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MYTHS AND FACTS ABOUT HUMAN GROWTH HORMONE, B–12, AND OTHER SUBSTANCES

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

FEBRUARY 12, 2008

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MYTHS AND FACTS ABOUT HUMAN GROWTH HORMONE, B–12, AND OTHER SUBSTANCES

TUESDAY, FEBRUARY 12, 2008

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Henry A. Waxman (chairman of the committee) presiding.

Present: Representatives Waxman, Cummings, Tierney, Watson, Norton, Sarbanes, Davis of Virginia, Shays, Issa, and Bilbray.

Staff present: Phil Schiliro, chief of staff; Phil Barnett, staff director and chief counsel; Karen Lightfoot, communications director and senior policy advisor; John Williams, deputy chief investigative counsel; Sarah Despres, senior health counsel; Steve Cha, professional staff member; Earley Green, chief clerk; Teresa Coufal, deputy clerk; Caren Auchman and Ella Hoffman, press assistants; Zhongrui "JR" Deng, chief information officer; Leneal Scott, information systems manager; Miriam Edelman, staff assistant; Bret Schothorst, special assistant; David Marin, minority staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Brian McNicoll, minority communications director; Benjamin Chance, minority clerk; and Jill Schmalz, minority professional staff member.

Chairman WAXMAN. Good morning. The committee will please come to order.

For the last 3 years, our committee has been investigating the use of performance-enhancing drugs in professional sports and by high school children. A lot of developments have surprised me but none more than the fact that there is a great deal of misinformation and widespread confusion that surrounds steroids, human growth hormone, vitamin B–12 and other substances. Even highly paid, presumably sophisticated professional athletes often seem to know the myths and not the facts about these substances.

That's why we're having today's hearing. It's an opportunity to provide essential and accurate information not just to professional athletes, not just to high school kids but to senior citizens, baby boomers turning 60 and everyone in between.

In previous hearings, experts have testified about the potentially deadly risks associated with steroid use. The side effects range from serious damage to the heart and liver to well-documented psychiatric problems. Steroids can be especially dangerous for children by impeding normal development and inflicting long-lasting harm.

We will discuss those issues again today, but we'll also focus on our long-overdue attention on the growing use of other substances.

Senator Mitchell's report on the use of performance-enhancing drugs in baseball found that the use of human growth hormone by professional baseball players is rising. Just last week, Sylvester Stallone seemed to be endorsing the use of HGH to reverse the aging process. It's an unfortunate reality that what professional athletes and celebrities do serves as a health guide to millions of Americans.

Even worse, there seems to be an almost unlimited number of unscrupulous scam artists ready to exploit this reality. Here's an advertisement that we can see on the screen by GenF20 that reads, HGH could actually prevent biological aging. It's like your body is immune to the passage of time.

Here are the frequently asked questions from another product, Growlean 15, that says, our product can be taken at any age, safely, with no harmful side effects.

Well, if any of us search the Internet today, we would find thousands of similar sites and a blizzard of confusing claims. It's no wonder that so many are confused by the facts about HGH. Today, we have a distinguished panel of experts who are going to tell us, while there are appropriate uses for HGH, there are also serious risks from abusing this powerful drug.

In adults, HGH is used to treat adult growth hormone deficiency and the wasting syndrome of late-stage AIDS, both of which are relatively rare. When HGH is used to treat these conditions, there are extensive blood tests used to diagnose the patient; and patients being treated with HGH are closely monitored by physicians.

For children, HGH is approved to treat a few uncommon conditions such as idiopathic short stature growth hormone deficiency and chronic kidney disease. It's also used to treat a few genetic diseases such as Turner Syndrome and Prader-Willi Syndrome. In these cases, HGH can have a clear therapeutic benefit.

But careful studies conclude that, when it comes to reversing the aging process, HGH is more snake oil than cure.

In 2002, the National Institute on Aging sponsored the most comprehensive single study of the anti-aging effects of HGH and found marginal benefits and significant side effects. It warned that HGH should not be widely prescribed and should be limited to controlled research studies.

Another study, this one released in 2007 by researchers at Stanford University, concluded that HGH cannot be recommended as an anti-aging therapy.

Well, many athletes believe they get an edge by using HGH, even though it is outlawed in all professional sports. They think it can make them faster and stronger, and they also think that it can help them heal more quickly. But there is only limited scientific evidence to support these beliefs. In fact, according to one expert, the best way to maximize growth hormone production is to get 8 hours of sleep a night, not take injections.

Today, we'll hear from our experts that the increase in muscle mass that can result from taking HGH may actually be due to water retention. There are real risks from the improper use of HGH. Human growth hormone can elevate blood sugar levels and

cause diabetes. It can increase triglyceride levels in blood which can contribute to heart disease. HGH can also result in fluid retention, which then can cause swelling, joint and muscle pain and carpal tunnel syndrome.

We know that HGH can cause problems, because it's actually a disease where the body produces too much HGH. Doctors call that disease acromegaly. It can lead to diabetes, heart problems, liver problems, kidney problems, cancer and even death.

It can also cause permanent changes in the face. We know what these changes look like. The pro wrestler, Andre the Giant, died of complications of untreated acromegaly; and Richard Kiel, better known as Jaws from the James Bond movies, has publicly spoken about his experience with this disease. There are also cases where bodybuilders are injecting such large doses of HGH that they are seeing some of these same problems.

HGH purchased from the Internet may carry additional risks. It may not be made in FDA-approved plants, and it may not even be HGH. In many cases, it is contaminated with other drugs, including steroids.

Because of these dangers, HGH is subject to special scrutiny by the Food and Drug Administration. HGH is unique in that doctors are actually prohibited from prescribing it for any use that has not been specifically approved by the FDA. This means the doctors who are prescribing the drug to enhance performance or to reverse aging are actually breaking the law.

We will also focus today on the use of injectable vitamin B–12. There seems to be a widespread myth that B–12 injections can increase energy, fight off colds and generally promote good health. The reality is that B–12 injections are useful for those who suffer from pernicious anemia or have difficulty absorbing B–12 from their food or B–12 tablets. For everyone else, injectable B–12 appears to be an unnecessary needle and a waste of money.

When we began our investigation into steroids in baseball 3 years ago, the committee's primary focus was the health of teenagers who emulate their sports heroes. That remains our focus, and that's why this hearing is so important. But, beyond teenagers, we have these widespread myths that are leading others to use these drugs and wasting their money and may be jeopardizing their health.

I want to thank our witnesses for being here today, and I look forward to their testimony. I will introduce them in a minute. But I want to call on Ranking Member Tom Davis for his opening statement.

[The prepared statement of Chairman Henry A. Waxman follows:]

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Opening Statement of Rep. Henry A. Waxman
Committee on Oversight and Government Reform
Hearing on Myths and Facts about Human Growth Hormone, B12 and Other Substances
February 12, 2008

For the last three years our Committee has been investigating the use of performance enhancing drugs in professional sports and by high school children.

A lot of developments have surprised me, but none more than the amount of misinformation and widespread confusion that surrounds steroids, human growth hormone, vitamin B12, and other substances. Even highly paid, presumably sophisticated professional athletes often seem to know the myths — not the facts — about these substances.

That's why we are having today's hearing. It is an opportunity to provide essential and accurate information not just to professional athletes, but to high school kids, senior citizens, baby boomers turning 60, and everyone in between.

In previous hearings, experts have testified about the potentially deadly risks associated with steroid use. The side effects range from serious damage to the heart and liver to well-documented psychiatric problems. Steroids can be especially dangerous for children by impeding normal development and inflicting long-lasting harm.

We will discuss those issues again today, but we will also focus long-overdue attention on the growing use of other substances.

Senator Mitchell's report on the use of performance-enhancing substances in baseball found that the use of human growth hormone (HGH) by professional baseball players is rising. Just last week Sylvester Stallone seemed to be endorsing the use of HGH to reverse the aging process.

It is an unfortunate reality that what professional athletes and celebrities do serves as a health guide to millions of Americans. Even worse, there seem to be an almost unlimited number of unscrupulous scam artists ready to exploit this reality.

Here's an advertisement by Genf20 that reads: "HGH actually prevents biological aging! It's like your body is immune to the passage of time." Here are the frequently asked questions for another product, GrowLean 15, which says: "Our product can be taken at any age safely with no harmful side effects."

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Today we have a distinguished panel of experts who are going to tell us that while there are appropriate uses for HGH, there are also serious risks from abusing this powerful drug.

In adults, HGH is used to treat adult growth hormone deficiency and the wasting syndrome of late stage AIDS, both of which are relatively rare. When HGH is used to treat these conditions, there are extensive blood tests used to diagnose the patient, and patients being treated with HGH are closely monitored by physicians.

For children, HGH is approved to treat a few uncommon conditions, including idiopathic short stature, growth-hormone deficiency, and chronic kidney disease. It is also used to treat a few genetic diseases such as Turner Syndrome and Prader-Willi Syndrome.

In these cases, HGH can have a clear therapeutic benefit. But careful studies conclude that when it comes to reversing the aging process, HGH is more snake oil than cure. In 2002, the National Institute on Aging sponsored the most comprehensive single study of the anti-aging effects of HGH and found marginal benefits and significant side effects. It warned that HGH should not be widely prescribed and should be limited "to controlled research studies."

Another study, this one released in 2007 by researchers at Stanford University, concluded that "[H]GH cannot be recommended as an anti-aging therapy."

Many athletes believe they get an edge by using HGH, even though it is outlawed in all professional sports. They think it can make them faster and stronger. And they also think that it can help them heal more quickly. But there is only limited scientific evidence to support these beliefs. In fact, according to one expert, the best way to maximize growth hormone production is to get eight hours of sleep a night, not take injections.

Today we will hear from our experts that the increase in muscle mass that can result from taking HGH may actually be due to water retention.

There are real risks from the improper use of HGH. Human growth hormone can elevate blood sugar levels and cause diabetes. It can increase triglyceride levels in blood, which can contribute to heart disease. HGH can also result in fluid retention, which then can cause swelling, joint and muscle pain, and carpal tunnel syndrome.

We know that HGH can cause problems because it's actually a disease when the body produces too much HGH. Doctors call it acromegaly. It can lead to diabetes, heart problems, liver problems, kidney problems, cancer, and even death. It can also cause permanent changes in the face. We know what these changes looks like. The pro wrestler, Andre the Giant, died of complications of untreated acromegaly, and Richard Kiel, better known as Jaws from the James Bond movies, has publicly spoken about his experience with the disease.

There are also cases where body builders are injecting such large doses of HGH that they are seeing some of these same problems.

HGH purchased from the internet may carry additional risks. It may not be made in FDA-approved plants and it may not even be HGH. In many cases it is contaminated with other drugs, including steroids.

Because of these dangers, HGH is subject to special scrutiny by the Food and Drug Administration. HGH is unique in that doctors are actually prohibited from prescribing it for any use that has not been specifically approved by the FDA. This means that doctors who are prescribing the drug to enhance performance or to reverse aging are actually breaking the law.

We will also focus today on the use of injectible vitamin B12. There seems to be a widespread myth that B12 injections can increase energy, fight off colds, and generally promote good health.

The reality is that B12 injections are useful for those who suffer from pernicious anemia or have difficulty absorbing B12 from their food or from B12 tablets. For everyone else, injectible B12 appears to be an unnecessary needle and a waste of money.

When we began our investigation into steroids in baseball three years ago, the Committee's primary focus was the health of teenagers who emulate their sports heroes. That remains my focus today. And that is why this hearing is so important.

I want to thank our witnesses for being here and I look forward to their testimony.

Mr. DAVIS OF VIRGINIA. Mr. Chairman, thank you very much and thank you for your leadership and for holding the hearing today.

Athletes at all levels, from the sandlot to the Super Bowl, look for an edge, that little something extra that could mean the difference between winning and losing. Advances in training equipment and nutrition offer modern competitive paths to strength, skill and longevity not available to previous generations, but that high-pressure quest for physical prowess has also spawned a thriving subculture of claims hyping the benefits and downplaying the risks of everything from vitamin supplements to steroids. Today, we try to sort through some of those claims, focusing our discussion on two substances much in the news lately, human growth hormone [HGH], and vitamin B–12.

The committee's 3-year bipartisan investigation of performance-enhancing substance abuse in professional sports uncovered an industry dangerous and tolerant of pseudo-science and medical mysteries in its locker rooms. The Mitchell Report added to that picture, making clear that, while steroid abuse continues to be a concern, the newest trend is HGH abuse, alleged to speed recovery from injuries and building muscle mass.

Without question, those attempting to market or distribute HGH claiming it will aid, heal, slow or reverse the aging process, assist in weight loss or cure depression are scamming consumers and breaking the law. These crass moneymaking schemes play on vanity and promise scientifically unproven results, while openly promoting unapproved uses of a serious biological therapy.

Synthetic HGH is approved by the Food and Drug Administration for a limited number of scientifically supported uses: children with growth hormone deficiency; wasting associated with HIV and AIDS; and, in rare instances, adult growth hormone deficiency. For these indications, HGH is an important therapy for real medical needs. But even when used appropriately, HGH is not without possible long-term side effects, including an increased risk of diabetes, carpal tunnel syndrome, nerve pain, hypothyroidism, arthritis and cancer.

No long-term clinical studies have been conducted on the effects of HGH in healthy adults or in anyone with doses exceeding the FDA approved levels, and those are only the known risks associated with the abuse of real HGH. Even the quickest Internet search produces countless advertisements for nonprescription or dietary supplement HGH and pills, sprays and topical creams. Consumers ordering these products run the risk of putting counterfeit, contaminated or altered substances in their bodies.

It's impossible to differentiate legitimate drugs from fakes by just looking at them. Best case, gullable people are only being scammed out of their money; worst case, they are placing their health in the hands of criminals who could be operating beyond the reach of our laws anywhere in the world.

B–12 abuse involves similar scams but admittedly fewer risks. The vitamin is essential for normal nervous system function and blood cell production. For most people, a balanced diet captures adequate amounts of B–12. Injections of additional B–12 under the supervision of a physician can be therapeutic for patients diagnosed with a specific vitamin deficiency or anemia. But there's no

reliable evidence to prove or even suggest B–12 injections given to healthy people produce increased energy, aid in weight loss or improve athletic performance. Nevertheless, Web sites, anti-aging centers and so-called sports medicine experts continue to flout the law and promote unproven unapproved uses for HGH, B–12 and a variety of other products.

Hearings like this have to be but one part of a much larger effort involving parents, coaches and health providers to educate consumers, especially young people, about the gauzy myths and harsher realities of HGH, B–12 and other alleged pharmacological shortcuts to athletic success. That in the end is what makes this oversight so important, preventing drug abuse and other physically damaging activities by young athletes. Even tacit acquiescence by professional sports franchises and locker room malpractice and quackery glamorizes harmful, even illegal practices that young impressionable aspirants are bound to mimic. In that respect, HGH and B–12 can be seen as gateway drugs to steroid abuse.

We have to find a way to block transmission of that false incentive and convince young athletes there are no magic pills or wonder drugs that will grease the path to the hall of fame. Only hard work and the most effective antidote to illicit drugs, the truth, should fuel the bodies and minds of those seeking athletic excellence at any level.

Today's witnesses bring invaluable expertise to our oversight, and we appreciate their willingness to testify. I look forward to a frank and informative discussion of the myths and realities of performance-enhancing drugs.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Tom Davis follows:]

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Today, we try to sort through some of those claims, focusing our discussion on two substances much in the news lately: Human Growth Hormone and vitamin B12.

The Committee's three year, bipartisan investigation of performance enhancing substance abuse in professional sports uncovered an industry dangerously tolerant of pseudo-science and medical mischief in its locker rooms. The Mitchell Report added to that picture, making clear that while steroid abuse continues to be a concern, the newest trend is HGH abuse, alleged to speed recovery from injuries and build lean muscle mass.

Without question, those attempting to market or distribute HGH claiming it will aid healing, slow or reverse the aging process, assist in weight loss, or cure depression are scamming consumers and breaking the law. These crass, money-making schemes play on vanity and promise scientifically unproven results while openly promoting unapproved uses of a serious biologic therapy.

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Today's witnesses bring invaluable expertise to our oversight and we appreciate their willingness to testify. I look forward to a frank and informative discussion of the myths and realities of performance enhancing drugs.

Chairman WAXMAN. Thank you very much, Mr. Davis.

Our panel of witnesses today:

Dr. Susan Shurin. Dr. Shurin is the Deputy Director of the National Institutes of Health's National Heart, Lung and Blood Institute. She's an expert in pediatric hematology and oncology.

Dr. Thomas Perls is an attending physician in the geriatrics section at Boston Medical Center. He is also a visiting scholar at the gerontology department at Boston University and has published a number of peer-reviewed articles about aging and also about anti-aging medicine.

Dr. Alan Rogol is a practicing pediatric endocrinologist in Charlottesville, VA. He is also a professor of clinical pediatrics at the University of Virginia and a professor of clinical pediatrics at the Indiana University School of Medicine. Today, he's representing the Endocrine Society. Among his patients are children who are being appropriately treated with human growth hormone, and he is an expert on the effects of HGH on children.

And Dr. Todd Schlifstein. Dr. Schlifstein practices sports medicine in New York City and treats athletes, among others. He is an attending physician at both the RUSK Institute of Rehabilitation Medicine at New York University School of Medicine and also at the Orthopedic Institute of New York University School for Joint Disease. He is an assistant professor at the New York University School of Medicine.

We're pleased to have each of you here today. It's the practice of this committee that all witnesses testify under oath. So if you would please rise and raise your right hands.

[Witnesses sworn.]

Chairman WAXMAN. Thank you.

The record will indicate that the witnesses answered in the affirmative.

Your prepared statements will be in the record in its entirety. What we'd like to ask each of you to do is be sure the button of the mic is pressed so that it's on and then try to limit your oral presentation to us to around 5 minutes.

There's a little clock sitting there; and it will be green for 4 minutes, yellow for the last minute. And when it turns red it will indicate to you that the 5 minutes are up, and we'd like you to then be sure to summarize your statement.

Dr. Shurin, why don't we start with you.

STATEMENTS OF SUSAN B. SHURIN, M.D., DEPUTY DIRECTOR, NATIONAL HEART, LUNG AND BLOOD INSTITUTE, NATIONAL INSTITUTES OF HEALTH; THOMAS T. PERLS, M.D., MPH, ASSOCIATE PROFESSOR OF MEDICINE AND DIRECTOR, NEW ENGLAND CENTENARIAN STUDY, BOSTON UNIVERSITY SCHOOL OF MEDICINE; ALAN D. ROGOL, M.D., PH.D., PROFESSOR OF CLINICAL PEDIATRICS, UNIVERSITY OF VIRGINIA, PROFESSOR OF CLINICAL PEDIATRICS, INDIANA UNIVERSITY SCHOOL OF MEDICINE, ALSO REPRESENTING THE ENDOCRINE SOCIETY; AND TODD SCHLIFSTEIN, M.D., DEPARTMENT OF REHABILITATION MEDICINE, HOSPITAL FOR JOINT DISEASES

STATEMENT OF SUSAN B. SHURIN, M.D.

Dr. SHURIN. Mr. Chairman, members of the committee, thank you for the opportunity to appear before you in my capacity as Deputy Director of the National Heart, Lung and Blood Institute, which is part of the National Institutes of Health, an agency of the Department of Health and Human Services. I'm here today to discuss the current state of the science of vitamin B–12 and to briefly outline what we know about vitamin B–12 deficiency and the administration of vitamin B–12 to healthy persons.

A vitamin is a chemical substance that is required for a particular chemical reaction in the body but is not synthesized by the body and therefore needs to be included in the diet. The dietary requirements for normal function are usually relatively small. Most vitamins that are known today were recognized because their deficiency causes recognizable diseases. Examples, for instance, would be scurvy, caused by a deficiency of vitamin C, which ultimately motivated British sailors to carry limes onboard ship, and beriberi, which is caused by a deficiency of thiamine, or vitamin B1.

Supplemental vitamins are usually not required by people who have varied, well-balanced diets and normal metabolism. However, supplements are often advisable for people who are on limited diets or have increased requirements for vitamins, such as pregnant women and growing children. Moreover, a number of gastrointestinal diseases can interfere with absorption of vitamins and cause deficiencies even in people who have adequate dietary supplies.

Vitamin B–12 is required for a number of vital biologic reactions. Two of its most important roles are in the production of components of DNA and in the proper functioning of different parts of the neurologic system. Tissues in which cells are constantly dividing, such as bone marrow and the lining of the entire gastrointestinal and respiratory tracts, require a constant supply of vitamin B–12. Normal function of cells throughout the nervous system and spinal cord also requires vitamin B–12.

Vitamin B–12 comes from animal products and from bacteria. The stomach produces a factor that binds to the vitamin in food and allows it to be absorbed in the small intestine. Therefore, the primary causes of vitamin B–12 deficiency are dietary deficiency and malabsorption.

Diets that lack food from animal sources tend to be low in vitamin B–12. Strict vegans, for instance, need a source of vitamin B–

12. However, it can take 5 years for someone with adequate stores of vitamin B–12 to develop a deficiency after a major change in diet.

