensure that people who are receiving these medications for a valid medical purpose are not swept into the net of those who are not. Second, our recommendations focus primarily on ways to discourage the improper prescribing and dispensing of these medications by practitioners. If we are able to dramatically reduce the number of prescriptions being issued for dubious purposes, we will see a significant reduction in the cost to the taxpayer, an increase in the investigation and prosecution of doctors acting in nefarious ways and stem the flow of these substances not only to law enforcement, but to the general public. Third, our recommendations take into account laws, policies and procedures that are already in existence or are being expanded to strengthen existing authority. One of the clear results of our investigation was that authority already exists to investigate both doctors and patients engaged in this type of conduct but a combination of difficult criminal proofs, the general regulatory approach of initiating investigations based on patient complaints rather than the cultivation of sources, lack of communication among agencies and the possibility that the actions are not as widespread as has been publicly reported, all conspired to limit the number of investigations and prosecutions the state and its entities might have otherwise engaged in. Finally, it is clear that prosecutions of individuals who receive prescriptions from medical practitioners pose challenges that we do not encounter when individuals acquire these substances from "black market" sources.

⁷⁸ Id.

⁷⁹ Id.

More generally, our recommendations are informed by several issues regarding gaps in detection: (1) prescription drug plan managers who have not scrutinized data to detect irregular, inappropriate or anomalous levels of prescriptions of steroids, HGH, and/or HCG; (2) the SBME's decision to focus on matters brought to its attention via patient complaints as opposed to initiating investigations based on existing regulatory prohibitions and its oversight authority; (3) the SBME's inability to track prescription medications through a centralized database; and (4) the absence of a drug testing procedure that includes screening for steroids. Our recommendations target each of these gaps and seek to create "chokepoints" throughout the system that will reduce the improper prescription, dispensing and use of steroids and growth hormones.

Improving Oversight Through Existing PBM Resources. There are several potential chokepoints where improper prescriptions for steroids, HGH and/or HCG can be flagged. First, insurers review prescription forms and, as noted by a spokesperson for Horizon Blue Cross/Blue Shield, can "challenge and seek additional information from the provider making a request for the prescription of a human growth hormone or steroid. Awhile ago, that would have just gone through the system."⁸⁰ When clear spikes in the prescription of these substances occur, as happened in Jersey City where spending on growth hormone went from \$255,000 in 2006 to \$677,000 in 2007, or where a clear anomaly exists, as where Express Scripts, Jersey City's pharmacy benefits manager, found that while treatment for hormone-related deficiencies ranked 1st in Jersey City, it ranked 43rd among its other government clients,⁸¹ more aggressive intervention by the health insurer approving these prescriptions is necessary.

To that end, the Study Group initiated discussions with the Division of Pensions and Benefits ("DPB") to discuss the oversight of our prescription drug benefits plan. In New Jersey, the "Pharmacy Benefits Manager" ("PBM"), who oversees the prescription drug plan for both active and retired state employees and many local governmental employees, is a company called Medco. In addition, the state allows municipalities and school districts to participate in the state benefits plan. DPB advised us that of the 1,976 non-state public employers in New Jersey, 1,063 participate in our health plan (Horizon BC/BS), and of those, 921 utilize our PBM (Medco), while the rest (142) purchase a prescription plan elsewhere. In total, DPB estimates that roughly 855,000 employees, retirees and family dependents are covered by the state plan. As of June 30, 2010, there were 543,880 active state workers in our various pension funds, of which, 252,923, or 46.5 percent, were enrolled in the health benefits plan (including the prescription drug plan). In addition, there were 255,813 pensioners (including widows and widowers) receiving pension benefits, of which, 145,035, or 55.9 percent, were enrolled in the health benefits plan (including the prescription drug plan).⁸²

The design of our prescription drug plan is created by the State Health Benefit Commission, a group comprised of appointees from the Department of Banking and

⁸⁰ See fn. 53 *supra*.

⁸¹ *Id.*

⁸² The balance of those covered by the prescription drug plan are local governmental employees and family dependents.

Insurance, Department of Treasury, Civil Service Commission, and representatives from the AFL/CIO who, working with DPB and its Office of Policy and Planning, create the plan specifics, from which drugs are covered, to what the co-pay for each medication will be, among many other issues. DPB works in collaboration with Medco and ultimately maintains oversight authority over the PBM and retains the ability to modify/alter requirements during the contract period.