Diseases of the stomach and small intestine can cause problems with absorption and consequent vitamin B–12 deficiency. Some people make antibodies to the cells that produce the stomach factor which is necessary for absorption of B–12 and therefore cannot produce the factor. As a result, they develop a condition called pernicious anemia, to which Representative Waxman, referred which can cause a decrease in the number of blood cells. Extensive bowel resections, removal of much of the stomach or inflammatory bowel disease can also cause vitamin B–12 deficiency. In all of these conditions, they need to be treated with monthly B–12 injections, because the vitamin cannot be absorbed from food or pills without the stomach factor.

B–12 deficiency has several major manifestations. A very characteristic anemia, in which the red blood cells are larger than normal, may progress to include low numbers of white blood cells and platelets. The symptoms of anemia include fatigue and shortness of breath on exertion. The lining of the mouth and the gastrointestinal tract can be thin and abnormal. The neurologic symptoms are particularly serious and may be hard to recognize.

Difficulty with position sense, nerve damage, depression, memory loss and dementia are seen with vitamin B–12 deficiency, even when the hematologic manifestation are not obvious.

Recent studies have highlighted the value of screening for vitamin B–12 in older people with mild dementia. B–12 deficiency in older individuals is probably related to changes in the GI tract with aging and fairly limited diets. Both problems appear to be more common with advancing age. For this reason, the 2005 Dietary Guidelines for Americans recommends that persons over 50 consume vitamin B–12 in its crystalline form, such as fortified pills or pills. Pernicious anemia is most common in older women, who must receive vitamin B–12 by injection.

Diagnosing mild cases in B–12 deficiency can be difficult. While looking for low B–12 levels can be useful for diagnosis of severe deficiency, serum levels of folate, homocysteine, methylmalonic acid, 2-methylcitric acid and cystathionine can help make the diagnosis in milder cases.

The only medical indications for administration of vitamin B–12 are deficiency of a vitamin or risk factors for developing such deficiency, such as stomach or bowel disease or a limited diet.

Some manufacturers and distributors of dietary supplements may claim that vitamin B–12 administration will improve energy levels, memory, concentration and mood. All of these are true when the person has vitamin B–12 deficiency and are treated with B–12. However, there is no evidence at all that these clinical benefits occur when the vitamin is given to people who are not deficient.

Vitamin B–12 is not toxic when given to nondeficient persons. It is simply excreted in the urine. So you don't buildup your stores beyond a certain level. Administration of vitamin B–12 does not enhance physical or cognitive function of persons who are not B–12 deficient.

Thank you for the opportunity to provide information on this topic. I'd be happy to answer any questions the committee may have.

Chairman WAXMAN. Thank you very much, Dr. Shurin. We're going to have questions after all the witnesses testify.

[The prepared statement of Dr. Shurin follows:]

Testimony
Before the
Committee on Oversight and Government Reform
United States House of Representatives

Vitamin B12—State of the Science

Statement of
Susan B. Shurin, M.D.
Deputy Director
National Heart, Lung, and Blood Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
February 12, 2008

Mr. Chairman and members of the Committee, thank you for the opportunity to appear before you in my capacity as Deputy Director of the National Heart, Lung, and Blood Institute, part of the National Institutes of Health, an agency of the Department of Health and Human Services. I am here today to discuss the current state of the science of vitamin B12 and to briefly outline what we know about B12 deficiency and administration of vitamin B12 to healthy persons.

A vitamin is a chemical substance that is required for a particular chemical reaction to occur in the body, but is not synthesized by the body, and therefore needs to be included in the diet. The dietary requirements for normal function are usually relatively small. Most vitamins that are known today were discovered because their deficiency causes recognizable diseases. Examples are scurvy, caused by a deficiency of vitamin C, which ultimately motivated British sailors to carry limes onboard ship, and beriberi, caused by a deficiency of thiamin, or vitamin B1.

Supplemental vitamins are usually not required by people who have varied, well-balanced diets and normal metabolism. However, supplements are often advisable for people with limited diets or increased requirements for vitamins, such as pregnant women and growing children. Moreover, a number of gastrointestinal diseases can interfere with absorption of vitamins and cause deficiencies even in persons who have adequate dietary supplies.

Vitamin B12 is required for a number of vital biological reactions. Two of its most important roles are in the production of components of DNA and the proper functioning of different parts of the neurological system. Tissues in which cells are constantly dividing, such as bone marrow and the lining of the entire gastrointestinal and respiratory tracts, require a constant supply of vitamin B12. Normal function of cells throughout the nervous system and spinal cord also requires vitamin B12.

Vitamin B12 comes from animal products and bacteria. The stomach produces a factor that binds to the vitamin in food and allows it to be absorbed in the small intestine. Therefore, the primary causes of vitamin B12 deficiency are dietary deficiency and malabsorption.

Diets that lack foods from animal sources tend to be low in vitamin B12; strict vegans, for instance, need a source of B12. However, it can take five years for someone with adequate stores of vitamin B12 to develop a deficiency after a major change in diet.

Diseases of the stomach and small intestine can cause problems with absorption and consequent vitamin B12 deficiency. Some people make antibodies to the cells that produce the stomach factor necessary for absorption of B12, and therefore cannot produce the factor. As a result, they develop a condition called "pernicious anemia", which can cause a decrease in the number of blood cells. Extensive bowel resections, removal of much of the stomach, or inflammatory bowel disease can also cause vitamin B12 deficiency. All of these conditions need to be treated with monthly vitamin B12 injections since the vitamin cannot be absorbed from food or pills without the stomach factor.

Vitamin B12 deficiency has several major manifestations. A very characteristic anemia, in which the red blood cells are larger than normal, may progress to include low numbers of white blood cells and platelets as well. The symptoms of anemia include fatigue and shortness of breath on exertion. The lining of the mouth and gastrointestinal tract can be thin and abnormal. The neurologic symptoms are particularly serious and often hard to recognize. Difficulty with position sense, nerve damage, depression, memory loss, and dementia are seen with vitamin B12 deficiency even when the hematologic manifestations are not obvious. Recent studies have highlighted the value

of screening for B12 deficiency in older people with mild dementia. B12 deficiency in older individuals is probably related to changes in the gastrointestinal tract with aging and fairly limited diets, both problems that appear to be more common with advancing age. Pernicious anemia is most common in older women. For this reason, the 2005 Dietary Guidelines for Americans recommends that people over age 50 consume vitamin B12 in its crystalline form (i.e., fortified foods or supplement pills).

Diagnosing mild cases of vitamin B12 deficiency can be difficult. While looking for low B12 levels can be useful for diagnosis of severe deficiency, serum levels of folate, homocysteine, methylmalonic acid, 2-methylcitric acid, and cystathionine can help make the diagnosis in milder cases.

The only medical indications for administration of vitamin B12 are deficiency of the vitamin or risk factors for developing such deficiency, such as stomach or bowel disease or a limited diet.

Under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration regulates most vitamin products as dietary supplements. Although manufacturers and distributors of dietary supplements must have substantiation for the claims they make for their products, there is no pre-market approval requirement for dietary supplements or many of the claims they make, such as claims related to classical nutrient deficiency diseases or claims related to the structure or function of the body. Claims are made that vitamin B12 administration will improve energy levels, memory, concentration and mood. All of these are true when persons deficient in vitamin B12 are treated; however, there is no evidence at all of those clinical benefits when the vitamin is given to persons who are not deficient. Vitamin B12 is not toxic when given to non-deficient persons — it is simply excreted in the urine. Administration of vitamin B12 does

not enhance the physical or cognitive function of persons who are not Vitamin B12 deficient.

Thank you for the opportunity to provide information on this topic. I would be pleased to answer any questions the committee may have.

Chairman WAXMAN. Dr. Perls.

STATEMENT OF THOMAS T. PERLS, M.D.

Dr. PERLS. Thank you, Chairman.

Chairman WAXMAN. Be sure the mic is pulled up close to you and that it's on.

Dr. PERLS. What is growth hormone? Human growth hormone [HGH], is produced by a pea-sized endocrine gland near the base of the brain called the pituitary gland. Its primary utility relates to growth in the height of children.

What about deficiency in adults? Human growth hormone levels gradually decline in adults with minimal or no negative health consequences for the vast majority of the population with aging. The anti-aging industry, the primary pusher and seller of growth hormone in this country, advertises that normal declines of growth hormone causes decreases in strength, muscle mass, sleep and sexual performance and a long list of other attributes. They go on to claim that replenishing growth hormone to levels present at younger age stops or reverses these problems as well as aging itself. This is a ruse.

There are few medical conditions in adults that merit the use of growth hormone. Recognizing the potential for growth hormone abuse, Congress amended the Food Drug and Cosmetic Act in the late 1980's and the early 1990's, stipulating that growth hormone can be distributed to adults for only three specific indications approved by the Secretary of Health and Human Services. These are: AIDS Wasting Syndrome, Short Bowel Syndrome and Growth Hormone Deficiency, also called Adult Growth Hormone Deficiency Syndrome.

Growth Hormone Deficiency is very rare, occurring at a rate of about 1 adult per 10,000; and the legal diagnosis requires documentation of disease, such as a cancer or trauma to the pituitary gland and a failed stimulation test. Oftentimes, Growth Hormone Deficiency is accompanied by deficiencies of other pituitary gland-produced hormones.

In January 2007, the FDA released an alert reminding those that distribute growth hormone for anti-aging body building and athletic enhancement that they are doing so illegally. I have a copy of that at the end of my prepared remarks.

A recent Stanford University review of 31 clinical studies of growth hormone used among healthy, normal aging adults found the only benefit to be a slight increase in muscle mass. The documented negative side effects include soft tissue swelling, joint pains, carpal tunnel-like syndrome, breast enlargement and diabetes. Other side effects include liver and heart enlargement, increased pressure around the brain and high blood pressure.

In a 2002 Johns Hopkins study published in JAMA, about 50 percent of subjects experienced side effects, primarily joint pains; and 13 percent developed elevated blood sugar levels or even diabetes.

Recent studies demonstrate strong associations between growth hormone and prostate, colon and breast cancers. In another study, investigators found that growth hormone enhances the ability of cancer to spread. It is theoretically possible that normal declines of

growth hormone with age may actually be protective against cancer.

Ironically, there's no credible evidence that growth hormone substantially increases muscle strength or aerobic exercise capacity in normal individuals.

What about the illegal and medically inappropriate distribution of growth hormone? Since 1990, a growing network of compounding pharmacies, anti-aging clinics and physicians have created what some within the industry estimate is a $2-billion-a-year business for distributing growth hormone—a distribution network involving hundreds of thousands of weight training enthusiasts, practitioners and promoters of anti-aging medicine and those who have fallen victim to the growth hormone replacement scams.

I personally have found Web sites of 279 anti-aging clinics that advertise growth hormone treatment and 26 pharmacies or what are called "compounding pharmacies" that distribute the drug to these clinics and sometimes directly to users. I certainly discovered only a fraction of what exists out there. There's a map at the end of my remarks that spell out the number of some of these entities per State.

Of the seized anti-aging clinic records I have reviewed for the DEA, the average patient that first presents to the clinic is not a person in their 60's or 70's seeking alleviation of their age-related problems but, rather, a male in their late 20's to mid 40's, weight training nearly daily, in otherwise excellent health, clearly seeking anabolic steroids and growth hormone.

In summary, one, experts in the care of patients with growth hormone related problems clearly state that giving growth hormone for anti-aging or age management is not medically appropriate, particularly when weighing the potential benefits versus risks.

In this modern day and age, we have witnessed the re-emergence of the health and longevity salesman. Many members of the public have been misled to believe in the magical powers of growth hormone and, because of the associated risks and other drugs typically sold along with growth hormone, this is a major health problem. The cash-only business of Web sites or clinics working closely together with compounding pharmacies to turn huge profits, the national and international organizations promoting the illegal use of the drug, and drug companies turning a blind eye to how and to whom their product is distributed bear similarity to what some investigative reporters have likened to a narcotics trafficking ring.

Thank you.

Chairman WAXMAN. Thank you very much, Dr. Perls.

[The prepared statement of Dr. Perls follows:]

The Growth Hormone Craze

Prepared testimony for the Oversight Committee, The United States House of Representatives.
Hon. Henry Waxman, Chairman
110th Congress

Thomas T. Perls MD, MPH, FACP
Associate Professor of Medicine
Boston University School of Medicine
February 12, 2008

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Oral Testimony

What is growth hormone?

Human growth hormone or hGH is produced by a pea-sized endocrine gland near the base of the brain called the pituitary gland. Its primary utility relates to growth in the height of children.

Deficiency in adults

HGH levels gradually decline in adults with minimal or no negative health consequences for the vast majority of the population. The anti-aging industry, the primary pusher and seller of hGH in this country, advertizes that normal declines in hGH cause decreases in strength, muscle mass, sleep, and sexual performance. They go on to claim that replenishing growth hormone to levels present at younger ages stops or reverses these problems as well as aging itself.[1, 2] This is a ruse.[3, 4]

There are a few medical conditions in adults that merit the use of growth hormone.

The medically appropriate and legal indications for hGH distribution

Recognizing the potential for growth hormone abuse, Congress amended the Food Drug and Cosmetic Act in the late 1980s and early 1990's[5] stipulating that hGH can be distributed to adults for only three specific indications approved by the Secretary of Health and Human Services.[6, 7]

1. AIDS Wasting Syndrome
2. Short bowel syndrome, and
3. Growth Hormone Deficiency (GHD)

GHD is very rare, occurring at a rate of about 1 adult out of 10,000[8] and the legal diagnosis requires documentation of disease, such as a cancer, or trauma to the pituitary gland and a failed stimulation test.[9] Often times, GHD is accompanied by deficiencies of other pituitary gland-produced hormones.

In January, 2007, the FDA released an alert reminding those that distribute growth hormone for anti-aging, body-building and athletic enhancement that they are doing so illegally.[10] *[see supporting document A]*

Use of hGH supplementation in healthy adults and potential risks

A recent Stanford University review of 31 clinical studies of hGH use among healthy, normally aging individuals found the only benefit to be a slight increase in muscle mass. The documented negative side effects included soft tissue swelling, joint pains, carpal tunnel-like syndrome, breast enlargement, and diabetes.[11] Other side effects include liver and heart enlargement, increased pressure around the brain and high blood pressure. In a 2002 Johns Hopkins study published in JAMA, about 50% of subjects experienced side effects, primarily joint pains. 13% developed elevated blood sugars or diabetes.[12]

Recent studies demonstrate strong associations between hGH and prostate, colon and breast cancers.[13, 14] In another study, investigators found that hGH enhances the ability of cancer to spread.[15] It is theoretically possible that normal declines in hGH with age may actually be protective against cancer.

Ironically, there is no credible scientific evidence that hGH substantively increases muscle strength or aerobic exercise capacity in normal individuals.[12, 16-18]

Illegal and medically inappropriate distribution of hGH

Since 1990, a growing network of compounding pharmacies, anti-aging clinics, and physicians have created what some within the industry estimate is a 2 billion dollar-a-year business for distributing hGH[19]– a distribution network involving hundreds of thousands[20] of weight training enthusiasts, practitioners and promoters of anti-aging medicine, and those who have fallen victim to growth hormone replacement scams.

I personally have found websites of 279 anti-aging clinics that advertise hGH treatment and 26 pharmacies that distribute the drug to these clinics or sometimes directly to users. I have certainly discovered only a fraction of what exists out there.

Of the seized anti-aging clinic records I have reviewed for the DEA, the average patient that first presents to the clinic is not a person in their 60s or 70s seeking alleviation of their age-related problems, but rather, a male in his late 20's to mid 40's, weight training nearly daily, in otherwise excellent health, clearly seeking anabolic steroids and hGH.

In summary:

1. Experts in the care of patients with hGH related problems clearly state that giving hGH for anti-aging or age-management is not medically appropriate particularly when weighing the potential benefits and risks.[21-23]

2. In his modern day and age, we have witnessed the reemergence of the health and longevity salesman. Many members of the public have been misled to believe in the magical powers of growth hormone and because of the associated risks and other drugs typically sold along with growth hormone, this is a major public health problem. The cash-only business of websites or clinics working closely together with compounding pharmacies to turn huge profits, the national and international organizations promoting the illegal use of the drug, and drug companies turning a blind eye to how and to whom their product is distributed bear similarity to what some investigative reporters have likened to a narcotics trafficking ring.[24, 25]

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[10] FDA Alert, IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html. *Section 303(e) (1) of the FDCA, 21 USC 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans 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 (HHS) under section 505 of the FDCA (21 USC 355) and pursuant to the order of a physician The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 years imprisonment and fines.*

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[24] Dunn S. Greeley Doctors Implicated in Illegal Steroid Ring *Greeley Tribune, Colorado*. January 26, 2008.
[25] Lyons B. Steroids beyond sports. Celebrities now among those linked to drug shipments *Albany Times Union*. January 13, 2008. URL: http://timesunion.com/AspStories/story.asp?storyID=654817&category=NATIONAL&BCCode=HOME&newsdate=1/13/2008.

SUPPORTING DOCUMENTS

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A. *FDA document clearly stating the distribution laws regarding growth hormone. See especially highlights in yellow.*

FDA Alert, IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html.

B. *A press release by a Beverly Hills clinic asserting the utility of replacing growth hormone and multiple other hormones to "youthful levels".*
URL: http://www.myhealthcollection.com/hormone_replacement_therapy_2.htm

C. *A compounding pharmacy sponsored meeting with talks about growth hormone for anti-aging and how to establish an anti-aging practice that distributes hormones.*

D. *United States map indicating, by State, a sampling of the number of compounding pharmacies and anti-aging, wellness and other clinics that advertise growth hormone replacement.* The true numbers of each are likely much larger. The top 4: California, Florida, Texas and Arizona.

IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN"

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

NOTE: This import alert contains the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person and it does not operate to bind FDA or the public.

PRODUCT: Human Growth Hormone (HGH); Somatropin

PRODUCT CODE:
64R[][]18 Human Growth Hormone (Hormone)
64R[][]20 Somatrem (Hormone)
64R[][]21 Somatropin (Hormone), Serostim, Nutropin, Humatrope
64R[][]22 Somatropin (RDNA Origin) (Hormone)
64R[][]23 Somatropin, Biosynthetic (Hormone)

PROBLEM: Unapproved new drugs; Misbranded drugs

PAC: 56008H

PAF: AAP-Approval

COUNTRIES: All

MANUFACTURER/ SHIPPER: All. Please see guidance for exceptions.

CHARGES: For finished drug products: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an effective new drug application (NDA)[Unapproved New Drug, Section 505(a)".]

and/or

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded in that it lacks adequate directions for its intended use. [Misbranding, Section 502(f)(1)]."

For all active pharmaceutical ingredients (APIs), including

those APIs intended for use in pharmaceutical compounding: "The article is subject to refusal of admission pursuant to section 801(a)(3) of the FDCA because it appears to be misbranded in that it lacks adequate directions for its intended use and it is not exempt from this requirement. (Misbranding, section 502(f)(1) of the FDCA) OASIS CHARGE CODE: UNAPPROVED; DRUGS DIRECTIONS

RECOMMENDING OFFICE: CDER, OC, Division of New Drugs and Labeling Compliance (HFD-310)

REASON FOR ALERT: Human Growth Hormone (HGH) is the active ingredient in a number of human prescription drugs approved for marketing in the U.S. under new drug applications (NDAs). FDA-approved HGH can be legally prescribed for a limited number of conditions including:

* hormonal deficiency that causes short stature in children;
* long-term treatment of growth failure due to lack of exogenous GH secretion;
* long-term treatment of short stature associated with Turner syndrome;
* adult short bowel syndrome;
* adult deficiency due to rare pituitary tumors or their treatment; and
* muscle-wasting disease associated with HIV/AIDS.

HGH has important benefits, but also serious, known risks. Among the possible long-term side effects of HGH is an increased risk of cancer, and other dangerous side effects have been reported, including nerve pain and elevated cholesterol and glucose levels. For this reason, HGH is carefully regulated in the U.S.

The cost of approved HGH products is high, averaging several hundred dollars per dose. Because of this high cost, HGH drugs have been counterfeited and unapproved HGH products

are offered for sale to U.S. consumers. For example, we have encountered HGH products imported as a lyophilized powder and declared as an active pharmaceutical ingredient (API) for pharmacy compounding. Some pharmacies promote compounded HGH for anti-aging purposes. It is sold as a "fountain of youth" in longevity clinics and to build body mass, weight loss, increase libido, and gain stamina. None of these indications are in the labeling of the FDA approved products.

The agency is aware of unapproved HGH finished dosage form products being imported into the U.S. and recently noted a large increase of HGH being offered for import for pharmacy compounding. If the drug is bought from foreign sources or over the Internet, safeguards built into the U.S. drug distribution system may be bypassed, placing consumers who use HGH at higher risk.

Section 303(e) (1) of the FDCA, 21 U.S.C. ⊥ 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans 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 (HHS) under section 505 of the FDCA (21 U.S.C. ⊥ 355) and pursuant to the order of a physician. The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement. Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA. A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 years imprisonment and fines.

HGH products are new drugs and cannot be legally marketed in the U.S. without an approved application. The few HGH products that have been approved for sale by FDA are sold either in liquid form or as lyophilized powders that are labeled for reconstitution by the health care professionals who dispense them. Accordingly, FDA considers both imported HGH lyophilized powder products and liquid HGH products to be finished dosage form drugs, not APIs. Unless these products are the subject of approved new drug applications, they violate section 505 of the FDCA, 21 U.S.C. ⊥ 355, and

may not be legally imported into the U.S.

Some HGH marketers may claim that their HGH drug products are intended for use in pharmaceutical compounding. These drugs should be evaluated on a case-by-case basis considering the factors in FDA Compliance Policy Guide, section 460.200, and the specific prohibitions set forth in section 303(e) of the FDCA, 21 U.S.C. ⊥ 333(e). The use of HGH in pharmacy compounding is addressed in more detail, below.

Some HGH marketers may claim that their HGH products are dietary supplements. FDA first approved HGH as a new drug in 1940, and HGH was not marketed as a dietary supplement, or as a food, before then. Accordingly, HGH is excluded from the definition of a dietary supplement under section 201(ff) (1) of the FDCA (21 U.S.C. ⊥ 321(ff) (3) (A)) because growth hormone was an article approved as a new drug under section 505 of the FDCA (21 U.S.C. ⊥ 355) before its introduction as a dietary supplement.

GUIDANCE: Districts may detain without physical examination all shipments of HGH finished drug products and all shipments of HGH APIs intended for the manufacture of a drug that is not subject to an approved new drug application (NDA). If field personnel are unsure of whether the HGH product at issue is an API or finished drug product, those personnel should contact CDER Compliance at the number listed below for further guidance.

Exceptions include:

(1) Finished drug products that are covered by approved NDAs;

Note: Shipments should be intended for persons who can lawfully possess and/or distribute HGH;

(2) APIs that are intended for use in the manufacture of finished drug products subject to approved or pending applications and where the approved/pending application covers the production and delivery of the API to the application holder by persons named in the application;

Note: Districts should contact the CDER Import-Export Team if they cannot confirm in CDER's databases that an HGH finished drug product is covered by an approved application or if an API is covered by an approved or pending application.

(3) APIs that are intended solely for tests in vitro or in animals used only for laboratory research, and are labeled in accordance with 21 CFR ⊥ 312.160(a)(1)(i);

(4) APIs that will be used for non-clinical research and development, under the conditions set forth in 21 CFR ⊥ 201.125;

Note: Importers of HGH API that claim to fall within exceptions (3) or (4) may obtain release of the detained substance only by providing documentation establishing that the substance meets the conditions set forth in 21 CFR ⊥⊥ 312.160 or 201.125.

(5) HGH intended for pharmacy compounding should be reviewed on a case-by-case basis. Consistent with its Compliance Policy Guide on human drug compounding and the prohibitions set forth in section 303(e) of the Act, 21 U.S.C. ⊥ 333(e), FDA may exercise its enforcement discretion in certain instances to allow the importation of HGH for use in traditional pharmacy compounding. In general, FDA should exercise its enforcement discretion only in those instances where (1) the compounded product is intended for a use that has been authorized by FDA for HGH under section 505 of the FDCA; and (2) the drug will be compounded to meet the individual medical needs of a specific patient who cannot be treated with an FDA-approved HGH drug product (e.g., the patient is allergic to the commercially available FDA-approved HGH product. To this end, FDA should consider the following factors when making a determination about whether it is appropriate to exercise enforcement discretion to allow entry of a shipment:

* the indication for which the HGH is being compounded;

* information indicating the individual medical

need for a specific patient; e.g., letter from physician or prescription;

* the volume of HGH imported and the appropriateness of the volume, based on considerations such as the amount of HGH used to compound a typical prescription;

* the medical need for the compounded product;

* the identity of the firms that will receive HGH from the shipment;

* the identity of the firms that have received the HGH in the past;

* the presence of statements on the HGH label, at the time that it is imported or offered for import, that the HGH is "For Prescription Compounding" and "Rx only";

* whether the HGH meets official compendia requirements where applicable (for example, as shown on a certificate of analysis), and

* whether the HGH comes from a firm that complies with drug registration and listing requirements

Additionally, the importer should affirm in writing that the HGH will be used solely for human drug compounding.

In order to facilitate FDA's case-by-case review, the information identified in points (1)-(5) above should be made available to FDA at the time the offer to import is made.

Discretionary release of these products under the Personal Importation guidance of Chapter 9 of the Regulatory Procedures Manual (RPM) is not appropriate.

If the District Offices have questions concerning the importation of Human Growth Hormone (HGH) they should contact CDER/OC/DNLC immediately.

Ada Irizarry 301-827-8967

PRIORITIZATION
GUIDANCE: N/A

FOI: No purging required

KEYWORDS: HGH, human growth hormone, somatropin; somatrem

PREPARED BY: Nawab A. Siddiqui, DIOP, 301-594-3871
William G. Nychis/CDER/OC/DNLC 301-827-8959

DATE LOADED
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The Truth about Human Growth Hormones (HGH) and Hormone Replacement Therapy from a Trusted Physician

Recent publicity around human growth hormones (HGH) and its use by athletes and celebrities prompts the question: "Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?" A trusted Beverly Hills Physician speaks out.

"Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?"

Beverly Hills, CA (PRWEB) February 1, 2008 -- With the recent publicity and press around human growth hormones (HGH) and its use by athletes and celebrities one might ask, "Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?" A trusted Beverly Hills physician, founder of Rejuvalife Vitality Institute in Beverly Hills, offers his own opinion.

"The whole truth," says Dr. Berger, "is that prescribed advanced human growth hormone therapy (HGH) for the treatment of diagnosed adult growth hormone deficiencies has also helped thousands of men and women feel more energetic, and more vibrant."



What you haven't read in many news accounts is that healthy people naturally secrete growth hormone throughout their lifespan, as it is produced by the pituitary gland. We have the highest concentration coming during our adolescence, but HGH levels fall off as we get older. Depending on the person, starting somewhere between the ages of 21 to 30 they aggressively start declining, averaging around an average drop of around 14% per decade. A 60-year-old can make half as much growth hormone as they did in their 20s. Any one with a history of a head injury in the past, no matter how subtle or slight is very likely to experience a deficiency of human growth hormone as well as other essential hormones. In 1996, the FDA approved growth hormone as a

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Skin reduction surgery
Hair Loss , Hair Care
Traumatic Brain Injury (TBI)
Stroke Rehabilitation
Irritable bowel syndrome (IBS)
Cancer Treatments

repla[illegible]ent therapy for adults whose HGH secretions had fallen belo[illegible]eir normal levels.

Dr. Andre Berger specializes in anti-aging treatments and non-surgical cosmetic procedures. As part of any treatment he offers, "We start by performing a comprehensive patient interview and examination and a series of diagnostic lab tests to determine if and where any hormonal deficiencies may be present, and then we correct any deficiencies. The Rejuvalife personalized hormone replacement therapy program modulates hormonal and metabolic balance to optimal youthful levels, so our patients can live and function at a stronger, healthier, and more efficient level."

"We understand that everyone is an individual with different hormonal and supplementary needs," says Dr. Berger. Rejuvalife's personalized hormone replacement therapy involves a series of hormones, supplements and other treatments designed to support and balance individual deficient hormone levels. The main types of hormones involved are estrogen, progesterone, testosterone, thyroid, DHEA, pregnenolone, and human growth hormone (HGH).

Some of the medical benefits seen from prescribed human growth hormone therapy (HGH) have been improved quality of life measures, energy and psychological well being, decreased fat and increased lean muscle mass, decreased blood pressure and improved cholesterol profile, improved bone-mineral density and skin tone, and enhanced memory and brain responsiveness.

Other hormone therapies for conditions associated with menopause also yield benefits. Menopause hormone therapy using bioidentical hormones can provide relief from menopausal symptoms and can reduce the risk of osteopenia that can lead to osteoporosis. Younger women with hormone deficiencies, premature ovarian failure or surgical menopause may use hormone replacement therapy for many years.

Though men don't experience menopause the way women do, they do go through an age-related change called viropause or andropause or "man-o-pause". Gradually, the symptoms become more apparent, driving male testosterone deficiency symptoms or andropause. They include increased fatigue both in the morning and at night, decreased interest in sex and increased irritability.

Unfortunately, many men are reluctant to seek hormone treatment which in the past has been cumbersome and time consuming. Thanks to scientific advancements, treatments are now available that are convenient, and offer an unobtrusive approach to hormone replacement therapy for men. It's been found that testosterone replacement in men improves libido, erectile dysfunction, mood, depression, memory, Alzheimer's, angina, heart disease, type 2 diabetes, muscle mass, fat, bone inflammation, and other quality of life issues.

If you have any questions or concerns about hormone replacement therapy treatments for women and men, or would like to find out more about Rejuvalife's treatments, please call (310) 276-4494 or go to www.rejuvalife.md.

About Rejuvalife Vitality Institute
The skilled and experienced physicians, nurses, nutritionists, exercise physiologists, dieticians, and estheticians at the Rejuvalife Vitality Institute are trained in the most cutting-edge scientific advances in less-invasive lipolysis procedures and anti-aging treatments. The Rejuvalife Vitality Institute is founded on an all-inclusive balanced approach to health and beauty with a special emphasis on customized patient care, education, and lifestyle changes.

Dental Directory , Menopause
Pregnancy Symptoms
MayoClinic , Dementia-memory loss
Reverse memory loss
Multiple sclerosis (MS)
Weight Loss , Influenza
Andropause-Male Menopause
Prostate Problems
Chiropractic and Pain Management
Headaches , Sinus

Alternative Medicine & Healing

Massage therapy , Stress Reliever
Bach's flower therapy , Wild Hoodia
Herbal Remedies , Meditation
Meditation - Breathing Tips , Yoga
Manuka Honey , Autism Diets
Meditation & Relaxation , Kinesiology

Healthy Lifestyle

Healthy Eating
Traditional Home Health Remedies
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Omega-3 , Elmore Oil , Antioxidants
Stress Relief - Natural Supplement
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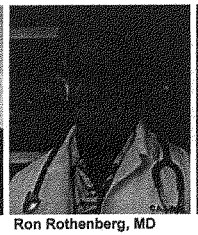
A Practical Application for Treating Adult Hormone and Nutraceutical Deficiencies

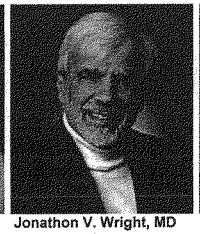
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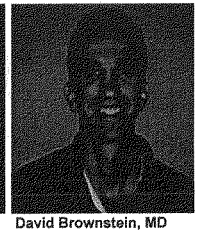
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Thierry Hertoghe, MD


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BIO-IDENTICAL HORMONE REPLACEMENT THERAPY SEMINAR

A Practical Application in Treating Adult Hormone and Nutritional Deficiencies
Utilizing Advanced Testing Protocols, Bio-Identical Hormones and Nutraceuticals.
Advanced Course with Basic Introduction.

February 28 - March 2, 2008

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4-DAY SEMINAR

- Thursday, February 28th
- Friday, February 29th
- Saturday, March 1st
- Sunday, March 2nd, 2008

This ***approved 26 CME Course*** will be held at:
HARRAH'S LAS VEGAS

- **To Register:**
  CALL: 866-444-9475 or 619-398-2740
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THIS COURSE WILL COVER THE FOLLOWING TOPICS!

- Introduction to Treating Adult Hormone Deficiencies
- Female Bio-Identical Hormone Replacement Therapy
- Lab Testing - Blood & Urine Testing
- The Laws & Hormone Replacement
- How to Prescribe - Algorithms for Hormone Optimization
- Andropause - Treating the Adult Male
- Treating Adult GH Deficiencies
- Iodine: Most Misunderstood Nutrient
- Nutraceuticals and Hormones
- Testosterone for Males and Females
- Oxytocin and Sexual Orgasms
- A Clinical Approach to Diagnosing and Treating Hypothyroidism
- The Importance of Hormones and the Cardiovascular System
- Case Studies on Female Hormone Replacement
- DHEA - Melatonin - Progesterone - Pregnenolone - Estradiol - Estriol - Testosterone - Cortisone
- Questions and Answers for Physicians
- Live Diagnosis of the Audience
- Physician Networking
- Bone Loss and Parathyroid

This course is approved by Medical Educators Consortium for a maximum of 26 CME credit hours toward category 1 AMA physician recognition award.

BIO-IDENTICAL HORMONE REPLACEMENT THERAPY SEMINAR

A Practical Application in Treating Adult Hormone and Nutritional Deficiencies Utilizing Advanced Testing Protocols, Bio-Identical Hormones and Nutraceuticals.

Advanced Course with Basic Introduction.

Thursday, February 28

The Basics of BHRT

11:00-12:00	Registration
12:00-1:00	Overview of Hormone Replacement in Age Management - Testosterone, DHEA, Pregnenolone, Melatonin, Growth Hormone, Estriol, Estradiol – Ron Rothenberg, MD
1:00-3:00	Origins of BHRT—We haven't caught up yet! – Jonathan Wright, MD The importance of Copying Nature with BHRT – Jonathan Wright, MD Hormone Replacement for Women, Basics – Wendy Ellis, ND Lab Testing Considerations: Saliva, Serum, 24 Hour Urine – Wendy Ellis, ND
3:00-3:30	Break
3:30-5:00	How to prescribe - The nuts and bolts of using Bio-identical hormones in age management. You will learn what tests to prescribe, the hormones and their dosages and what to do as problems arise – Ron Rothenberg, MD
5:00-6:00	The laws you need to know! BHRT: What compounds are used? Governing laws relative to prescribing, safety in prescribing – John Grasela, Pharmacist

Friday, February 29

BHRT Advanced Course

7:00-8:00	Continental Breakfast. How to open a turn key weight management program – Kim Ruby, CN (No CME)
8:00-10:00	An in Depth review of the clinical signs of endocrine deficiencies. This will be Doctor Hertoghe's best lecture pointing out hormone deficiencies that he sees in his practice and how you now can easily find these problems
10:00-10:30	Break
10:30-11:00	Lab Testing Considerations: The Serum testing done for the hormonally deficient patient – Thierry Hertoghe, MD
11:00-12:00	Treating Adult Growth Hormone Deficiencies In Your Practice – Ron Rothenberg, MD
12:00-1:30	Lunch on your own
1:30-2:00	Steroid "Treatment Failure" and Steroid Retention – Jonathan Wright, MD Estrogen Quotient & the Importance of Estriol – Jonathan Wright, MD
2:00-3:00	A clinical approach - Diagnosing and Treating Hypothyroidism – David Brownstein, MD Understand how to clinically diagnose hypothyroidism. How to recognize and treat Thyroid Hormone resistance? How to recognize and treat T4 to T3 conversion problems? – David Brownstein, MD
3:00-3:30	Break
3:30-5:00	The scientific data behind the clinical signs and symptoms of hypothyroidism Thyroid: the victories for improved diagnosis of hypothyroidism therapies The evidence for narrower reference ranges for the TSH is compelling. The population-based reference ranges for thyroid tests are too wide. Individual reference ranges are much narrower. Thyroid test values within the reference values associated with pathology, the scientific data – Thierry Hertoghe, MD
5:00-6:00	Testosterone Therapeutics and its modulation – Jonathan Wright, MD

This course is designed for medical professionals and is particularly relevant to naturopathic doctors, general practitioners, endocrinologists, internists, geriatricians, psychiatrists, sports medicine doctors, dermatologists, and cardiologists. Additionally, other health professionals including physician assistants, nurse practitioners and others in this field will find this highly relevant.

Educational Goals: To provide physicians with the theoretical and applied knowledge concerning the impact of the age-related decline in hormones on the body and the occurrence of somatic age-related diseases. To provide, in a comprehensive manner, the skills required to diagnose and effectively treat hormone deficiencies in their patients.

Educational Objectives: At the end of this educational activity, the attendee will be able to • Discuss the complex interrelationships of many hormones • Know how to diagnose hormone deficiencies and dysfunctions • Know how to use laboratory tests to confirm diagnoses and monitor therapies • Know how to formulate customized balanced therapies for patients with hormone related diseases

Educational Formats: Lectures, question and answer sessions, audio/visual aids, extensive printed syllabus.

Accreditation: The Medical Educator Consortium, is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit Hours: The Medical Educator Consortium, designates this educational activity for a maximum of 26 credit hours in category 1 towards the AMA Physician's Recognition award.

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of MEC and University Compounding Pharmacy. MEC is accredited by the ACCME to provide continuing medical education for physicians.

Faculty Disclosure Statement: The Medical Educator Consortium, in accordance with accreditation requirements, will disclose any significant financial interest or other relationship with the manufacturers of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and with any commercial supporters of the activity.

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Suzie Schuder M.D.
John Grasela R.Ph.
Rod Comunale M.D.
Errol Korn M.D.
Jay Mead M.D.
Allan Broughton M.D.
Angelica ZaidM.D.
Steven Center M.D.
Kim Ruby

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"A Practical Application of Treating Adult Hormone Deficiency"

Hormones control a lot more of our lives than we believe.

FRIDAY 8am-7pm

8:8:30	**The Unified Theory of Wellness – Ron Rothenberg M.D.** How the prevention of chronic inflammation affects nutrition, exercise, vitamins, stress reduction and optimal hormones. How to measure inflammation. How to apply these principles to a primary care, preventive or an anti-aging practice.
8:30-9:15am	**Patient Assesment.** Everything a doctor should do in assessing the patient from initial consultation, physical examination lab tests follow up lab tests , vitamin lab tests, starting doses and maintenence dose for the typical male and female patient. .**Andrea Cole Raub D.O.**
9:15-10am	**Lab testing** Urine spot testing used in hormone replacement . Latest advancements in GH testing IGF1, TSH, T-3, Lab assessment PSA ratios, estradiol levels in treating the Adult Hormone deficient patient. **Alan Broghton M.D.**
10-10:30	Break
10:30-11:00	**Saliva Lab testing.** How to use them in your office to test hormone replacement levels. **Jay Mead M.D.**
11:00-12:00	**Growth Hormone Replacement Therapy- Ron Rothenberg M.D.** Growth Hormone Replacement therapy of normal aging will be discussed in detail. Data on Cardiovascular, cognitive, immune system, body composition and quality of life benefits will be presented. Cancer risks and side effects will be analyzed. Differences between traditional endocrinology and anti-aging medicine approaches will be explained. Lab testing and treatment algorithms will be presented.
12:00-1:15	Lunch
1:15-3:15	**Bio-identical Estrogens and Progesterone Replacement Therapy. – Pam Smith** - Bio-identical hormone replacement therapy will be contrasted with traditional HRT with Premarin and Provera. The Women's Health Initiate studies will be discussed. Cancer risks assessed. The importance of Estriol (E3). A Practical plan will be presented.
3:15-3:45	**Break – Compounding demonstrations – visit the booths**
3:45-5:15	Doctor Zaid a practicing gynecologist will be discussing case studies of common problems and follow up treatments a physician would encounter in her practice treating women. This will include dosing, PMS, heavy menstruation, peri-menopause dosing, breast tenderness and more. **Angelica Zaid M.D.**
5:15-6PM	**"Compounds Used in Adult Hormone Deficiency"** present information on the most frequently used drugs used in the Bio-Identical Hormone Replacement Therapy along with cosmeceuticals that will improve your appearance. **John Grasela R.Ph.**
6:00-7Pm	**Social hour visit University Compounding Pharmacy - America's Finest Compounding Pharmacy** located 5 minutes away in America's Finest City. Complementary bus ride will take you to the pharmacy for cocktails and appetizers, only 5 minutes away and bring you back to the hotel.