Recently, Medco instituted a “protocol” that became effective on March 1, 2011 placing several new restrictions on the distribution of anabolic steroids and HGH. First, Medco now requires pre-authorization before a prescription for steroids will be approved.⁸³ Prior authorization requires the prescribing physician to fill out a form related to the prescription in question, the diagnosis, symptoms and other information to confirm that the prescription is appropriate before Medco will approve the medication. Depending on the medication, each form requires the doctor to confirm a specific diagnosis consistent with those treatments Medco provides reimbursement for (see below).

Second, coverage for testosterone treatment is explicitly limited to: (1) patients with a testosterone level of less than 300 nanograms/deciliter (“300 ng/dl”) as confirmed by a blood test;⁸⁴ (2) treatment for the delayed onset of puberty; and (3) for females suffering from metastatic inoperable breast cancer.

Third, anabolic steroid prescriptions⁸⁵ are only covered for: (1) the treatment of hereditary angioedema;⁸⁶ (2) to promote weight gain;⁸⁷ and (3) for the treatment of anemia/stimulation of erythropoiesis.⁸⁸ Finally, Medco will not approve HGH prescriptions for use in reversing or delaying the aging process or for conditions where the effectiveness of HGH is unknown, including treatment of constitutional delayed growth, infertility, and severe insulin-resistant diabetes or less severe forms of IGF-1 deficiency.

This heightened level of scrutiny for HGH and steroid prescriptions is also subject, as all prescriptions requiring pre-authorization and filled by Medco are, to two levels of examination. The first, termed “coverage review,” attempts to flag improper prescriptions based on the doctor’s representations. Coverage review requires a doctor to

⁸³ Medco already requires pre-authorization for HGH and HCG.

⁸⁴ The 300 ng/dl standard is recognized among endocrinologists as an appropriate level to diagnose legitimate incidences of hypogonadism. In a study of men ages 30-69, less than 7 percent of men had this level of testosterone. A second study of men in their 60s, 70s and 80s, indicated that the hypogonadal range was 20 percent, 30 percent and 50 percent respectively.

⁸⁵ As part of our discussion with Medco, they compared the list of 49 anabolic steroids referenced in the federal Controlled Substances Act with those available through our prescription drug plan. Medco advised us that only five of the 49 types of steroids referenced in the CSA are available through our plan.

⁸⁶ A disorder passed by parents to children involving swelling in tissues of the body, particularly of the larynx.

⁸⁷ This particular treatment would be given to patients with cachexia (wasting syndrome) which is often associated with severe auto-immune diseases or cancer, chronic infection, surgery, prolonged corticosteroid use or severe trauma.

⁸⁸ Anemia occurs when the body fails to produce enough red blood cells. Erythropoiesis is the process by which new red blood cells are generated.

fill out a form that asks questions to confirm that the diagnosis upon which the medication is being prescribed is one that is covered by the plan sponsor (State of New Jersey). For example, now that the protocol is in place, a doctor prescribing testosterone will have to confirm that the patient's testosterone level is below 300 ng/dl or, if prescribing an anabolic steroid, that the patient presents with one of the ailments for which the State of New Jersey permits reimbursement. For prescriptions that are filled directly by Medco (typically by mail), a second level "safety review" occurs. The safety review drills deeper into the patient history, including a review of what other prescriptions the patient is taking, whether the doctor has been flagged as one who may be improperly prescribing medications and other security checks. Medco's "safety review" is only done by Medco where prescriptions are filled directly by it. We recommend that the new protocol and the proposed changes discussed herein be shared with other insurers who provide prescription drug coverage in New Jersey.

Building on the March 1, 2011 protocol, we recommend that Medco be engaged to limit the dispensing of steroids and growth hormone to "mail order" only. By restricting the filling of these prescriptions in this way, the more stringent "safety review" conducted by Medco will be triggered and there will be no question or concern regarding compliance with the March 1, 2011 protocol. With regard to HGH, such a conversion would not be unduly burdensome. According to Medco, slightly more than 97 percent of the prescriptions it filled for HGH in 2010 were done by mail. Conversely, Medco only filled about 20 percent of steroid prescriptions by mail in 2010. If requiring all steroids prescriptions be filled by mail is deemed impractical, we recommend the mail order protocol be instituted based on certain delivery methods. For example, 71 percent of retail steroid prescriptions are for transdermal⁸⁹ methods of drug delivery and close to 16 percent are for intramuscular methods of delivery. Requiring mail ordering for these two types of steroids, when added to those prescriptions already filled by mail order, would subject 90 percent of all steroid prescriptions filled by Medco to heightened levels of scrutiny.