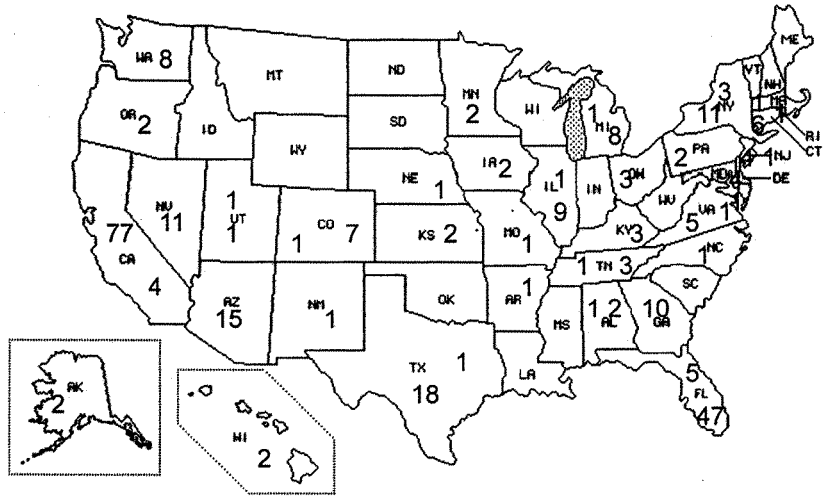
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SATURDAY 8:00am-6pm

8:00-8:30	**DHEA Replacement therapy- Ron Rothenberg M.D.** -DHEA replacement therapy for normal aging in men and women will be presented. DHEA and testosterone, cognitive function, immune system, body composition and inflammation will be discussed. .
8:30-9:00pm	**Melatonin** and the importance of Sleep & **Pregnenolone** and memory. **Ron Rothenberg M.D.**
9:00-9:45	**Testosterone Replacement therapy in men and women. Steven Center M.D.** Testosterone replacement and cardiovascular function, cognitive function, body composition, sexual function and inflammation. Cancer risks? Methods of delivery, lab testing & treatmentTestosterone
9:45-10:15	**BREAK**
10:15-11:15	**"Vitamins: Hype or Hope?" will teach the importance of taking Vitamins, Minerals, Essential Fatty Acids and Protein supplementation.** You will learn the importance of nutraceutical in the hormone deficient patient such as Indol 3- Carbinal, Co- Enzme Q, Vitamins and Minerals used as part of the age management process. **Pam Smith M.D**
11:15-12:00	**Comparison of weight management programs** for your obese patient- Zone Diet, Atkins Diet, Medi-Fast Diet programs A nutritionalist view of the best way to treat your obese patients and provide you with the knowledge to treat your motivated patients. Kim Ruby Nutritionalist.
12:00-1:15PM	**Lunch**
1:00pm 1:15	**Medifast weight loss program** and profit center for your office - **Kim Ruby Nutritionalist.**
1:15 -2:15pm	**Hormones: The Body-Mind Connection** –The effect of hormone insufficiencies on mood, memory and the ability to think will be presented for each hormone: thyroid hormone, testosterone, estrogen, progesterone, cortisol, and growth hormone. Reversing depressed or anxious mood and slowed mentation with bioequivalent hormone replacement therapy **Suzie Schuder, M.D.**
2:15pm-3:15	**Stress Management** - is an important part of preventing the aging process that a patient can do at home that works. How stress effects hormone levels by **Rod Comunale, M.D. & Errol Korn, M.D.**
3:15-3:45	Break
3:45-4:30	Safe use of cortisol –How cortisol effects cortisol levels and aging. Replacement cortisol therapy will be discussed. **Susie Schudder M.D.**
4:30-5pm	**Optimal Thyroid Replacement Therapy** – *Ron Rothenberg M.D.* Optimal Thyroid Replacement will be contrasted with traditional thyroid replacement with just T4 (synthroid). The problems with just looking at the TSH will be stressed. The prevalence of sub-clinical hypothyroidism. Optimal, (not just normal) Free T3 and T4 and treatment algorithms with T3 and T4 will be presented

5:00-6:00 How to open a successful anti-aging practice. Questions and answers. - **Pam Smith & Ron Rothenberg M.D.**

Sample of
Compounding pharmacies n=26 &
Anti-aging, age-management, longevity, rejuvenation or wellness clinics n=276
advertising on the internet that they provide growth hormone



Researched and constructed by Thomas Perls MD, MPH for the
Oversight Committee, House of Representatives. February, 2008

Chairman WAXMAN. Dr. Rogol.

STATEMENT OF ALAN D. ROGOL, M.D.

Dr. ROGOL. Good morning, Mr. Chairman and members of the committee. I am pleased that the committee has taken the time to examine this issue as hormone abuse and misuse has long been a concern to the Endocrine Society and its membership. The Endocrine Society's is the world's largest and most active professional organization of endocrinologists, representing over 14,000 members worldwide. We are dedicated to quality research, patient care and education.

Growth hormone is a natural hormone made by the pituitary or master gland. Once it circulates in the blood, growth hormone travels to bone, muscle and other tissues where it has many growth-promoting or anabolic effects and metabolic effects. In children, for example, growth hormone stimulates lineal growth or height. It is also important for the development of muscle and bone and the distribution of body fat throughout the body. In adults, growth hormone affects energy, muscle strength, bone health and psychological well-being. Having either too much or too little growth hormone can cause health problems.

The most common efficacy outcome for the use of growth hormone is an increase in linear growth. Growth hormone therapy employing replacement doses and modestly high doses is very safe. Very large data bases have noticed only minimal increases in scoliosis and slipped capital femoral epiphysis, both likely due to rapid growth and can occur in any therapy that promotes rapid growth or just during normal puberty.

The single most serious side effect is increased intercranial pressures and visual disturbance, which usually occurs in the first month of therapy as the kidney is re—learning how to handle salt and water. Stopping growth hormone therapy for a few days and then beginning again at half dose is usually all that is necessary to combat these side effects.

Growth hormone is also administered by physicians to promote psychological well-being and alter body composition in adults, as Dr. Perls has mentioned.

Now I want to address the off-label uses of growth hormone. Off-label use usually occurs in adults in two main spheres, the anti-aging market and the body image or athletic market.

It should be noted that off-label use comes with increased risk. One risk factor is that most off-label users are usually unaware of the correct doses, at least for athletes, and one can only assume that the doses administered to athletes must be very much greater than those used for the legitimate uses noted above. As I am sure you are aware, increased doses often mean increased risk.

With increased doses one might get into the range of acromegaly, as was mentioned. In children with growth potential this may cause gigantism, but I am unaware of anyone being able to take these doses—and actually pay for them—in the athletic sphere as teenagers. It should be noted that acromegaly is a serious disease with weak muscle and very significant heart disease.

Perhaps the most insidious off-label use is by athletes who are told they are receiving growth hormone but may actually be receiv-

ing a different substance or substances. Growth hormone is an injectable medication. Magazines and the Internet are replete with advertisements for growth hormone. Many of these preparations are taken orally and cannot be the protein hormone HGH, for it is not active by this route. Most likely, they contain amino acids, which do release growth hormone but usually only in much larger doses and given intravenously.

In fact, the amino acid arginine is administered as a test for growth hormone sufficiency. Most of the releasers are water soluble compounds and are excreted in the urine, with the main side effect being expensive urine. Some of the compounds purported to be growth hormone may have many ingredients, including anabolic steroids or steroid precursors in unknown quantities and the entire preparation of unknown purity and with multiple safety concerns. Longer term use of this anabolic agent may promote tumor growth.

In addition, the vast majority of clinically administered growth hormone is made by recombinant DNA techniques and thus not from human tissue. Growth hormone made from human tissue has been largely removed from the market because of a rare but fatal disease called Creutzfeldt-Jacob. Some of the growth hormone now available clandestinely is of human origin and may carry this biological agent.

Also worth noting is that, as with any injectable, one is at risk for diseases of shared needles: Hepatitis and HIV/AIDS, both of which are serious and may be fatal.

In summary, there are a number of FDA-approved uses of growth hormone in children and adults. These do not include anti-aging or improvement in athletic performance. The larger the dose of growth hormone administered, the more likely moderate and serious side effects may occur.

Mr. Chairman, thank you.

Chairman WAXMAN. Thank you very much, Dr. Rogol.

[The prepared statement of Dr. Rogol follows:]

THE ENDOCRINE SOCIETY

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TESTIMONY

Presented by:
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Representing:
The Endocrine Society

Presented to:
House Government Reform Committee on
February 12, 2008

Topic:
"Myths and Facts About Human Growth Hormone, B-12, and Other Substances"

The Mission of the The Endocrine Society is to advance excellence in endocrinology and promote its essential role as an integrative force in scientific research and medical practice.

Statement of Alan D. Rogol, M.D., Ph.D.

Before the House Government Reform Committee

February 12, 2008

Mr. Chairman and members of the subcommittee, I am pleased that the committee has taken the time to examine this issue as hormone abuse & misuse have long been a concern to The Endocrine Society and its membership. The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing over 14,000 members worldwide. We are dedicated to quality research, patient care, and education.

One of the remarkable roles of the endocrine system is the regulation of growth and development throughout our bodies. This work is directed by the pituitary gland — perhaps the most important "master gland" of the endocrine system. A small oval-shaped organ at the base of the brain, the pituitary gland releases a variety of hormones into the blood stream. One of these is growth hormone called *somatotropin.* Once in the blood, growth hormone travels to bone, muscle, and other tissues where it has many effects.

The hypothalamus, a small structure located at the base of the brain just above the pituitary, controls the release of growth hormone by the pituitary gland. In children, for example, growth hormone stimulates linear growth, or height. It is also important for the development of muscle and bone, and the distribution of body fat throughout the body. In adults, growth hormone affects energy, muscle strength, bone health, and psychological well being. Having either too much or too little growth hormone can cause health problems.

Allow me first to outline the clinical role of growth hormone. Growth hormone is administered to promote linear growth in short children. The FDA-approved indications for administering growth hormone are as follows:

- Growth hormone-deficiency
- Chronic kidney disease
- Turner syndrome
- Small for gestational age infants who fail to catch-up to the normal growth percentiles
- Prader-Willi syndrome
- Idiopathic short stature
- SHOX gene haploinsufficiency
- Noonan syndrome

The most common efficacy outcome for the use of growth hormone is increase in linear growth. Growth hormone therapy employing replacement doses and modestly high doses is quite safe. Very large data bases have noted only minimal increases in scoliosis and slipped capital femoral epiphysis, both likely due to rapid growth and can occur with any therapy that promotes rapid growth, or even normal puberty.

The single serious side effect is increased intracranial pressure and visual disturbance which usually occurs in the first month of therapy as the kidney is re-learning how to handle salt and water. Stopping growth hormone therapy for a few days and then beginning again at half-dose is usually all that is necessary to combat these side effects.

Growth hormone is also administered by physicians to promote psychological wellbeing and alter body composition in adults with:

- Growth hormone deficiency
- Muscle wasting due to HIV/AIDS

Now I want to address the off-label uses of growth hormone. Off-label use usually occurs in adults in two main spheres, the anti-aging market and the body image or athletic market.

It should be noted that off-label use comes with increased risk. One risk factor is that most off label users are usually unaware of the correct doses (at least for athletes) and one can only assume that the doses administered to athletes must be much greater than those used for the legitimate uses noted above. As I'm sure you are aware increased dosages often mean increased risk(s).

With increased doses one might get into the range of acromegaly—a serious disease that results from too much growth hormone in the body. In a child with growth potential this might cause gigantism, but I am unaware of anyone being able to take these doses (and pay for them) in the athletic sphere. It should be noted that acromegaly is a serious disease with weak muscle and very significant heart disease.

Perhaps the most insidious off-label use is by athletes who are told they are receiving "growth hormone", but may actually be receiving a different substance(s). Growth hormone is an injectable medication. Magazines and the internet are replete with advertisements for "growth hormone." Many of these preparations are taken orally and cannot be the protein hormone hGH, for it is not active by this route. Most likely they may contain amino acids, which do release growth hormone, but usually only in much larger doses given intravenously.

In fact, the amino acid arginine (or ornithine) is administered as a test for growth hormone sufficiency. Most of the releasers are water soluble compounds and are excreted in the urine with the main side effect of having expensive urine. Some of the compounds purported to be growth hormone have many ingredients including anabolic steroid hormones or steroid precursors in unknown quantities and the entire preparation of unknown purity and with multiple safety concerns. Longer term use of this anbolic agent may promote tumor growth.

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Also worth noting is that, as with any injectable, one is at risk for diseases of shared needles: Hepatitis and HIV/AIDS both of which are serious and may be fatal.

In summary, there are a number of FDA-approved uses of growth hormone in children and adults. These do not include anti-aging or "improvement" in athletic performance. The larger the doses of growth hormone administered the more like moderate and serious side effects may occur.

Chairman WAXMAN. Dr. Schlifstein.

STATEMENT OF TODD SCHLIFSTEIN, M.D.

Dr. SCHLIFSTEIN. Good morning. Thank you.

Not to be redundant, I'm going to focus in on the efficacy or the lack of efficacy of human growth hormone in regards to performance-enhancing ability or as a performance-enhancing drug.

As a performance-enhancing drug, human growth hormone is believed to increase energy, maintain or increase lean body mass, meaning the muscle-to-fat ratio in the body, help energy and muscles recover and help recover from previous injuries. It has only been shown to increase lean body mass, meaning the muscle-to-fat ratio. Studies have shown the benefits of human growth hormone healing from an injury have not been done or done well, and there's no shown benefit or efficacy of it as a healing agent for recovery from surgery and/or trauma. However, I have seen individual case evidence of that, yes.

When human growth hormone is used in combination with anabolic steroids, the effects of the steroids are believed to be amplified or improved. The combined use of anabolic steroids with human growth hormone together have shown increased muscle mass, speed and size. However, when the human growth hormone and the steroids combined were compared to studies were just using the steroids alone, it was very similar improvements, meaning, it was a questionable benefit whether the human growth hormone added upon the anabolic steroids really didn't really improve increased muscle mass, size and speed.

For example, test performance enhancements really typically means a repeatable exercise activity of like a bench press which you would do and then 6 weeks later, without practicing, do it again, 6 weeks again, to see if there's any improvement benefit from beginning to end without practicing, doing that activity.

When human growth hormone was tested by itself and in that short interval of 6 weeks, it was not shown to improve any functional compacitants or functional benefit gained during that time period when used alone. When used with anabolic steroids, it was a benefit, but it was very similar to the amount of benefit that was gained with using the anabolic steroids by itself.

There are a lot of limitations in the medical literature currently available looking at human growth hormone as a performance-enhancing drug, as a healing agent. Most of these studies were looking at it only in the short term. There's no studies really looking at somebody using human growth hormone in another capacity, which is looking at human growth hormone in combination with steroids, but someone who is cycling on steroids and then cycling off but still maintaining usually the human growth hormone. Meaning if they're taking both together in a cycle which could be anywhere from 6 to 12 weeks of the anabolic steroid, when completing that cycle, in order to come off that, cycling off that and then maintaining the use of the human growth hormone, the believed benefit is to hopefully help maintain or prevent loss of that muscle mass gained when using the anabolic steroid with the human growth hormone. It may delay loss of muscle mass or strength during that time period but really fails to maintain them

at the same level when using the human growth with the anabolic steroid in combination.

As regards to healing from injuries, we know that it does have a direct effect on bone tissue and case reports of faster healing of fracture injuries with doses of human growth hormone have been out there but no clinical evidence in a study-based format. However, there was also a believed potential benefit in users of it in young athletic patients that they have more energy, which hasn't really been assessed and is difficult to measure. Improving soreness and recuperation from a workout, meaning are they able to work out better and harder because they are able to recuperate faster? And no assessment of how much soreness or prevention of lactic acid buildup and prevention of soreness and muscle pain after a workout to allow to work out again. There's questionable benefit from that respect as well.

Certainly the side effects of human growth hormone are plentiful, as previously discussed; and many of these people who were self-treating themselves and using human growth hormone in this manner as a performance enhancer are finding out the side effects by titrating it and then, once they get the side effect, backing off.

We do see acute onset of carpal tunnel, large hands, swollen hands, numbness, tingling from acute onset, meaning they're taking too much. We do get joint pain, muscle pain, joint swelling, enlargement of the joints, especially the fingers and knuckles. As the bone grows and it grows wider, as the growth plates already—and doesn't elongate anymore, you get excessive bone growth, which is not only causing problems in the short term but we're seeing patients with much earlier and much more advanced degenerative or osteoarthritis formation in these joints. The bones are overgrowing tremendously and can't take that strain and wear and tear.

Yes, we've seen incidences of patients with getting elevated blood sugars and continuing elevated blood sugars from the fact they're treating themselves with insulin in order to get their sugars under control and, in cases, turning themselves into diabetics. Quite often, on a lot of these Web sites you'll see adjunct medications, meaning medications to control side effects, sold right next to the place where they're selling the human growth hormone, where they're selling insulin, they're selling Lasix so you get rid of the excess water—it's a diuretic—painkillers for joint pain and stiffness, anti-inflammatories, pain medicine, anti-anxiety medication, and then other medication to help them wake up after sleeping well. Sleeping well is important for anyone who works out regularly, because that's when your body tends to heal more; and getting enough sleep certainly helps them maintain muscle mass as well.

So, with anything you inject, there's a risk of skin infection, cellulitis, abscess formation, fibrosis scar tissue, which I have seen. I have seen a lot of it. After a while, they start running out of places to inject themselves because there's so much scar tissue in there. Having to have areas resected because there's fluid collections in there, especially with anabolic steroids that are oil based because they don't dissolve. They really don't break down, and they tend to sit there and get infected chronically and have to be resected.

When patients are treating themselves or self-treating themselves, then they're usually using multiple poly pharmacy techniques in order to control or limit some of the side effects in order to maintain the supposed benefits of using those drugs.

Also, with a tremendously large fraudulent market—meaning a fake product—out there, there's a lot of other drugs that are being used in replacement of the human growth hormone that's very hard to distinguish between the two by looking at it. Most of the companies—pharmaceutical companies that produce this and legitimately produce this, you have on their Web sites ways to detect fraudulent market or fake products, because they're very hard to distinguish. They're very well done, and they're changing all the time in order to keep ahead of the market.

Quite often, it's HCG which is very inexpensive and easy to get. HCG is sometimes used by people who are on anabolic steroids but are tapering off a cycle. It helps simulate your body to help produce more hormones itself. So they taper off. They don't bottom out completely from having a low testosterone level. So they get a little benefit in feeling like it's working, but it's really not doing much. And then, also, it's sometimes combined with an anabolic steroid, so they really think they're getting a benefit where they're really not getting a benefit from that.

Chairman WAXMAN. Dr. Schlifstein, let me stop you there, because I wanted to ask some questions.

[The prepared statement of Dr. Schlifstein follows:]

Congress of the United States

House of Representatives

Committee On Oversight and Government Reform

February 12, 2008

Clinical Realities of Human Growth Hormone (HGH), B 12, and other Substances of Abuse as Related to Committee's Investigation Into Allegations of Abuse in Major League Baseball

Dr. Todd Schlifstein

Department of Rehabilitation Medicine

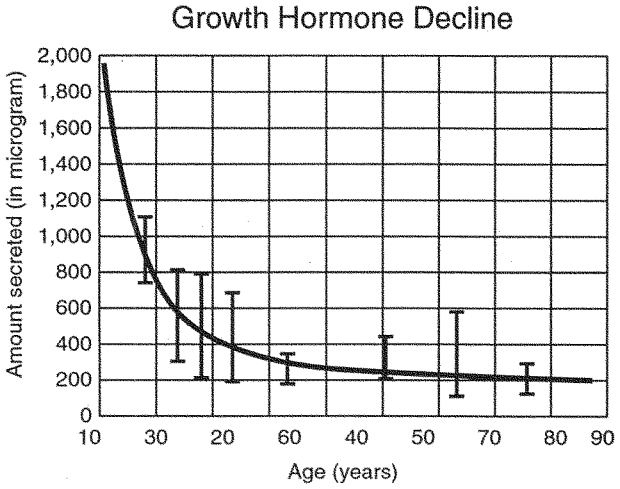
NYU Medical Center-RUSK Institute of Rehabilitation Medicine

Assistant Professor, NYU School of Medicine

Human Growth Hormone (HGH) use has been increasing over the past several years in professional ports, but also in other populations. When professional athletes and other celebrities use HGH, it has a trickledown effect to the rest of the population. HGH is used for its potential performance enhancing effects, muscle building effects and as an anti-aging treatment. These uses of HGH are not what these medications were indicated to do. As with any medication, there are side effects.

Human Growth Hormone is normally found in the body and produced by the pituitary gland. Its affects many body systems including muscle, bone, and skin. Normally, after the age of 30, the production by the body gradually decreases. It is medically indicated for dwarfism (when the body doesn't produce enough

HGH) and in HIV patients to prevent and treat wasting by helping to increase Lean Body Mass (LBM). From studies from these indications, we also see some of the side effects of HGH.



As a performance enhancing drug, HGH is believed to increase energy, increase or maintain lean body mass (muscle to fat ratio), helps muscle recovery and helps to recover from injuries faster. It has been shown to increase Lean Body Mass. Studies showing the benefits of HGH with regards to healing, have not been done. I have seen case evidence of this benefit. When HGH is used in combination with anabolic steroids, the effects are amplified. The combined use increases muscle strength, speed and size. When HGH and anabolic steroid are used together, they did show increased performance. Studies have had mixed results when comparing the performance enhancing benefits of using both HGH and steroids versus using steroids alone. Performance enhancement means an increase in speed or strength in a measureable activity without practice of that activity. For example, the number of reps in a bench

press at start and then again at 6 weeks. When studying the performance enhancing effects of HGH by itself, it has failed to improve performance. It has been shown to increase muscle mass.

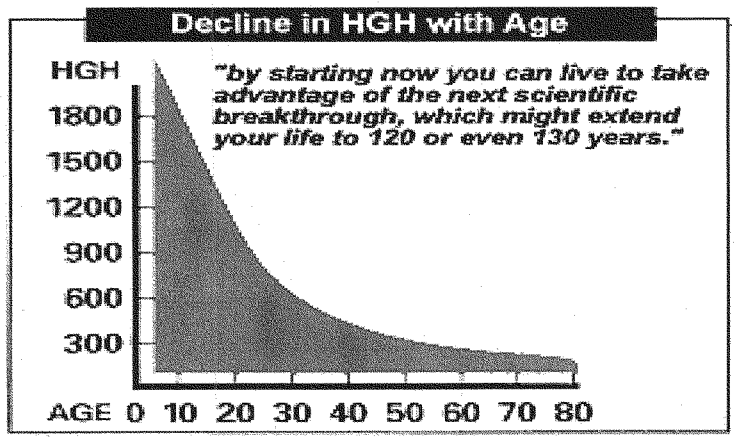
There are many limitations in the medical research that is available. The studies do not look at HGH use over the long term. The studies do not look at the effects of HGH when cycling on and off steroids. When used in this manner, it is used to help maintain the gains made when on steroids. Need to compare people who cycle on and off steroids with and without HGH to see if performance enhancement better when off steroids but still using HGH. Also, it is difficult to assess if it gives energy to help workout out better or harder. No assessment as to length of recovery time from workout or injury. No assessment as to whether it decreases muscle soreness post workout.

At the present time, there is no urine test for HGH and no reliable blood test for HGH. Recent developments in Australia have found a blood test that was effective in detecting HGH when it is used with anabolic steroids.

Body builders and weightlifters have been using HGH for many years. It is through their trials and errors where we see the benefits of HGH, but we also see the side effects and limitations. HGH has helped body builders and weight lifters gain strength and size as never before.

Anti-aging medicine has also expanded its use into other populations. Trying to slow the aging process and appear younger, people have been prescribed and self prescribed HGH as well as other drugs. HGH will make your skin appear more youthful by increasing blood flow, maintaining Lean Body Mass, and increasing elasticity. It helps keep muscle mass even when decreasing caloric

intake. This type of use has also greatly increased the demand for HGH.



Websites have very misleading information. Live to 120 or 130 years old? HGH has not been shown to increase your lifespan. In animal studies, it actually decreased life span as animals died of tumors growing at extremely fast rates.

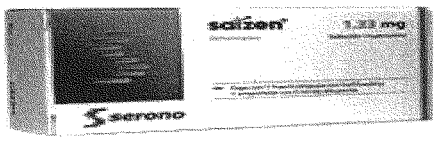
Side effects of HGH depend on type, dose, and length of use. Side effects also can be amplified by steroid use. Without close medical monitoring, undiagnosed tumors will grow much faster than normal. When too much is used acutely, rapid onset carpal tunnel syndrome is seen with large, swollen, painful, and numb hands. I see patients come to the office with this presentation, and they are surprised that I know what they are doing.

HGH also elevates your blood sugar levels which can make you feel tired, nausea and fatigued. With continued use in this manner, there are cases of causing diabetes.

Growth plates in adults are closed. When using too much for too long a period of time, bones will overgrow at growth plates as

the can no longer elongate. In the face, peri-orbital ridges thicken giving a cro-magnum appearance with a square face. Hands and feet get wider with large knuckles. Joints may get stiffer and degenerate faster.

Muscles that grow beyond their normal limits get tears, sprains and strains in atypical locations in atypical ways. The muscle growth is out of proportion to the tendon growth, thus changing your body's natural biomechanics. Often, patients come in with unusual and severe muscle and tendon tears with minimal stress causing the tear.



As with anything injected, there are risks of infection, bruising, scarring, and disease transmission with needle reuse (hepatitis, HIV). I have seen abscess formation, cellulitis, and scar tissue formation. Sometimes these problems need antibiotics and even surgery.

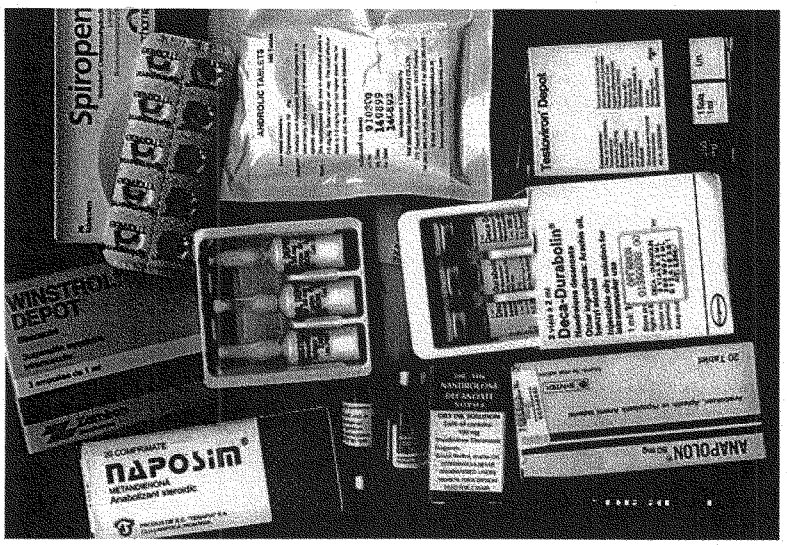
There is also a large market of fraudulent products being sold. Most of these are HcG. It has only a small physical benefit, but it is hard to distinguish real from fake. With such good forgeries out there, the market place is quite large.

With people self treating, the incidence of these side effects is certainly higher. Websites that sell these drugs often give instructions and offer remedies for side effects. These remedies are often other drugs. For example, they sell insulin to inject to help lower their

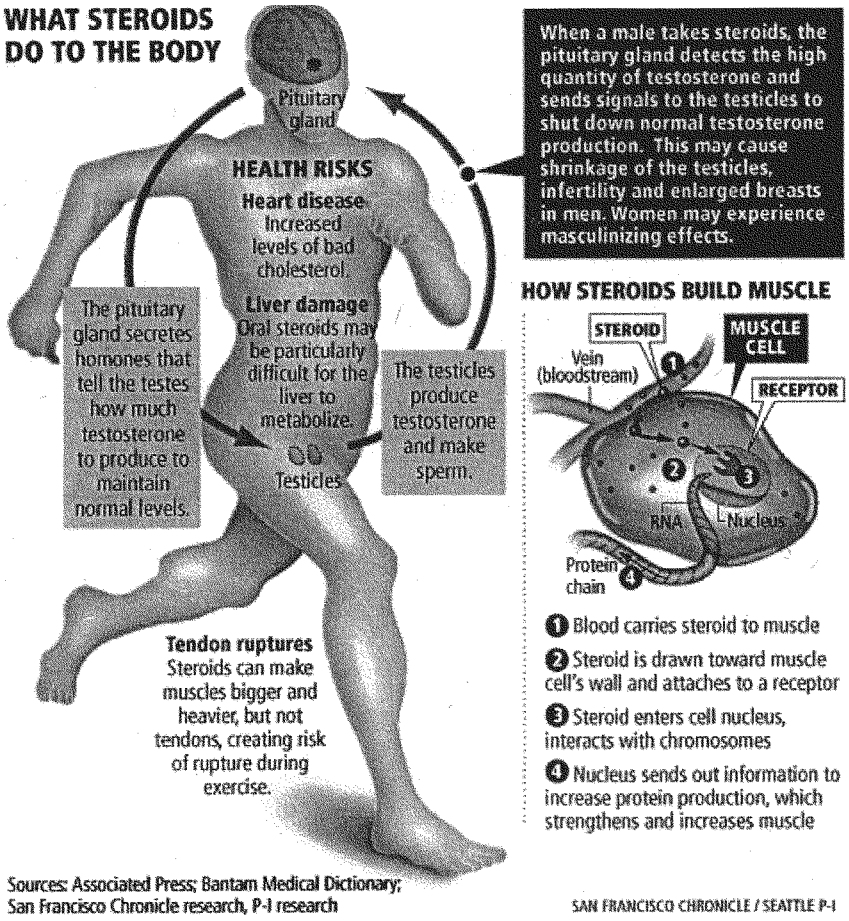
elevated blood sugar from HGH. Diuretics are used to help mask drug testing and lose excess water from retention.

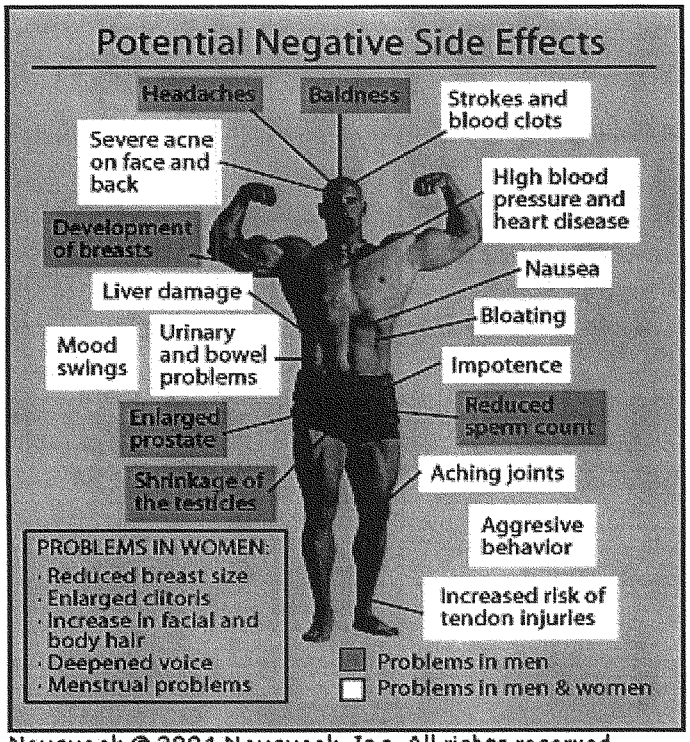
Opioid analgesics are largest growing drugs of abuse in the United States. Abusers of HGH and steroids often use opioids to help control muscle and joint pain .Other medications such as valium and xanax are used to control anxiety and help them sleep. Stimulants help to wake up, increase attention and focus. These drugs are also part of the polypharmacy of self treatment. Studies of anabolic steroid users show that they often are using multiple drugs.

Anabolic steroids should be mentioned as they are often taken with HGH for performance enhancement.



Oral, topical and injectable forms are available.


WHAT STEROIDS DO TO THE BODY
Pituitary gland
HEALTH RISKS
Heart disease
Increased levels of bad cholesterol.
Liver damage
Oral steroids may be particularly difficult for the liver to metabolize.
Testicles
The pituitary gland secretes homones that tell the testes how much testosterone to produce to maintain normal levels.
The testicles produce testosterone and make sperm.
Tendon ruptures
Steroids can make muscles bigger and heavier, but not tendons, creating risk of rupture during exercise.
When a male takes steroids, the pituitary gland detects the high quantity of testosterone and sends signals to the testicles to shut down normal testosterone production. This may cause shrinkage of the testicles, infertility and enlarged breasts in men. Women may experience masculinizing effects.
HOW STEROIDS BUILD MUSCLE
STEROID
MUSCLE CELL
Vein (bloodstream)
RECEPTOR
RNA
Nucleus
Protein chain
1 Blood carries steroid to muscle
2 Steroid is drawn toward muscle cell's wall and attaches to a receptor
3 Steroid enters cell nucleus, interacts with chromosomes
4 Nucleus sends out information to increase protein production, which strengthens and increases muscle
Sources: Associated Press; Bantam Medical Dictionary; San Francisco Chronicle research, P-I research
SAN FRANCISCO CHRONICLE / SEATTLE P-I



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The benefits from these drugs may be very appealing to some people, and these drugs seem even better when sports stars use them. The use of performance enhancing drugs by professional athletes endorses its use. Athletes get millions of dollars to endorse a soft drink or energy drink, so we shouldn't under estimate their influence on drug use. This increases demand. On line, other countries as well as other sources create a large supply. Lets not take our eye of the ball. Whether a record has an astericks or not makes

an interesting sports debate. But the bigger issue is the health and well being of millions of people.

Chairman WAXMAN. I wanted to start the questions for the 5 minutes that each Member will have.

We pay a lot of attention on steroids because steroids does enhance performance. Isn't that accurate?

Dr. SCHLIFSTEIN. Yes, that's an accurate statement.

Chairman WAXMAN. But it has very dangerous side effects. And we know that, if children use it, it can even cause psychiatric problems as well as other medical problems. There's also a test. So if an athlete is using a steroid, it can be detected in the urine.

Human growth hormone, on the other hand, cannot be detected by any tests that we know of at the present time. Isn't that accurate?

Dr. SCHLIFSTEIN. Yes. At the present time, there's pending stuff working——

Chairman WAXMAN. People are working on it. But some athletes believe that if they use human growth hormone, it's going to increase their performance and they won't get caught.

Dr. SCHLIFSTEIN. Right.

Chairman WAXMAN. Are they mistaken? Does it increase their performance?

Dr. SCHLIFSTEIN. Well, the reason it has that appeal that way is because you can't detect it; and if you are on like a steroid and you stop it, you try to falsely inflate yourself into thinking you're going to maintain the benefits you have gotten from the steroids and hopefully make it longer lasting. It may help a little bit in the short term, but that effect I think will be very short lived.

Chairman WAXMAN. That's a short term in conjunction with steroids.

Dr. SCHLIFSTEIN. Right. As it tapers off, you want to try and hold onto that benefit because it's really not going to——

Chairman WAXMAN. A lot of them are using it instead of steroids.

Dr. Rogol, there is this widespread belief that using human growth hormone can increase your muscle mass. Does it make you faster? Does it make you stronger?

Dr. ROGOL. Well, this is the second time—that's two out of three for the Olympics: ciltius, altius and fortius—higher stronger and faster. And the answer is, probably not by itself. So as you look at Sylvester Stallone and say that's a different body for a 61-year-old man, he may very well have been taking growth hormone, Jintropin, that he said he was taking. None of us in this room knows what else he was taking; and I think it's the "what else," meaning anabolic steroids, that made the difference.

There is, sir, no question that there is a lipolytic, that is, fat breakdown effect and mild anabolic effect. So if you're a bodybuilder and you want that ripped look, that might make sense. But that's about the only place. There are no studies of people who are honest-to-goodness growth hormone deficient given growth hormone legitimately that shows that their strength is very much better and certainly no performance data, sir.

Chairman WAXMAN. Well, some people believe it's going to make them more ripped and stronger and faster and more able to perform. What risks are they taking?

Dr. ROGOL. Well, if you are an adult—most of them have been mentioned by the two gentlemen who flank me. The major risks

are, first of all, early on, the edema, muscle aches, joint aches. And remember, sir, these are anabolic hormones. They lead to the production of insulin-like growth factor one, IGF–1, which is really pro growth of tumors. So the aging population, whether it's men like we are and prostate cancer or women with breast cancer, harbor smaller, earlier tumors than the older people; and this may just lead to their growth. Theoretical to be sure. But absolutely true in vitro. In addition, can show the effects of growth hormone but especially IGF–1 on that particular biological effect.

Chairman WAXMAN. Dr. Perls, you know a lot about human growth hormone. If a young athlete were asking you whether you should take it because he thinks it will increase his muscle mass, lower his fat and help him be a better athlete, what would you say?

Dr. PERLS. First, it's certainly not worth the risk; and, second, you know that I would hope that he would go about these things in an honest way. One of the dangers of the athletes or entertainers taking this stuff is providing a very bad example for all these young people certainly. There are no clinical studies showing the long-term risk in terms of cancer, but certainly short-term studies show that there is substantial risk.

I think kind of the bigger picture is is that we have an anti-aging industry and other areas of the market that do an unbelievably good job of marketing an incredible false sense of safety and an incredible false sense of tremendous benefits from these drugs; and out of that comes a huge amount of money, $2 billion a year, for these hucksters.

I think that there's—you know, if you look at the Internet, blogs where a lot of these athletes or bodybuilders are discussing what to do in terms of the recipes and cocktails and what have you, everybody's just kind of playing a guessing game, saying this works, this works, this doesn't work, don't do this because you'll get caught. It's almost like a cult-like presence, and nobody is really like making any decisions with the help of caring physicians like from the Endocrine Society or elsewhere that really understand the risks and benefits.

Chairman WAXMAN. They're not relying on the science; they're relying on mythology. Is that correct sir?

Dr. PERLS. And it's almost how much of this is placebo. Again, they're not just a danger to their bodies. It's a huge danger to their pocketbook. And a lot of the people that are taking this stuff, they're not getting the lab tests. They're not being well followed.

So they are really in danger of developing really significant heart disease, for example. Not so much from the growth hormone, but I very rarely have ever saw growth hormone taken in isolation. It's—you're almost always given it with a lot of other drugs, anabolic steroids, HCG, Eliminex, all kinds of drugs. So it's really amazing to me that they can take all these things. They're not getting followed by any lab tests. They're not really being followed by a physician. They're really putting themselves in significant danger.

Chairman WAXMAN. Thank you very much.

Mr. Davis.

Mr. ISSA. Thank you, Mr. Chairman.

I guess I'll start off with B–12, since that's a relatively new part of our investigation.

Dr. Shurin, you spoke mostly on B–12. Let me ask it, if you will, on behalf of the vitamin industry. Medical professionals thought, by and large, will tell us that the—whatever it is—several billion dollar industry, from One a Day to every other vitamin, just gives you expensive urine. Is that a generalization that it's pretty darn accurate that the medical industry and the science industry and certainly pharma tells us that there's very little benefit to most vitamins, particularly oral?

Dr. SHURIN. Yeah. I think the shotgun approach, in which you just give lots of vitamins because, for the most part, more doesn't do you any harm—there are situations in which it does. People tend to take it rather than or figuring out how to eat a balanced diet, how to get vitamins in the ways that are far better for their bodies.

Mr. ISSA. The medical profession tends to give antibiotics without knowing exactly what the infection is.

Dr. SHURIN. It happens all the time, yes.

Mr. ISSA. The reason why I want to focus on that, from a practical standpoint, B–12 is simply another vitamin that a vast, vast number of people believe will help them.

Dr. SHURIN. Right.

Mr. ISSA. Now I happen to have a mother who, during most of her pre-menopausal days, was getting various vitamin B–12 supplements by injections by my own first cousin who was a family doctor who thoroughly believed that this was something that was helpful for her persistent anemia. He may have been right. He may have been wrong. But I grew up with those injections.

Is there any reason for this panel to get involved in a multibillion dollar industry and debate the merits of vitamin supplements in general here today that would be—where we would be effective? We have in the past weighed in, both this committee and the chairman's other committee and my other committee, the Energy and Commerce Committee. We have gotten involved in the vitamin industry; and, at the end of the day, it's still a conundrum. Would you say that is roughly correct?

Dr. SHURIN. Yeah.

There are several issues here. One is that many of the vitamins—certainly, the evolution of discovery of these vitamins is people gave cocktails, like all the B vitamins sort of came together, and so you could only give them together. And then, as you've dissected out, we now have a lot more components. So it's a common practice for many older practitioners to give these sort of cocktails.

The biggest danger for situations in which they're given without a clear understanding of what you are giving them for is you may not—if you actually have a problem, is you may not be making the underlying diagnosis.

For instance, one of the common situations as you are describing with your mother is that the person may have a mild hematologic disease, such as beta thalassemia minor, which is an inherited blood disease that doesn't get better no matter what you give. And the biggest problem is that there's an anxiety that's associated with

it because I've got anemia and is that—does that mean that there's something serious?

The vitamins themselves generally don't hurt. Excess iron, of course, can hurt.

I would say that the major damage that's done is the failure to diagnosis and to treat significant problems and then just the costs.

Mr. ISSA. OK. And because so much of our hearings have focused on athletics, I'm going to assume for today that the taking of vitamins by athletes of all levels probably is so benign as to not be a major part of what we should be looking into today. Rather, steroids and human growth hormone are. Which brings up a real point that I'd like to make in the remaining time.

It appears as though this committee's good work under both the chairman and ranking member have led to professional and amateur athletics doing testings for steroids, and I think that we should all be very proud that's happened and happened without legislation. However, it appears that since there's no test for human growth hormone and it appears as though there is a legitimate—I'm going to rephrase that—there is a reason that people would think that it works as part of an ongoing attempt to evade detection, that we need—this committee needs to look at the development of a test for human growth hormone, perhaps federally funded.

And, last, if—and anyone can answer that disagrees—whether Sylvester Stallone, Jesse Ventura, Arnold Schwarzenegger or Hulk Hogan—two of whom became Governors. It appears as though there is, unfortunately, a tendency for the good-looking body on the runway to be part of both steroids and human growth hormone; and, up until now, we really haven't, as a committee, attacked that. Because, basically, looking good on the runway, looking good running for—well, the chairman looking good running for re-election in Hollywood and Los Angeles has not—and he does look good, and he does get elected by a wide margin with Hollywood and Beverly Hills——

Chairman WAXMAN. It ain't my looks.

Mr. ISSA. It could just be the physique, though.

But if you would comment on the fact that, as of right now, that has not been successfully looked at. In other words, outside of athletics, we're not presently testing; and we do have at least two Governors who had incredibly good-looking bodies that may have contributed to their election.

Chairman WAXMAN. The gentleman's time is up, but let's see if the panel wants to answer any of these points.

Dr. ROGOL. In full disclosure, I'm working with both USADA and WADA on the growth hormone testing. There's certain things I can say; there's certain things I can't.

Mr. ISSA. We can keep a secret.

Dr. ROGOL. Yeah, right. Is this the IRS?

It is a blood test, first of all, No. 1; and, No. 2, so there are a lot of difficulties with labor contracts, what you're allowed to do and what you're not. There are some very good tests in the urine that prove you can't find HGH in the urine. So while there are no tests that are presently available that will show HGH use beyond

a couple of weeks, there indeed are tests and they are in the mill that pass the International Olympic Committee's standards, sir.

Chairman WAXMAN. Thank you very much.

Dr. Perls, you wanted to make a quick comment.