Lastly, as it relates to enhancing oversight, one area where improved collaboration is already happening is between Medco and OIFP. Medco has referred several cases of potential fraud to OIFP and we would like to see this partnership continue and deepen as greater scrutiny is placed on the misappropriation of steroids and HGH.

Amend the Attorney General's Drug Policy Guidelines to add steroids to the list of substances screened for and require supporting documentation by law enforcement personnel when they self-disclose that they are taking certain medications under a doctor's prescription.

We recommend that the current Attorney General's Law Enforcement Drug Testing Policy, which applies to applicants, trainees and sworn law enforcement officers who come under the jurisdiction of the Police Training Act and are authorized to carry a firearm, be amended to add steroids to the list of substances screened for and require supporting documentation by law enforcement personnel when they self-disclose that

⁸⁹ Transdermal delivery is "across the skin," *e.g.*, medication delivered by a patch.

they are taking anabolic steroids or HGH under a doctor's prescription. Adding steroids to the list of substances subject to testing will allow those agencies that have random drug testing policies to test for steroids⁹⁰ and authorize such testing if departments implement random testing in the future. While we recognize that adding steroids to the testing list may place a financial burden on police departments that randomly test, we think that expressly allowing for random anabolic steroid testing will have a deterrent effect on those officers who now believe that their use of such drugs will go undetected.

Adding steroids to the list of substances screened for under the Attorney General's Drug Policy Guidelines is not a modification subject to the collective bargaining agreement in effect with unions representing police officers; however, the manner in which officers are selected to be randomly tested may be subject to collective bargaining. While testing for steroids will add cost to those samples screened for steroids, we think this modest financial burden is appropriate in light of the significant amount of money potentially at risk where officers are having prescriptions improperly filled and/or when considering the risk of liability associated with "roid rage" accusations leveled at officers as part of civil litigation.

Next, we recommend that the Drug Testing Policy, whether referring to random or reasonable suspicion testing, be clarified in the following respect. Currently, it is unclear whether, after confirming a positive result from a controlled dangerous substance, the State Toxicology Laboratory must notify the submitting agency that it compared the test results with the medical questionnaire submitted by the officer and determined that one or more substances currently being used by the officer explained its findings. We think that it is imperative that a police department know whether one of its officers is ingesting a controlled dangerous substance or steroid for at least two reasons: (1) given the degree to which substances such as steroids, oxycodone or HGH are illegally trafficked, police departments have an obligation to ensure that its officers are obtaining them for legitimate medical reasons from a licensed medical provider; and (2) given the powerful, and sometimes deleterious effects these substances have on the human body, the department – and the public – need to know that the officer is fit for duty. While there are legitimate medical privacy issues involved in such disclosure, we do not think any of those issues outweigh the public health and welfare that would be put at risk by armed policemen patrolling our streets while under the influence of narcotic or other drugs, whether lawfully obtained or otherwise.

Therefore, we further recommend that whenever a department is advised by the State Toxicology Laboratory that an officer, after testing positive, is, according to his/her medical history, taking a CDS or steroid, the Drug Testing Policy should provide that the officer be required to produce a legally-obtained prescription, along with a letter from the prescribing physician that: (1) the CDS/steroid is being administered for a medically-recognized ailment/condition that was diagnosed following appropriate diagnostic procedures; and (2) the officer is not rendered unfit for duty due to the administration of

⁹⁰ The current policy mandates drug testing when reasonable suspicion exists to think that an officer is using drugs and permits random drug testing. Moreover, it references the fact that as to the New Jersey State Police, the "unauthorized" use of steroids is prohibited.

the CDS/steroid. Should the officer's treating physician fail or refuse to provide the necessary documentation set forth above, the department would have the right to have the officer examined by an independent physician or expert. We caution that in accepting this recommendation, you will be requiring police departments to more affirmatively scrutinize the medical treatment of officers using certain substances since current procedure tends to rely on the prescription "speaking for itself" with regard to it having been properly given.