Dr. PERLS. Another interesting idea would be to compel the pharmaceutical companies to add some kind of inert marker to the drug so that it does absolutely nothing in terms of biological activity, but it would be easy to detect. This could be with growth hormone. It could be with anabolic steroids and so on. That would be a little difficult to compel Chinese makers of the growth hormone, but, hopefully, the government has other ways to interrupt the flow of that. But that might be another idea to pursue.

Chairman WAXMAN. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Dr. Rogol, you know, as we sit here, we have national surveys—and I'm sure you are familiar with them—that tell us as many as 4 percent of high schoolers are taking anabolic steroids and as many as 5 percent, 1 out of 20, are using human growth hormone. A recent confidential survey of kids in grades 8 to 12 is even more disturbing. Over half of the kids who have used steroids said that pro athletes influence their decision to use those drugs. Does that surprise you at all, any of you?

Dr. ROGOL. No. I've looked at the data. The data are anywhere from 2 to even up to 12 percent. I think the issue of HGH is not correct, and the reason is—many kids think they're taking HGH and, when you ask them, they're taking something by mouth. That could not be HGH. The wallet test is probably the most difficult test for the teenage athlete to pass. We're talking about tens of thousands of dollars for a year. So I think the abuse of honest-to-goodness HGH is really quite a bit lower. The steroid numbers are exactly in the range that you mention.

Mr. CUMMINGS. The fact is is that those steroids are harming our children, though.

Dr. ROGOL. I believe so, yes.

Mr. CUMMINGS. And the fact is is that I think sometimes the media concern me because they seem to think that the committee is just showboating. And the reason why we started these hearings from the very beginning is because we were concerned that young men and women were taking these substances, trying to emulate their sports heroes. And here's the most concerning part of the survey, it's that three of every five kids using steroids were also willing to take it even if it shortened their life.

Dr. ROGOL. Yes.

Mr. CUMMINGS. That's deep.

Dr. ROGOL. It is. It goes back to an athlete dying young. It's exactly the same phenomenon. If they could win a gold medal, they didn't care what happened 10 or 20 years down the road. Yes, sir.

Mr. CUMMINGS. Is that, Doctor, because—when we're younger we feel like we could do anything and we—or is it just that—are we going for the goal, are we going for the glory, and figure when we get the glory it's OK that we just burn out? I mean, what is that about?

And is it something to do with a person just being young and not understanding—as one of my people in my district once said to me after they had used this kind of stuff, he said, I used it; and he said, I can forgive myself, but my body won't forgive me.

I mean, is it that kind of thing, Doctor?

Dr. ROGOL. Well I'm not sure it's—that's a very telling comment. But, remember, we're talking about adolescents. I deal a lot with adolescents. They are invincible. We all were. Never mind voting yes, but we all were.

But the point is, you know, the brain isn't fully developed; and so the executive function, the frontal lobe part that tells you, hey, you might not want to do this because of the consequences, isn't so developed. So you have the push to take it and you don't have the pull back. And so the immature—even though it's an adolescent, the immature brain is a bad thing to have, by the way.

Mr. CUMMINGS. The immature brain says take me? Is that what you are saying?

Dr. ROGOL. Yes. This is Alice in Wonderland.

Mr. CUMMINGS. All right. That's all right. And then the immature brain also says, hey, you know, we're doing pretty good, let's not go backward. Is that——

Dr. ROGOL. Well, I don't know about let's not go backward. Let's not look forwards is probably a better way of saying it, Mr. Cummings.

Mr. CUMMINGS. I got you. Now, let me just go to your testimony. And I saw in your testimony that there is a long list of legitimate uses for children. And some of these diseases have names I'm not even sure how to pronounce. So can we simplify this list by saying that growth hormones is used for kids who are not growing enough? Is that——

Dr. ROGOL. Well, that are not growing enough for reasons that are stated here. Kids who are caloric deficient also don't grow well. Growth hormone would not be an appropriate drug. So it is not growing well or normally and having one of these conditions. In double blind trials or at least in legitimate trials, the FDA has approved the use of growth hormone in these conditions, most of which are rare as can be.

Mr. CUMMINGS. And—I mean—and when you say rare as can be, can you give me some numbers? I'm trying to figure out if somebody would be using these things and——

Dr. ROGOL. Growth hormone deficiency is about 1 in 4,000; chronic kidney disease is probably about the same. Turner Syndrome is 1 in 2,500 girls. Small for gestational infants who fail to catch up to normal growth is probably 1 in 5,000. Prader-Willi is more like 1 in 15,000. Idiopathic short stature is the bottom 1 percent. So it is a 1 out of every 100 of us. SHOX haploinsufficiency is a gene problem. That is about 1 in 4 or 5,000. Noonan syndrome is about the same. On average, between 1 in 4,000 and 1 in 10,000, sir.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Cummings. Mr. Bilbray.

Mr. DAVIS OF VIRGINIA. Let me go next. Thank you. Thank you all for being here today. I think this sheds a lot of light on the situation. One of the difficulties is even if you think HGH and B–12

can do the job, with this mail order stuff, you're not sure what you are getting. Isn't that one of the problems? It is a huge problem, isn't it? And so contaminants get into the system very, very quickly. I'm trying to look at this B–12 problem.

This has come up before this committee before. We had a situation a year ago where—or a couple of years ago where one of the ball players tested positive for steroids, and he thought he was getting a B–12 injection. This seems to be fairly commonplace where athletes get B–12 injections and thinks it can do something. We talked—are there any adverse effects of getting a B–12 shot, Dr. Shurin?

Dr. SHURIN. No, there really are not.

Mr. DAVIS OF VIRGINIA. It is, like, drinking too much V–8 or something like that?

Dr. SHURIN. Pretty much, pretty much. And there is absolutely no interference in the assays for B–12 and steroids, because one of the things that is implied by some of this is, as well, if I weren't—it gave you a false positive test for steroids or any—or other substances. That actually is not—is not possible. Now, many of these substances are coming in through tested and legitimate sources, and it is anybody's guess.

Mr. DAVIS OF VIRGINIA. So again, the problem with B–12, particularly through the mail is you don't know what your' e getting. It is not FDA regulated or anything else.

Dr. SHURIN. That's correct. If you're really getting B–12, it is not—it is not harmful.

Mr. DAVIS OF VIRGINIA. Have any of you ever encountered a situation or a patient or known patients who thought they were getting one drug through the mail, particularly a B–12 or HGH, and ended up getting something that was contaminated?

Dr. SCHLIFSTEIN. Absolutely. I've tested it. It was HGC and an anabolic steroid combined in a powder that looked identical to the human growth hormone.

Mr. DAVIS OF VIRGINIA. And would it have been harmful if somebody injected it, do you think?

Dr. SCHLIFSTEIN. Well, if someone thought they were getting human growth hormone, it would have an effect but it wouldn't be the effect from the human growth hormone, it would be the effect of the anabolic steroid combined with the HGC, which would enhance it somewhat.

Dr. ROGOL. And if you were a woman, it would be much worse.

Dr. SCHLIFSTEIN. Absolutely, absolutely. If a woman—if she thought she was getting that, that could have dramatic secondary sex characteristics, deepening of her voice, facial hair, excessive weight gain, hair loss, acne. Or—I had a woman whose husband was buying steroids on line and didn't tell her. They went away on vacation, he put his pills in her sleeping pill bottle. She took them for a week thinking they were sleeping pills and in a week she grew facial hair, a beard, deepened voice, gained 15 pounds, acne, clitoral hypertrophy just from 1 week; 6 months later, it still never reversed itself; 25 years old. Just by taking it accidentally for a week.

Mr. DAVIS OF VIRGINIA. So this stuff is dangerous?

Mr. SCHLIFSTEIN. Yep.

Mr. DAVIS OF VIRGINIA. On the HGH side, we talked a little bit about some of the side effects from using that—not just contaminated, but using regular human growth hormone. There are a large and a growing number of Web sites marketing HGH injections. How do you respond to proponents of HGH that believe it is a safe alternative to steroids? Go ahead, Dr. Perls.

Dr. PERLS. There are thousands of Web sites. You put in human growth hormone or HGH and antiaging into Google and you get somewhere in the range of a million, 500,000 hits. And I'm not so sure they market it as an alternative to growth hormones, they just—I mean, to steroids. It is just a—it is the greatest thing since sliced bread. I mean, it is really snake oil. It is the fountain of youth. And they push this to the hilt.

In terms of the medical records that I reviewed for the DEA, I almost, however, never saw a growth hormone given in isolation. I think the reason for this is because the clients would never see much of any benefit and they'd wonder where is my $1,000 a month going. And so they see the growth hormone combined with all these other drugs that we've been talking about. Just—the other very interesting thing that I saw with these clinics is that the compounding pharmacies were, in fact, giving the growth hormone with B–12. They would write a prescription that said somatropin and B–12. And the only reason that I can think of for them doing this is trying to get around the law a little bit because giving growth hormone for antiaging, athletic use or bodybuilding is illegal. There is no such thing as legal off-label use. The Secretary of Health and Human Services says that in adults, it can only be used for three purposes. Maybe the compounding pharmacies are trying to skirt around the law a little bit by saying, well, we're doing very individualized therapy, we're trying to produce something that is individualized for that specific patient. But it does not get around the fact that patient has requested it in the setting of an antiaging clinic.

Mr. DAVIS OF VIRGINIA. Thank you.

Chairman WAXMAN. Thank you, Mr. Davis. Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman. Just so I—the human growth hormone doesn't really do anything for performance enhancement taken alone, correct?

Dr. ROGOL. As far as studies have gone, I'll let my partners say more. As far as studies have gone, no. But remember for those of us who do remember when the anabolic steroids came back, we as physicians were the worst actors of all. We said steroids did nothing and then there were some proper double blind studies done by Dr. Baseen, who is at your institution and they do work. So there are no studies that show unequivocally or not even really equivocally.

Dr. SCHLIFSTEIN. I think also the studies that are available don't look at it in the way it was intended to be used, meaning they are looking at taking that in isolation by itself, testing before and testing after to see if there is a change in performance. And that is not really its intended use by its users, meaning its users in conjunction with something else.

Mr. TIERNEY. Like the steroids?

Dr. SCHLIFSTEIN. Right. To maintain hopefully that benefit from that amount of steroid, to amplify the effect later on in the steroid. And when you're off the steroid, hopefully to maintain those benefits. And it really wasn't looked at in that way. Also it really wasn't looked at in how it effects the individual performance, meaning are you able to tolerate more of a workout, are you able to tolerate more muscle recuperation from that. Just like something like creatine, which is an acid buffer, it allows you work out more because you can tolerate more lactic acid buildup, that allows you to tolerate more working out, working out sooner. That has a benefit in the longer term, but immediately by itself nothing.

Mr. TIERNEY. The research on the harm that it does seems to be a little more advance.

Dr. SCHLIFSTEIN. Absolutely.

Mr. TIERNEY. Now, all these advertisements we've seen about people aging, this is going to reverse the aging process, this is the fountain of youth on that basis. Even some well-named actors trying to indicate to people—anybody over 40 should take it. And they indicate in those advertisements that they believe HGH actually causes aging. It doesn't cause aging, does it, Dr. Perls?

Dr. PERLS. I can speak to that. They claim that growth hormone levels drop with aging, which is true, and therefore the growth hormone causes aging. Aging is caused by multiple problems involving our—hits to our DNA, our cells, chronic damage to many different entities of our body by free radicals and so on. It is not caused by declines in growth hormone or other substances.

Mr. TIERNEY. Does it do anything beneficial to—regarding aging at all?

Dr. PERLS. Say again?

Mr. TIERNEY. Does it do anything beneficial regarding aging?

Dr. PERLS. In fact, my guess is that it does bad things with regard to aging. Studies and lower organisms in mine show that animals that are deficient in growth hormone actually live 30 to 40 percent longer. These animals also have a marketedly reduced rates of cancer. So it is actually—probably does the opposite effect.

Mr. TIERNEY. It sounds to me from your testimony earlier that the concerns we have with respect to women using HGH is even more pronounced than with males using it. Is that also correct?

Dr. PERLS. I'm not so sure—there are other hormones that some of these antiaging clinics—you know, the clinics make their bucks on what they call hormone replacement programs. And it is multiple hormones from steroids and—which are basically testosterone or variations of—and growth hormone. And it is really the anabolic steroids where we see the untoward effects with—in women in particular.

Mr. TIERNEY. All right. And you announced the problems for women using HGH earlier and I won't go over—you keep shaking your head, Doctor. Am I getting it wrong?

Dr. ROGOL. What my colleague to the left mentioned were the problems with steroids in women, not with HGH. That is why I was shaking my head.

Mr. TIERNEY. Are there any problems with women, in particular, using HGH?

Dr. SCHLIFSTEIN. As compared to men differentiating, I haven't seen any sexual differences between one and the other.

Mr. TIERNEY. So whatever problems exist for men taking it, it would be for women as well?

Dr. SCHLIFSTEIN. Right. I mean, with testosterone, the women's receptor is like 100 times more sensitive than the males. So even a low dose of something that is testosterone can have much amplified effects in women that may not reverse themselves even if taken off. And that is an anabolic steroid. That is not human growth hormone.

Dr. PERLS. One concern would be the 1 out of 9 women that go on to develop breast cancer and taking growth hormone for any woman. When you're looking at that kind of prevalence would probably be a very bad idea. And there are studies to show that—particularly with a breast cancer tumor, that one of the events to allow that breast cancer to spread is when it starts expressing its own growth hormone. So this is just a really bad idea.

Mr. TIERNEY. Well, thank you. I yield back, Mr. Chairman.

Chairman WAXMAN. Thank you very much, Mr. Tierney. Mr. Bilbray.

Mr. BILBRAY. Yes. Todd, in your testimony, you were talking about taking—administering which substance after doing a bench press?

Dr. SCHLIFSTEIN. That is one of the typical tests you do for performance enhancement. There were studies looking at the efficacy of human growth hormone used in combination with anabolic steroids versus anabolic steroids by themselves and looking at that at day 1 and then day 6. There was a slight benefit from using the human growth hormone when used with the anabolic steroid as compared to just using the anabolic steroid. So in that scenario, when combined with an antibiotic steroid, it did have some performance enhancing effect. Not in isolation, only when used with a combination with something else.

Mr. BILBRAY. The growth hormone itself, you stated that after the workout, the administration of the substance after a period of time, there was no net difference between the application of the growth hormone and not—and without it?

Dr. SCHLIFSTEIN. Right. When just looking at pure performance enhancing assessment from day 1 to day—you know, week 6, growth hormone was nothing. There was no benefit in a test of pure performance enhancing in that timeframe.

Mr. BILBRAY. Doctor, I think any, you know, sophomore in high school would tell that you if he is an athlete, that is not—they'd perceive that not being worth the paper it is written on because they're exercising, working out at least 3 days a week. They are going through extensive weight training. And the perception would be, then, do we do these tests showing that the use of the hormone or—during regular training sessions where at least 3 times a week there is extensive workout, you know, strain to the muscle mass, do we do that kind of real world testing that these kids are perceiving that they are going to go through?

Dr. SCHLIFSTEIN. That's why I said I really don't think there is testing appropriate to what we're really looking for the potential benefit of. It is looking at a benefit in the short term. And anyone

who takes it will tell you that is a more longer term benefit. And even by itself or potentiated by something else. So I don't know if that assessment tool really applies to that by itself is really applicable. And not to draw too many conclusions by that, just by saying in the short term.

Mr. BILBRAY. I'm glad to say that you have brought that up, because I think that is really critical. Because when we bring data forward to persuade young people to stay off this stuff, we need to make sure we have a credible argument that they will accept. And I don't think any of my kids would look at this and say, yeah, dad, of course if you're not working out, you're not going to get any benefit from—you know, this is a supplement to a major workout program, so it has to be real life.

So I just hope that when—we're really careful that when we give the argument why kids should stay away from this, it is one that is very defensible, it is not able to be assailed or justified. I—the flip side is I kind of tell them, look, you're working out anyways, you're going to put muscle mass on and, yeah, there might be a placebo effect. But until we do those kind of real world testing, our ability to sort of argue the point is diminished to some degree. These kids are not idiots. The fact is they may be getting into this drug and that is stupid. But still, as I said, the—some parts of the brain haven't developed but other parts are very well developed.

And we have to make sure that we approach this with an intelligent argument. Because once our arguments get debunked, then we're really in trouble trying to give science to these kids. That is within the guy that is pushing the drugs, pushing the substance really is saying, see, they're really not giving the data and here is the argument. There is already enough bad propaganda out there already. I just hope that we have the substance—I mean, have the substance in our argument.

Do we—are we testing real life application? Do we have that data so we can show these young people, look, here is an athlete working out here and here is the application over here, this is your life? Because any high school/college student is going to tell you, you know, doing one sets of bench presses, taking the injections and then waiting for a month is not my world. I'm working out three times a week extensively and I'm just looking for something that will give me that little edge. I'm not talking about a silver bullet that is going to do it all for me. Do we have the ability to give them that kind of information?

Dr. SCHLIFSTEIN. I mean, I think we have the ability to give them certainly the downside, the side effects. I don't know if we have enough ammunition to be convincing by itself. I think that would be a little more difficult. But certainly it makes it more difficult when you have other people endorsing it by using it and saying they are using it. And so it makes it that much harder for your argument to say and this doesn't work. But someone else is saying I'm using it like that is very hard to counterproduct, especially for a kid who is not looking at long-term side effects, they're going to get arthritis or diabetes later. He is looking at the short term.

Mr. BILBRAY. All of us will admit that the statement, if I knew I was going to last this long, I would have taken better care of myself. So the universe will turn. And so, Mr. Chairman, I just hope

that we—again, the fact is that they are not in a position to make the best judgments of anybody in the world and then they've got the ambition of success, which we all can suffer from. And then I just hope that we give them a lot more data than just this could hurt you when you're an old guy. Their attitude is I could give—I'm not looking forward to that. That's—how many young people do we still see smoking cigarettes. And when, you know, my God, if we can't get them off cigarettes, this is a hard argument to make. Thank you very much, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Bilbray.

Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman. I want to thank the ranking member as well. Following up—and I want to thank our panelists for helping us out with this issue. Following up on Mr. Bilbray's line of questioning, we have a hearing tomorrow regarding Major League Baseball, which HGH is an important issue and a significant danger in itself. But I think the hearing tomorrow has provided added focus. It has provided some context, I believe. And I think in a way the problems in baseball, are, I think, instructive as to the wider problem in society.

In baseball, we had a situation where—let's take steroids for example. Major League Baseball came back and they had a greater awareness program, a greater acknowledgement that steroids were bad. And that was—that was right up front and a big part of their push. They came up with a very aggressive testing program for steroids and a very thorough testing protocol for steroids. They had much stronger penalties for steroids. And as a result in the Mitchell Report, it reported that steroid use in baseball was down significantly. When they addressed the HGH or failed to address the HGH problem, Major League Baseball, they had no—there was reluctance to put in any testing protocol regarding HGH, there was not the same message put out there on the street that HGH is bad. And not surprisingly as a result, the report indicated that HGH use was on the rise. Now, if you look at the problem that we're having that you have described already where the message is not out there among our young people, it is not out there in the public. There is a very mixed message because you've got some of these athletes and sports figures—well, Stallone, the actor, there saying HGH is good. There is a real problem with the—I say popular opinion regarding HGH.

And it even comes to our laws. Our laws under Title III of the controlled substance act include steroids. It has very strong criminal penalties for mere possession of steroids without a position—without a prescription. We have no prohibition for simple possession of HGH. There is no criminal penalty for that. And that is what I'm getting at. That is something we here in Congress can control. And since you're the experts on this and—you know, if I could just, you know, personally thank Dr. Perls for your good work at Boston Medical Center and at Boston University, what do you think about the idea of including HGH in Title III to include all of these penalties to at least legislatively send out the signal that this is a seriously dangerous substance?

Dr. PERLS. I'm incredibly appreciative to the committee having this hearing in the first place to start to—not to start to, but to

look at growth hormone and the public health concern that it represents. And along with that, stiffer penalties such as making Schedule III, I think, is an excellent idea. Already there are very important laws on the books to go after the distributors for illegally distributing—for distributing growth hormone for legal uses that include imprisonment and fines. But adding it as a Schedule III has all kinds of great potential in terms of educating physicians as well. Because right now I think it is a little fuzzy for a lot of doctors out there in terms of what the law really is.

So I think that is also very important. Along with making it a Schedule III, though, I think it is very important to also do what Congress can to provide additional resources to the DEA in particular, who is short on staff and already has to pay a lot of attention to methamphetamines and heroin and other big drugs and this will be one more on their list.

So giving them the additional resources that they need to carry out their mission would be very important. The other thing, I think, is while you're at it, there are other hormones that go along with growth hormone. There is something called growth hormone, stimulating hormone, and then there is the already mentioned insulin growth factors. And as we've seen with other drugs, when one becomes hard to get, everybody starts looking out for one that is easy to get and is less expensive. When growth hormone—when things clamp down heavy on growth hormone, they'll start looking at growth hormone stimulating hormone and insulin growth factor, which are all part of the same endocrine access. And I would think it would be good to add those to the list as well.

Mr. LYNCH. Mr. Chairman, if I can ask, I have a letter to me but it is actually testimony to me from Gary Wadler, from the World Antidoping Agency that I would just ask to be included in the record if I may.

Chairman WAXMAN. Without objection, it will be included.

[The information referred to follows:]

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February 5, 2008

Congressman Stephen F. Lynch
221 Cannon House Office Building
Washington, D.C., 20515

Dear Congressman Lynch:

This letter is in response to your request for my thoughts regarding testing for the abuse of human Growth Hormone (hGH).

This subject was discussed at length at a three day symposium, (April 2004) hosted by the United States Anti-Doping Agency entitled: "Human Growth Hormone as it Relates to Doping Control." Attending were approximately 70 experts from approximately 17 countries.

These experts represented an array of disciplines – anti-doping laboratories, endocrinologists, pediatric endocrinologists, molecular medicine experts, biostatisticians/epidemiologists, chemists, developmental biologists, physicians, pharmacologists, forensic toxicologists, immunologists, and others. (Currently, there is a hGH WADA/USADA Working Group that meets and continues to assess the status of hGH testing.)

The subjects of urine testing and the testing of plasma ("blood") were discussed at great length as the April 2004 conference.

In summary, it was concluded:

- That for a variety of reasons, the likelihood of a urine test for hGH in the foreseeable future was extremely unlikely, in part because only exquisitely small amounts of hGH (<0.01%) are present in collected urine. In addition, the metabolism of hGH in urine is unknown, meaning that the differences between endogenous and recombinant hGH forms in urine are unknown.

- Two approaches to analyzing blood were discussed, the first was to analyze the plasma for changes in the relative content of 22 kDa hGH (which is both the major naturally occurring isoform and is also the form in the pharmaceutical preparations of hGH) in relation to the other isoforms of plasma hGH; and the second was to analyze the plasma for changes in various biologic markers that could only have resulted from the administration of exogenous hGH (marker approach).

To analyze the blood for the presence of recombinant hGH, sets of specific antibodies were developed by Prof. Christian Strasburger in his research laboratories in Munich and Berlin. These antibodies were used to analyze somewhat more than 300 athletes at the Athens Olympic Games and approximately 150 athletes at the Turino Olympic Games. The laboratory of Prof. Strasburger can produce antibodies at a research scale but cannot sustain broad commercial production of the antibodies as required for the implementation of the hGH detection method in all anti-doping laboratories.

What was needed for broad application of this methodology was the commercial production of these antibodies that are used in the analyses. Currently, a commercial company is preparing antibody kits for broad distribution planned in 2008.

This isoform approach has been well validated and it has been demonstrated that proper freezing and thawing of plasma had no ill-effect on the procedures. Accordingly, even if the antibodies were in short supply, the plasma could be stored for subsequent analysis. Studies are ongoing as to how many years the stored blood could be analyzed following the administration of recombinant hGH.

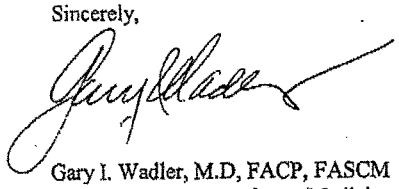
With respect to the markers approach, there has been significant progress in the development of this approach. Validation studies are on-going with respect to such variables as age, gender, ethnicity, body composition and nutrition.

Going forward, there is every likelihood that the isoform approach and the marker approach will be used in combination.

With respect to the concerns about the very short half life of hGH, it should be noted that depending upon the doping regimen, there are athletes who use hGH very frequently, at times daily, during the course of the year depending upon the doping regimen, and that changes are detectable for several hours after administration of hGH with the isoform approach and for several days after the markers approach. It should also be noted that hGH testing would be particularly effective in out-of-competition testing.

In conclusion, the assertion that there is no test for hGH abuse is not borne out by the facts. At the present time, the only hindrance to the broad application of the of the isoform assay approach to analyzing plasma has been the commercial availability of the antibodies, an issue that is currently being addressed. Until then, the proper freezing of plasma can be undertaken forthwith with subsequent analyses for recombinant hGH planned to occur in the very near future.

Sincerely,



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Chairman,
Prohibited List and Methods Committee
World Anti-Doping Agency (WADA)

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Mr. LYNCH. Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you. Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman. I've learned a ton here today, so I appreciate your holding the hearing. And I thank you for your testimony. What percentage of the people that are using HGH or B–12 would you say are using it exclusively without it being used in combination with anything else? Do you have any sense of what that would be?

Dr. ROGOL. No, sir.

Dr. PERLS. So my exposure to this comes again from reviewing seized medical records for the DEA from three antiaging clinics. And I can't think of any instance where the growth hormone B–12 was used in isolation. It's—they were always given with anabolic steroids and a number of other substances. And while we were talking about vitamins, I must also say that they were providing very expensive collections of a whole bunch of different vitamins, all on the idea of just making a lot of money.

Mr. SARBANES. So the adults in this equation have figured out that HGH by itself and B–12 by itself and other sort of vitamin supplements by themselves really are pretty useless for the goals they have it sounds like.

Dr. PERLS. The adults—well, I think it is the—it is the antiaging physicians, the owners of these clinics and the compounding pharmacies that are selling this stuff that have realized that selling it in isolation is going to make for some angry clients and that it is probably best to get this stuff in combination with other things. So that they try to see some—whatever benefit that might be. And that is all without saying much about the side effects I might add.

Mr. SARBANES. Are they being explicit in the blogosphere about the fact that the—the discussion on the blogosphere, is it explicit about the fact that, you know, it is the combination of steroid use with a growth hormone or vitamin supplement——

Dr. PERLS. Absolutely. Very explicit. It is amazing following these blogs how much time everybody is spending on what the right recipes and cocktails are and what works for whom.

Mr. SARBANES. So it still gets us back to the steroid use as being—that is the driver? I mean, that is the aspiration, is through that you enhance performance and these other things are sort of on the margin to help boost the effects of that?

Dr. PERLS. I think that is right. And I also—again, as was just intimated, this is not any kind of standard clinical trial. This is a bunch of nonscientists, nonclinicians just trying to feel their way through this and saying, oh, this worked for me and this worked—and without really any—monitoring for any long-term side effects or benefits for that matter.

Mr. SARBANES. How much complicity does—without assuming it, how much complicity would you say there has to be on the part of medical professionals to help perception? In other words, if all of those who have the science at their disposal were emphatic on the point of the dangers that are involved with steroid use or the fact that B–12 or HGH really doesn't help you do anything, then you would imagine that would be a significant deterrent to the use. But the high incidence of use suggests that there is some—some complicity. And I'm wondering——

Dr. PERLS. In terms of the—in terms of the physicians who are illegally writing prescriptions for hormone and steroids without ever seeing the patients or the owners and the physicians of the antiaging clinics, it is not a matter of complicity. They are the driving force.

Mr. SARBANES. OK. And I'm running out of time. So let me ask you this question. I raised this in another hearing we had, but now I've got some experts in front of me and I'd be curious on your perspective on this. I bought my son one of these pushup kits. OK? So it has some equipment with it and it has a video on how to use it. And then at the end of the video, lo and behold, it shows you two bottles of some kind of thing that you're supposed to take in conjunction with this regimen. What would that have been most likely do you think?

Dr. ROGOL. Hell of good marketing. That is terrific marketing. My guess would be if I had to guess would be something like HGH, but there would be a releaser or it would be something that you'd take by mouth that is likely something that is relatively harmless except to your wallet.

Mr. SARBANES. OK. Thank you.

Dr. ROGOL. But that is purely a guess, Mr. Sarbanes.

Mr. SARBANES. Understood.

Chairman WAXMAN. Thank you, Mr. Sarbanes.

Mr. SARBANES. He is not going to be using it anyway.

Dr. ROGOL. Is that for the record, sir?

Chairman WAXMAN. Ms. Watson.

Ms. WATSON. Thank you so much, Mr. Chairman, for having this hearing and to the doctors who are witnesses. We certainly appreciate you appearing before the committee to let us know about some of the threats to public health. I want to just probe a little bit and I think most of you have addressed the overuse of HGH. And I know there are a couple of conditions that occur normally when you have too much HGH in the system. And I think Dr.—I want to be sure I pronounce your name. Is it Schlifstein?

Dr. SCHLIFSTEIN. Schlifstein, yes.

Ms. WATSON. Yes. You mentioned a woman taking her husband's——

Dr. SCHLIFSTEIN. That was anabolic steroids. It was a steroid that she took by mistake.

Ms. WATSON. Oh, I see. OK. There is something called acromegaly. And, of course, we know about gigantism. And I would like any of you that can, can you describe the problems associated with acro—what is it, acromegaly? And—to us so we can understand it? And I see these hearings, Mr. Chairman, as very helpful to the general public and certainly helpful to us because we live in this drug culture. You can't turn your TV on, you can't listen to the radio—they are not pushing something over the counter or go talk to your doctor about this.

So I think our young people believe that the way to live their lives and to enhance their abilities is to take some of these drugs. Now, some of these things occur in the body normally, so, Dr. Rogol, maybe I should start with you. Can you describe the problems associated within acromegaly.

Dr. ROGOL. I'm actually going to let Dr. Perls do it. He is a big people's doctor. I'm a little people's doctor.

Dr. PERLS. Acromegaly involves usually a tumor of the pituitary gland where it is making too much growth hormone. And you'll see the facial characteristics that was mentioned with Andre the Giant, and so on where they get a bossing of the forehead, they get an enlarged jaw, they can have an increased incidence of certain cancerous tumors probably because of the effect of growth hormone in the terms of the ability of a tumor to grow and to spread. They get troubles with their heart and liver in particular, because they get heart enlargement and liver enlargement. And that doesn't necessarily make for a better functioning organ.

They get what is called insulin resistance or they can have elevated blood sugars and that can go on to develop to be diabetes. They do have shortened life spans, not increased life spans. And then there is all the other—you know, we had mentioned the enlarged hands and so on.

Ms. WATSON. Maybe you can tell us about if you can extrapolate from the—from this experience and to the elderly. What can you extrapolate from acromegaly to the elderly?

Dr. PERLS. Well, I first actually got interested in growth hormone because I run the New England centenarian study which is a large study of people who get to 100. And I'm a geriatrician who absolutely loves old people. And the very first concern for me was an antiaging industry that was portraying old people in a terrible light, saying that, you know, do you want to be demented and frail and really scaring the heck out of a very important population, the baby boom population, 70 million strong individuals who are very actively aging right now and just to scare them and then say, oh, by the way, we have the cure.

And that would be growth hormone, books like Stop the Clock, Reverse Aging Now, a huge number of Web sites popularizing this. And much of this happened—it began with a New England Journal of Medicine article in 1990 looking at growth hormone and a very small sample of older men and comparing the two with and without growth hormone and basically—unfortunately a statement saying that it took 10 to 20 years of aging off of the person's life.

The New England Journal editors have since come out saying they rued the day that they ever allowed that statement to happen because it led in part to a blooming of this industry. And what really surprised me was with my review of these charts for the antiaging clinics, was that the vast majority of them are not older people. It is again people in their late 20's, 30's and 40's who are going for the kinds of things we see the testimonials of, these good looking, strong athletic types. And I think unfortunately as a society we're very susceptible to looking at testimonials and taking them hook, line and sinker. But that is all this market is based on, is testimonials and not real silence. And I'm hoping that the elderly population as you mentioned are a relatively minor part of this very big public problem.

Ms. WATSON. Thank you. Mr. Chairman, can I have a few more minutes? I wanted to ask about vitamin B–12. Before I get there, I wanted to address this to Dr. Rogol. Sylvester Stallone once told the Today Show that HGH was just amino acids, just a collection

of proteins. And the body—that the body already produces. And how can 191 amino acids be all that dangerous? And is it just amino acids?

Dr. ROGOL. Ma'am, there is one problem with that. 191 amino acids probably aren't a problem. A 191 amino acids hooked together that form a protein called HGH, that is what the problem is. So it is a little B&A in the middle of that to try to take these things and make a growth hormone. And I suspect as some of you may have read in the article in last Wednesday in USA Today that Mr. Stallone said all of this was done by HGH. I am sure he took HGH. We are absolutely unsure the 17 or 23 other things that he said.

And as you probably also read, I was quoted as saying exactly that in the USA Today. So, yeah, he took HGH. But, again, with HGH and anything else—I am a clinical scientist. I know how to do experiments. The biggest issue in most experiments, once they're properly designed, is what the dose is. We know precisely what the dose is when we do an experiment. These doses are way beyond that. They're taken in a different way. And so we really don't have the idea of how to go about testing or studying as Dr. Schlifstein has said. So that is the long-winded answer to your question, ma'am.

Ms. WATSON. Thank you so much. And if I can shift now to injectable vitamin B–12. And, Dr. Shurin, can you tell us just very briefly—I'm out of my first period of questioning and into the second period. I'm almost out of time—but the appropriate use of the injectable vitamin B–12?

Dr. SHURIN. The appropriate use for the injectable vitamin B–12 are for people who are unable to absorb the oral form of B–12. Normally, if you have a perfectly normal gut, you can absorb vitamin B–12 from your diet. Even people who are strict vegans who don't take vitamin B–12 in their diet can take supplemental vitamin B–12, which they usually do from yeast and absorb it just fine. So it is people who have had—who got pernicious anemia, people who have had bowel resections, some people who have inflammatory bowel disease, all need to get vitamin B–12 by injection, otherwise it is perfectly appropriate and definitely safer to have it by mouth. It is not dangerous by injection, but it is not helpful either. It also means that there are syringes and needles around which—whether it is the locker room or the home is not a small issue.

I think the potential secondary complications of having needles and syringes around is not a trivial issue.

Chairman WAXMAN. Thank you, Ms. Watson. I think your time has expired.

Ms. WATSON. Fair enough.

Chairman WAXMAN. I want to ask—and you may want a second round. But I want to take a second round and ask some questions of Dr. Schlifstein. Dr. Perls treats the elderly, Dr. Rogol the children. But you've been a sports doctor and you've dealt with athletes. In your experience with athletes, if they use human growth hormone, are they more likely than not to be using it in conjunction with other drugs?

Dr. SCHLIFSTEIN. They almost in every case are using it with other drugs. There may be periods of time where they're only taking that and cycling off something else. But certainly it is the

mainstay, is using with something else. So that is why a lot of times these talks about human growth hormone in isolation isn't really true or we shouldn't just be talking about that. You have to talk in combination with some type of anabolic steroid.

Chairman WAXMAN. If an athlete tells me that he is taking human growth hormone to heal from a sports injury, how would you react to that? Is it credible? Is it helpful?

Dr. SCHLIFSTEIN. We really don't have any proof that it is beneficial in that manner. Certainly with its effect on both muscle and bone tissue, one could hypothesize that—like a fracture or something else may heal slightly faster than one without taking it. I've seen some cases where people have fractures, young people taking human growth hormone and they healed a lot faster than normal. Was that the only factor involved? It was only a case report. So it is not really scientific evidence. But possibly, yes.

Chairman WAXMAN. And when an athlete uses it—these are expensive items, this human growth hormone, $1,000 a month, are they taking very high doses do you expect from your experience?

Dr. SCHLIFSTEIN. From my experience with these people, patients, what they've been taking, the dosing that some of them would use for an HIV wasting syndrome, it can vary between a quarter and a half of that dosing, because sometimes they get it from those patients as well because they know they're getting legitimate sources of it and don't have to get a prescription themselves and they get it and they buy it off those people who get it——

Chairman WAXMAN. More than likely than not, they are people hanging around that they tell them, just get me some human growth hormone.

Dr. SCHLIFSTEIN. Well, these people get it automatically every month and they know they get a certain amount. That's why I know how much they have of it based on that dose. So it is already paid for and gotten through and gotten regularly and they know it is a legitimate source and a real source. And usually, it is about half that dose. But that has dramatic effects on someone who is in their 20's and 30's, taking that large of a dose, especially with whatever else they're taking.

Chairman WAXMAN. What is it that they think they're getting when they take a vitamin B–15 shot? I mean, you can't take it orally, so they get a shot. What do they think——

Dr. SCHLIFSTEIN. You referring to a B–12 shot?

Chairman WAXMAN. Yeah.

Dr. SCHLIFSTEIN. You know, I think a lot of that I think is the placebo effect. If you're already doing so many injections and you think you're going to get an energy boost from it and you have something that looks like red syrup and you think it is going to boost your energy, if you really believe in it, yeah, what is another shot if you're already taking, you know, 7, 10 a week anyway?

Chairman WAXMAN. 10 in a week of B–12?

Dr. SCHLIFSTEIN. Injections.

Chairman WAXMAN. Injections of other drugs?

Dr. SCHLIFSTEIN. Yeah. They are using it once or twice a day. The anabolic steroid, depending on which one, oil-based or water-based can be daily or twice a week. I mean, insulin growth factor

is even worse because they have to inject it into each individual muscle. So you have to do every muscle you worked out.

Chairman WAXMAN. Is B–15 injected in the muscle?

Dr. SCHLIFSTEIN. B–12 is. Usually it is an intramuscular injection, yes.

Chairman WAXMAN. I see. How about lidocaine? Tell us about lidocaine. And is it safe for a fitness trainer to inject someone with lidocaine or is it a dangerous drug?

Dr. SCHLIFSTEIN. Well, I don't think a fitness trainer should be injecting anything or recommending anything either on that behalf. But lidocaine is used as a local anesthetic. Now, as far as injections for pain management goes or for treatment of an injury, very specific reasons and uses for it. Now, it only is temporary, right? A short-lived, short-acting anesthetic. It just numbs the area temporarily, and in 2 hours it is gone. So if someone has an inflamed, irritated joint, we may put some corticoid steroid, an anti-inflammatory steroid combined with some lidocaine, inject it into a joint to get pain relief from an inflamed, irritated join. The lidocaine gives them temporary short-term pain relief, while the anti-inflammatory or corticoid steroid or cortisone takes time to work its anti-inflammatory effect.

Now, that can be injected into a muscle, yes. Sometimes it can be injected into a muscle usually with a corticoid steroid or anti-inflammatory steroid as well for pain relief into what we call a trigger point.

Chairman WAXMAN. Is this a dangerous drug?

Dr. SCHLIFSTEIN. It can be, depending on dose, amount and frequency. Now, usually a limited amount would be injected and—with joint space, most of it tends to stay in that joint space. Injected into a muscle, there is going to be some systemic absorption.

Chairman WAXMAN. Who do you think should give this kind of injection? You say not——

Dr. SCHLIFSTEIN. I mean, only a physician and I would say only a trained physician in that specialty.

Chairman WAXMAN. What specialty, sports medicine?

Dr. SCHLIFSTEIN. Sports medicine or pain management, somewhere where they know how much you're doing and where you're doing it. You can get other effects to nerves. You can do a nerve block by mistake, you can cause damage to that nerve. There are a lot of other potential problems with that. And when injecting it into a muscle, you want it just into that muscle, you don't want to damage any other tissue. If someone has what we call a trigger point or like back pain and you put into the muscle spasm, it helps that muscle relax but only temporarily.

Chairman WAXMAN. My last question. Is it a performance enhancing drug, this lidocaine.

Dr. SCHLIFSTEIN. It is not a performance enhancing drug. It is purely a local anesthetic or local pain reliever? Any other Members wish for more time? Mr. Bilbray.

Mr. BILBRAY. So lidocaine really just addresses the pain. So it doesn't——

Dr. SCHLIFSTEIN. So something wouldn't hurt.

Mr. BILBRAY. I guess the only way to performance enhancement would be to eliminate the pain so you could continue to perform

without knowing that you actually have damage going on there and probably create more damage?

Dr. SCHLIFSTEIN. Right, which is a dangerous scenario because you're going to have an anesthetic or numb area where you inject it. So potentially, during an athletic competition or an event, there are serious concerns about doing that kind of injection because you're not going to have the normal feedback.

Mr. BILBRAY. Pain tends to be nature's way of telling us to slow down?

Dr. SCHLIFSTEIN. Absolutely.

Mr. BILBRAY. OK. Well, those of us over 50 relate to that. The B–12 image of enhancement, is that the increased red blood cells thus the fact is that the blood is able to carry more oxygen, able to do that? Is that the image that is being given out on the B–12?

Dr. SHURIN. That is exactly right. The benefits of receiving B–12, if you're B–12 deficient, are all in exactly the areas where people want to have enhanced performance. You have more energy, your red count goes up, you have better memory, you have better concentration, your nerves function better. So all of those things are clearly benefited if you're B–12 deficient and you get treated with vitamin B–12. And I think what is happening is that they are extrapolating from that kind of situation to the idea that if you're starting——

Mr. BILBRAY. A little is good; a whole lot is better.

Dr. SHURIN. That is exactly right. And it is very clear that is, in fact, not the case.

Dr. ROGOL. Mr. Bilbray, I think there is a little confusion here. Most of the athletes who want that are taking erythropoietin rather than B–12. And so EPO is another hormonal drug of abuse, and that is where medals were lost in Salt Lake City based on compounds like that. And so there is quite a difference and most of the athletes are more likely to take erythropoietin than they are to take B–12.

Dr. SHURIN. B–12 use is very, very common. And I think what they're looking for is some of the same kind of benefit that they'd also look for from erythropoietin. The big difference is that the use of erythropoietin is not without major side effects. You said erythropoietin is a serious business and that is actually—that is the Tour de France problem as well.