With regard to fitness for duty, we recommend that you adopt a policy that would encourage police departments to require officers self-report the use of substances that may render them unfit for duty.⁹¹ While we understand that such a policy may require greater definition, we think it worth consideration and as an expression of the legitimate concerns underlying it should at least have a place at the collective bargaining table.⁹² At a minimum, we think self-reporting as to the use of steroids, HGH and their derivatives is warranted, relying on your authority to determine fitness for duty as it relates to an officer's authority to carry a firearm pursuant to the exceptions contained in N.J.S.A. 2C:39-6. We think such a policy would have a strong deterrent effect.

Lastly, we recommend that whatever modifications you agree should be made to the Drug Testing Policy be shared with those who have authority over other public safety officers in the state (e.g., correctional officers, firefighters, etc.) for their consideration of whether changes to their drug testing procedures are warranted.

Propose legislation to criminalize unlawful prescription of medications by doctors. While our criminal code currently provides for certain penalties for health care claims fraud⁹³ and the improper dispensing of Schedule III substances,⁹⁴ we recommend that you propose legislation that will criminalize the prescribing, dispensing and receipt of steroids, HGH and other controlled dangerous substances when there is no reasonable basis to believe that the patient-consumer has a medically-recognized need for the medication in question.

While the specific language should be subject to discussion with interested legislators and prosecutors, such legislation has already been enacted in other states, which could both inform the drafting of proposed legislation and serve as a way to identify and mitigate litigation risks if the bill is enacted into law.

Draft a legislative fix specifically incorporating steroids as a Schedule III under the New Jersey Controlled Substances Act, N.J.S.A. 24:21-1 et seq. We recommend that you call for the adoption of legislation that clearly incorporates anabolic steroids under the New Jersey Controlled Substances Act. While the Controlled Substances Act vests in

⁹¹ State Police SOP C33 already requires State Police to report all prescription medications and SOP A4 requires that they disclose all medications taken within the 14 days prior to taking a drug test.

⁹² Such self-reporting would not necessarily be limited to steroids, but could also include other medications such as painkillers, muscle relaxers, and other mood-stabilizing medications that could affect fitness for duty.

⁹³ N.J.S.A. 2C:21-4.1 to 4.6.

⁹⁴ N.J.S.A. 2C:35-5.

the Director of the Division of Consumer Affairs the responsibility for updating and re-publishing our state list of Schedule III substances (which does include anabolic steroids), the Study Group thinks that harmonizing in statute what is reflected in the federal Controlled Substances Act will avoid any possible confusion.

Modify Administrative Code to prohibit the prescription of HGH for Anti-Aging purposes and Utilize Existing Administrative Authority More Affirmatively.

Currently, SBME regulations strictly limit the prescribing and dispensing of HGH and prohibit its prescription “for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight.” N.J.A.C. 13:35-7.9(a). However, HGH is now being marketed aggressively for its purported “anti-aging” benefits, a use that is inappropriate under FDA guidelines. *See* 21 U.S.C. § 333(e)(1). Accordingly, we recommend that you direct the SBME to undertake a review of its current regulation after convening a panel of medical experts to propose amendments that will curtail prescription of HGH for anti-aging purposes. Further, one recommendation we would like to see the panel incorporate is the need for doctors who prescribe HGH to clearly identify, either in their records or as part of the prescription process, which of the permitted purposes under FDA guidelines HGH is being prescribed, or, if one of the three recognized treatments is not present, for what other, medically recognized purpose, HGH is being prescribed.

In terms of existing oversight authority, both the number of refills and the dosages prescribed would be two logical places where greater scrutiny could also result in detection of anomalous prescription and/or usage. For example, Schedule III substances cannot be refilled more than 5 times after the date of the initial prescription and all fills and refills must take place within 6 months unless renewed by the practitioner.⁹⁵ N.J.S.A. 24:21-15. Also, where medication is distributed directly at a doctor’s office, such medications are limited to seven day supplies. N.J.S.A. 45:9-22.11; N.J.A.C. 13:35-7.5.