Mr. BILBRAY. OK. Now, when we focus on the problems, the problems, the problems and trying to grasp for the answers, one other thing that I think that those of us here in the Federal Government have jurisdiction specifically on and may be able to address is this issue of the network that is distributing the propaganda out to our young people which is not necessarily over the traditional airwaves, but over the new vehicle of communication for the next generation, that is the Internet. Was it fair to say that the Internet could be, you know, a major line of communication on not only touting this—these substances, but also the possibility of distributing them?

Dr. SCHLIFSTEIN. I think it is a dangerous combination of both. You're getting information from the same place that is trying to sell you something. Of course, they're going to tell you the good sides or the potential good sides or even if they're not even truth.

But the myths of it—they're certainly not selling you the downsides and that is the same source of information you use in the purchase of something from—which is a dangerous combination when you do the two together.

Dr. PERLS. It goes beyond just individuals on the Internet marketing and pushing the stuff. There is coordinated efforts between clinicians or these clinics and the compounding pharmacies or a number of drug busts—Raw Deal was one of them. Another one is something called Witch Doctor—that these operations conducted by the DEA and others that showed that there are coordinated efforts between these entities to push and market the stuff to go into gyms and sports spas to actually recruit individuals to take the drug and then they get a kickback for that.

There are much larger almost pseudo medical societies bent around antiaging that have courses and symposia on how to take—how to deliver the drug, how to have successful antiaging practices. They produce books. They produce very large conventions, both nationally and internationally where they bring all these folks under one roof.

Mr. BILBRAY. So you've got a whole network. And the Internet, though, is a major part of that?

Dr. PERLS. Sure. Well, they have their Web sites and what have you——

Mr. BILBRAY. Even among those groups?

Dr. PERLS. The Internet is most dangerous because of such easy access by the—by everyone. And then——

Mr. BILBRAY. Especially at the high-risk population?

Dr. PERLS. Right.

Mr. BILBRAY. Young males wanting—Mr. Chairman, I just wanted to raise that issue because I think that one of the things that we have had a success in the past working on—and, in fact, you and I worked on the telecommunication bill over the energy and commerce back in the 1990's of addressing the use of the Internet as a predatorial vehicle on young people. I, have a feeling that we ought to be looking at the Internet as being part of the answer to this issue of those who are using these predatorial activities for selling these drugs and really trying to address how we monitor and enable to regulate the Internet to at least try to obstruct it from being a fast track to substance abuse. Thank you very much, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Bilbray. It would be Mr. Lynch first if you want more time and Ms. Watson if she wishes more time.

Mr. LYNCH. Just briefly. On that same topic again. I do know that the difficulty in policing some drugs, such as OxyContin was that doctors—individual physicians had the right to—to prescribe them so-called off—off labeled for reasons and for situations that weren't necessarily the primary reason for certain medications. Interestingly enough, HGH is one of a very rare examples—I can think of no other drug that we've investigated up here that has a prohibition that says you can't prescribe this off label. And that is what—that is what the FDA says about HGH.

So all of this stuff, whether it is on the Internet or whether it is in the mail or whether it is, you know, within these gyms, all

of this stuff is right now off label. It is prohibited flatly by the FDA.

So since—I think we already have the tools to stop this. And I just want to know, you know, from our panelists, is it a matter of enforcement that we're falling down on here or do you think that there is some other, you know, prohibition maybe regarding the Internet? And I just think that is the vehicle—that is just one way of selling this stuff. I think that we have the tools already to stop this if we were serious about it. I'd just like to hear your thoughts on that.

Dr. ROGOL. I presume that is correct if it really is human growth hormone. That is precisely the drug that the FDA talked about. But I could see the biggest amount of wiggle room with things that aren't HGH because they—they say, well, this is not proscribed. So that is where I think there might be a lot of difficulty because it is my opinion—I haven't looked at the Internet sites—but it is my opinion that the vast majority of the hype for this are things other than the 191 amino acid drug—HGH. So that might be another avenue to look at. It is just a little bit different than what you said, sir.

Mr. LYNCH. That is very good, Doctor. That explains a lot. Anybody else? Dr. Perls.

Dr. PERLS. I'd actually disagree. The amount of hype and literature in marketing that I've seen around growth hormone, the injectable is unfathomable in that it does represent a $2 billion a year market for the—what we call the off-label indications of growth hormone or the illegal indications. The laws are there to prevent the illegal distribution or to try and prevent the illegal distribution, but it doesn't get to possession as you have mentioned. And I do think that calling something a Schedule III has a great deal of education benefit to the people who prescribe the drug. There is—I think it became a big problem—it's been going on for about 17 years and it's been pretty much under the radar because it is a fairly obscure rule.

You said it is unique and it is. So I think taking the extra steps to bring it out of obscurity is very important and a bill to make it Schedule III I think would very much help in that vein. And then, of course, there is providing the resources to go after it. I think another big problem is a very overstretched FDA and DEA in their ability to deal with all the things that they have to deal with.

Mr. LYNCH. OK. All right. Thank you, Mr. Chairman.

Chairman WAXMAN. And, Ms. Watson, do you wish to ask further questions?

Ms. WATSON. Just very quickly. I wanted to raise an issue about lidocaine. Just recently we saw a very tragic news story about a young lady who was on her way, as we understand, to the laser hair removal clinic and spread lidocaine cream all over her leg, and I guess her body and she had a seizure, collapsed and died. Can someone comment on the cream that you can get? And should it be controlled by a professional?

Dr. ROGOL. I don't know about the cream, but I was going to mention before lidocaine is a drug that affects electrical activity, whether it is of your heart or your brain. So when physicians appropriately inject into a joint, shoulder, knee are the usual ones,

no problem. But when it gets systemic, that is when you have the problems. And so cardiac and brain arrhythmias, which is, in essence, what a seizure is, are a known side effect of that particular drug.

Dr. SCHLIFSTEIN. Right. It would have to be taken in very large quantities through the skin to be absorbed that way. Now, you can get it over the counter which is, like, 1 percent. Prescription strength is 5 percent. There is also a topical patch which is Lidoderm, which is lidocaine in a patch which is 5 percent. Now, if you keep doing that, your body is going to absorb more and more, and eventually it will get into your blood stream and you'll probably build it up over time.

Lidocaine is also an anti-arrhythmic. I mean, it is usually—to prevent a heart from having arrhythmias. But like any anti arrhythmic, it can be prorhythmic. And it also affects the electrical conductivity of your heart, and it certainly can affect the electrical conductivity of your brain. I think the perception is if it is over the counter, or if it is a topical medication, the perception is I can't take too much, it won't get absorbed. There have been cases of people from taking the topical aspirin creams who have died from salicylate toxicity or aspirin toxicity just because they perceive it as benign. They are putting the patch on, they are putting the cream on. They don't think they're going to be affected that way. Lidocaine would have to be taken in pretty large quantity to be absorbed to have that effect.

If you left three patches on for 24 hours a day, you'd only have about 1 percent absorption into your blood stream. So it would probably have to be a large dose and a continual dose to do that. But some patients, if they're given that, they need an instruction on how to take it appropriately. Just because you put more on, it doesn't mean the area is going to get more numb or penetrate more deeper. It really only works superficially. And I think people who are getting a procedure and want to anesthetize and someone prescribes that, has to give appropriation instruction on the use of that medication.

Ms. WATSON. What I'd like to have clarified, how much is too much of the cream?

Dr. SCHLIFSTEIN. I mean, it really has to only go on that area locally and it has to be on there a half hour beforehand. So if you were just doing your head, you just need enough to cover it. Once it is numb, it is not going to get more numb. It's not going to go deeper. So it is really going to—it is going to last 2 or 3 hours. That is how long it lasts. More on is not going to make it last longer or be more numb. Either it is anesthetized or it's not. There is no in between. Usually—I mean, those tubes come in large amounts, which is usually enough for weeks if not a month. At most it should be applied twice a day because it will stay—some are absorbed in the adipose or fat tissue on the subcutaneous tissue. I mean, just under the skin, there will be a little residual buildup.

If you continue to use it, you'll get continual buildup of additional lidocaine. So it probably wasn't a one time use. It was probably a continual use and probably had to put a lot of cream on it in order for that to occur. But, you know, if you weren't instructed properly, you probably wouldn't know any better. And if they had it ahead

of time before a procedure, someone is nervous, they are going to keep doing it just to hopefully have less problems later.

Chairman WAXMAN. Would the gentlelady yield to me?

Ms. WATSON. Yes. I'm finished. Thank you so much.

Chairman WAXMAN. If you heard about a professional athlete who had a lidocaine injection, but didn't go to a physician, what risks is that person taking?

Dr. SCHLIFSTEIN. I think a lot. I think—even—a lot of physicians wouldn't inject lidocaine without a lot of experience in doing it, and especially depending on what part of the body you're doing it into. Certainly there are nerves that go all over the body. Just as we talked about absorption from a topical, if you hit a blood vessel, it can be absorbed and you can have an arrhythmia or a seizure if it goes into a blood vessel because it will get absorbed really quickly.

So, I mean, I would say only a medical doctor and only one really trained in doing those—and experienced in doing those procedures. Otherwise, that is when something that seems like a benign drug—but let's remember, it is a drug. So an injectable makes a risk of anything more dramatic. Absorptions to the blood where we can get a problem like that to occur is a real possibility.

Chairman WAXMAN. Thank you. Well, this panel, I want to thank you all very much. You've done an excellent job in outlining the issues for us. Not just as it relates to professional athletes, but to the whole range of the population. And I think it has dispelled a lot of myths and it has also been very educational for us and for the American people. I'd like to ask unanimous consent that the record be held open for 2 weeks. There may be additional questions that we might ask you to respond to in writing.

Mr. SHAYS. Just 30 seconds.

Chairman WAXMAN. My colleague, Mr. Shays.

Mr. SHAYS. Mr. Chairman, I just wanted to thank you for holding this hearing and thank our witnesses. I know all the questions have been asked that needed to be. But I think it is important that you're doing this and I think it will lead to some insights on the part of the government and some action both on the part of the government and the private sector and the sports community that I think ultimately will have significant benefits. So thank you.

Chairman WAXMAN. Thank you. That is certainly our hope and we're going to work with you and others to try to achieve that goal. Thank you very much for being here. That concludes our hearing and we stand adjourned.

[Whereupon, at 12 p.m., the committee was adjourned.]

[The prepared statement of Hon. Elijah E. Cummings and additional information submitted for the hearing record follow:]

CONGRESSMAN ELIJAH E. CUMMINGS OF MARYLAND
OPENING STATEMENT

"MYTHS AND FACTS ABOUT HUMAN GROWTH HORMONE, B-12 AND OTHER SUBSTANCES"

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

TUESDAY, FEBRUARY 12, 2008

Mr. Chairman,

Thank you for holding this vitally important hearing to examine the myths and facts about performance-enhancing substances such as human growth hormone (HGH), B-12 and other substances.

When we first undertook the issue of performance-enhancing drugs in 2005, our concern was primarily with the public's health.

Although we had little hard evidence at the time, many were aware that steroid abuse was rampant in Major League Baseball and other professional sports.

We knew also that our young people were emulating their heroes, and that steroid abuse was widespread among high school athletes.

With the release of the Senator George Mitchell's report on steroids in baseball, we now know definitively what we knew anecdotally in 2005.

The use of performance-enhancing drugs in baseball was common, and the League was failing to address it.

Last month, we heard from Commissioner Bud Selig and Players' Association head Doug Fehr about how this was allowed to occur on their watch.

Tomorrow, we will hear from pitcher Roger Clemens and trainer Brian McNamee, to examine the findings of the Mitchell Report.

These hearings are necessary to learn the truth about steroids in baseball, to better inform our efforts to stymie this troubling trend.

But today, I appreciate the opportunity to return to the topic that brought us here in the first place: The public's health.

This Committee was the first to tell the American people the dangers of steroids—and I am pleased that our efforts appear to have had an effect.

Steroid use among youth is down, but disturbingly other performance-enhancing substances appear to be gaining popularity in its place.

That is why I appreciate the opportunity again, Mr. Chairman, to take a look at the other drugs that are out there.

As with steroids, HGH, B-12 and other substances should only be used for the purposes for which they are intended, under the supervision of a physician.

Every day, I see the youth in my neighborhood who see professional sports are their only way out.

Unfortunately, many of them also believe that they must cheat to get there.

We owe it to those young men and women to set the record straight—to let them know that the use of performance-enhancing drugs is not only illegal and immoral; it is incredibly dangerous to their health.

I look forward to the testimonies of today's witnesses and I yield back the remainder of my time.

ELIJAH E. CUMMINGS
Member of Congress



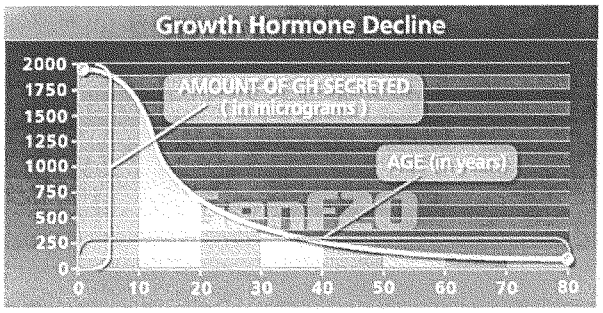
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HGH Immediate Benefits to You

Bottom line is this: When HGH decreases, AGING increases.

At the age of 25, the HGH level in the body is around 600ug. But by age 60, the amount can gradually go down to only 15% of that, or a mere 90ug or less. What's worse, many people have such an unbalanced and unhealthy diet that the 15% level can happen when they are only 40 years old! These people look saggy, worn out, and, well, just plain older!



Most hormones, like estrogen, progesterone, and testosterone, significantly decline as you age. Long ago, the medical community came up with ways to naturally or synthetically replace these hormones and to some extent slow the effects of aging. However, it's only been more recently that the focus has shifted to HGH. You see, HGH actually prevents biological aging! It's like your body is immune to the passage of time. And miraculously, the usual signs of aging -- wrinkling, age spots, memory loss, loss of libido, and the inevitable "spread" -- are all attacked by HGH. These signs of aging can be reversed with HGH.

GenF20™ HGH works by revitalizing the function of the pituitary gland to deliver more growth hormone. Every amount of growth hormone replacement has significant effects -- substantially rebuilding and revitalizing all organs of the body. Everything just

works better -- like a young person's body. So for instance, **GenF20™ HGH** ...

Has a positive impact on diseases, like stomach and lung conditions or even high cholesterol and high blood sugar

Reinvigorates and supports female and male sexual organs to restore potency and pleasure

Eliminates extra body fat in the abdomen and legs

Improves skin texture and elasticity

... and there's more! HGH is also proven to:

- Increase energy levels
- Improve cholesterol Level
- Improve immune system strength
- Equalize blood pressure
- Strengthen nails and hair
- Give your body super healing power
- Improve cardiovascular and respiratory functions
- Decrease body fat
- Reduce wrinkles & age spots
- Restore hair condition and color
- Improve memory
- Elevate mood and improve sleep
- Increase cardiac output and stamina
- Improve vision
- Enhances effects of exercise
- Increases bone density
- Lowers blood pressure

That's a long list of claims, we admit. But clinical tests have shown these effects in adults ranging in age from 30 to 90. HGH is remarkably helpful for a whole category of age-related complaints.

GO BACK ORDER GenF20™HGH TODAY! NEXT PAGE

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This product is not intended to diagnose, treat, cure, or prevent any disease.
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GrowLean15™

Weightloss and Anti-Aging Complex

FREQUENTLY ASKED QUESTIONS

Q - Can I get more information on HGH medical studies?

A- You can find more information on medical studies of HGH at www.newenglandjournalofmedicine.com.

Q - How do I take it and how long will it take to see results?

A- Simply take our product once a day before bedtime and that's it. Be sure to read and follow the instructions on the bottle carefully. Best results are seen after three months of continual and correct use, however, results may be seen in as little as two weeks.

Q - Is there any special diet I have to adhere to?

A- There is no special diet to adhere to while taking this product. However, results will be more prominent and show faster when combined with a sensible diet.

Q - What happens if I quit taking the product?

A- Our product works even better the longer you take it. If you do stop taking it, there will not be any harmful side effects. However, your HGH levels and its effects will return to their natural level as they were before taking the product.

Q - Can I take this product if I am young or old?

A- Our product can be taken at any age safely with no harmful side effects.

Q - What are the exact ingredients and how safe is it?

A- Our product is 100% safe because it is 100% natural and has no stimulants of any kind. This includes no caffein, ephedrien or Ma Huang. This also means no JITTERS! and there are no hormones in this product.

The ingredients are a proprietary blend of:

* Anterior Pituitary Peptides (derived from pork)
* Hypothalamus
* L-Glutamine
* L-Ornithine
* L-Arginine
* L-Pyroglutamate
* L-Glycine
* L-Lysine
* L-Tyrosine
* Phytosterol
* Soy Phosphatides Complex
* Panax Ginseng



Q - Can I take this product if I am pregnant or have cancer?

A- Do not take this product if you are pregnant, nursing, or have cancer (will not harm future pregnancies).

Q - Can I take this product with the current medication I am taking?

A- If you have any other concerns regarding your specific health conditions or prescription drugs you may be taking, please show the ingredients to your health care professional for further consultation.

Q - What are the possible side effects?

A- Slight headaches have been reported in about 1% of customers. Aspirin or ibuprofin were successful in headache relief.

Q - What if I don't like it and I want to return it?

A- Your order will come with return instructions. If for any reason you are not happy with the product, simply email ptlabschargebacks@fex.com. We will promptly refund your money upon receipt of your package.

* Note: Maximum results are seen after 3 months of continual correct use, so it would be smart to use it all if you are considering a return.

Q - Are there any special restrictions for Canadian Orders?

A- Canadian Customs prohibits entry of any dietary supplements that exceed a 3 month supply. You can either place 2 seperate orders of 3 month supply each or place the order for the 6 month supply promotion, if applicable, and contact ptlabsinfo@fex.com to split your order. Please note, in either case, that because the orders have been split, you will incur 2 Shipping & Handling fees as well.

Q - Is shipping and handling refundable?

A- Shipping & Handling charges are non-refundable.

Q - How long will it take to receive my order?

A- All orders placed for in-stock merchandise are processed the following business day, excluding holidays. Standard Shipping take up to 14 days. If you want a 3-4 day delivery choose RUSH Shipping and if you're a big spender and absolutely want it ASAP... choose FEDEX Overnight. Please email ptlabsinfo@fex.com to obtain status of your order. *For International shipments, please allow up to 3 weeks for delivery.

Q- What is your No-Questions-Asked 90 Day Money Back Guarantee?

A- Optimum benefits from nutritional supplements most often cannot be realized without at least 90 days of continued use. PrideTech Labs' Money Back Guarantee gives you the opportunity to experience the full benefits of our products and enough time to return if you are not completely satisfied the the results.

* 90-day guarantee is not applicable to any "Trial Offer" promotions. Strict compliance of our Returns & Refund policy applies.

Q - When will I see results, and what kind of results should I see?

A - The results most people experience while taking GrowLean15 are as follows;
Within the first few days to a couple of weeks many people say they feel an increase in energy and sharper thinking. They notice deeper sleeping patterns at night, and start to dream more often. We dream while in REM sleep, a deep sleep that is required for our cells to rejuvenate. They report feeling a "sense of well-being" they haven't felt in years. They notice faster healing, improved eye sight, better hearing, and increased libido. They feel stronger, and notice a change in the muscle/fat ratio, with increased muscle and decreased fat. The more significant visual results such as gray hair turning back to its youthful color, and skin wrinkles decreasing usually occur after a few months, but some have reported these benefits in the first 4-6 weeks. These are some of the benefits we have seen with our product. Everyone's body is different so positive results may vary.

Q - How long should I take GrowLean15 before I form my opinion of the benefits of the product?

A- You should see results in the first month, however certain benefits do take longer to become apparent than other benefits. In order to realize the full benefits of human growth hormone it is usually recommended that any human growth hormone product be taken as directed for three months before judgment is made. For instance, most people notice better sleep, more energy, and an enhanced mood in the first month, but it usually takes more than one month for the hair to return to its youthful color. The body does need time to adjust, and some time is usually needed to show all the benefits related to human growth hormone.

Q - Where does the HGH in your products come from?

A - Clinical studies and research have developed a combination of amino acids and natrual gland extractions that when combined correctly, and in the right amounts, actually stimulates the pituitary gland to begin releasing your own human growth hormone as you did in your adolesence! GrowLean15

has combined those ingredients of the highest quality in a capsule form that will be completely absorbed by your body. There are no hormones in our product.

Q - How do you derive the Pituitary extract and how disease free is it?

A - It is North American pork, which is harvested, tested, freeze dried, and quarantined. Once it is in the product, it is retested to ensure there are no contaminants.

TRY IT RISK FREE FOR 90 DAYS!

TELL A FRIEND!
Love GrowLean15™? Tell a friend about it!
Enter your information in the form below:

Friend's Email:

Your Name:

Tell a Friend About GrowLean15™!

To see other great products for your health and beauty, visit www.pridetechlabs.com.

Note: Before starting any diet, weight loss, fitness or exercise program seek the advice of your healthcare professional and always read the label instructions carefully.

"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."