While these limits generally restrict Schedule III drugs, no further regulation of Schedule III substances has been promulgated by the Director, even though more rigorous oversight of Schedule II controlled substances has been in place since 2003. *See* N.J.A.C. 13:35-7.6. Moreover, the 2007 amendments to the state’s Controlled Substances Act gave the Director of Consumer Affairs oversight and regulatory authority over controlled substances. N.J.S.A. 24:21-31. This authority, when coupled with the SBME’s general mission to discipline licensees who do not comply with established standards of practice, provides ample power to implement and enforce greater restrictions on the prescription of these substances.

Finally, where individuals are filling prescriptions without utilizing their prescription plans, the same level of attention and, where appropriate, investigation of doctors or pharmacies that provide these medications must be done.

⁹⁵ Such oversight is particularly important as the *Star-Ledger* report indicated that at least one officer, Jersey City police officer Victor Vargas, alleged to have been involved in a “steroid rage” incident, filled at least six prescriptions for HGH and steroids between January and August 2007.

Implement the NJPMP. The SBME will be able to more effectively monitor the doctors under its authority through the New Jersey Prescription Monitoring Program (“NJPMP”) that is scheduled to be online later this year. In-state and out-of-state prescribers and pharmacists who register with the NJPMP will submit information to the Division of Consumer Affairs on a regular basis on Schedule II-V medications, including the name, date of birth, address and phone number of the patient receiving the medication, the date the drug was prescribed, the National Drug Code of the drug, prescriber’s name and DEA registration number, name, strength and quantity of the drug, whether it was refilled, the source of payment, and other useful tracking information.

Moreover, state law permits the Director to collect and track prescription information on non-CDS drugs following the promulgation of a drug-specific regulation. N.J.S.A. 45:1-47. Under this statute, the Director is permitted to add to the NJPMP non-CDS provided certain criteria are met, including issues such as the potential for abuse of the substance, scientific evidence, if any, of the substance’s pharmacological impact, the scope, duration and significance of abuse.⁹⁶ Once a determination has been made that the non-CDS should be added to the NJPMP, it is added on a temporary basis with a follow-up determination made by the Director, as to whether it should be added permanently. As noted above, A3698, a bill pending in the Legislature, would require that HGH be added to the NJPMP. Regardless of whether the bill passes, DCA Director Calcagni is prepared to move forward and add HGH to the list of prescriptions tracked by the NJPMP.

The NJPMP is also intended to be used as a tool by prescribers and pharmacists, who must register with the Division of Consumer Affairs to gain access to the system, to combat prescription drug abuse and/or fraud. Authorized users, including Division personnel, will be permitted to conduct patient-specific inquiries of NJPMP data. The system will allow the Division to analyze the data for indications of fraud or abuse through system reports, permitting early detection of diversion or indiscriminate prescription of medication through prescriber-specific inquiries. The NJPMP has also been designed to enable the Division to flag abnormal patterns of prescribing. Specifically, the Division is obligated to notify law enforcement when a violation of a law or regulation has occurred or when a breach of an applicable standard or practice has occurred. N.J.S.A. 45:1-45. Further, the Division is obligated to turn over information that may be relevant to an investigation of any of these allegations. Id.

Distribute law enforcement wide letter/memorandum advising all members of law enforcement of changes to the Drug Testing Policy and penalties for improper acquisition of these prescription drugs. Once changes to the Drug Testing Policy are adopted, we recommend that you issue a law enforcement-wide directive clearly advising all members of the public safety community about the changes to the Policy and more generally, that: (1) anabolic steroids are a Schedule III CDS with limited appropriate medical uses; (2) HGH has limited, FDA-approved uses; and (3) HCG is understood to be a masking agent in men abusing steroids and that improper acquisition of any of these substances is both a federal and a state crime punishable, in some cases, with prison time.

⁹⁶ As noted above, S3698 would require the Director to add growth hormone to the list of drugs tracked by the NJPMP.

Moreover, the letter or memorandum should clearly state that we will aggressively prosecute individuals suspected of attempting to, or acquiring these medications improperly.

Institute regular meetings among agencies with oversight responsibility. We recommend that a working group of investigators, prosecutors and attorneys who work for agencies charged with licensing, oversight, investigation and/or prosecution of those involved in prescription drug fraud meet on a quarterly basis to share information, update counterparts on any new reporting being received about those who are involved in prescription fraud and to encourage an open dialogue about what is being learned through discussions with informants, defendants seeking plea deals and other “word on the street” anecdotal information that might be of use in identifying and investigating people suspected of illegal activity.