

**“BODY BUILDING PRODUCTS AND HIDDEN
STEROIDS: ENFORCEMENT BARRIERS”**

HEARING
BEFORE THE
SUBCOMMITTEE ON CRIME AND DRUGS
OF THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
ONE HUNDRED ELEVENTH CONGRESS
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TUESDAY, SEPTEMBER 29, 2009

U.S. SENATE,
SUBCOMMITTEE ON CRIME AND DRUGS,
COMMITTEE ON THE JUDICIARY,
Washington, DC

The Subcommittee met, pursuant to notice, at 2:30 p.m., in room SD-226, Dirksen Senate Office Building, Hon. Arlen Specter, Chairman of the Subcommittee, presiding.

Present: Senator Hatch.

**OPENING STATEMENT OF HON. ARLEN SPECTER, A U.S.
SENATOR FROM THE STATE OF PENNSYLVANIA**

Chairman SPECTER. Good afternoon, ladies and gentlemen. The hour of 2:30 having arrived, the Subcommittee on the Committee of the Judiciary on Crime and Drugs will now proceed with this hearing on bodybuilding supplements and the possibility of their containing steroids or steroid-like substances.

The Federal laws which govern this subject are complex. If the substance is a drug within the meaning of the Food and Drug Act, it is subject to preclearance by the FDA. Failure to comply with Federal law may result in criminal penalties. If the item comes within the Controlled Substances Act as one of the titled defining steroids, there again may be a criminal violation.

The legislation provides that substances produced before 1994, which are body-building, are not subject to the rules of the Food and Drug Administration. But experience has shown that there are many of these body-building supplements which are sold over the counter which may contain steroids or steroid-like substances which may cause very severe damage to the liver or the kidneys.

We find that our society, which is very much addicted to supports and very much addicted to excelling in sports, that athletes are very anxious to buildup their bodies to be able to excel or at least to do better. And this is an attitude which goes from professionals like Mark McGuire who received disciplinary action as a result of having steroids in his body to J. C. Romero of the Philadelphia Phillies who was suspended this year to the detriment, candidly, of my home town team for 50 games because he had steroid-like substances in his body. Or at least that was the allegation and the judgment of some.

So the question arises as to whether there needs to be a change in Federal law. The consequences can be very serious for using

steroids as identified by the Food and Drug Administration in serious terms as follows:

Anabolic steroids may cause serious long-term adverse health consequences in men and women. These include shrinkage of the testes and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and increased risk of heart attack and stroke. The consequences of liver failure and kidney disorder have already been identified.

On one of the morning television shows a young man appeared to say, in anticipation of this hearing there was television coverage, that he had used a steroid-like substance and became very ill, went to a doctor and was told that if he hadn't secured medical aid by 2 days he might well have been dead at that point.

There is a collateral issue which the Subcommittee will take a look at and that is a Federal court decision which prohibited the national football league from taking disciplinary action against athletes under the anti-doping provisions. There the Eight Circuit Court of Appeals upheld a District Court decision saying that it was a matter of Minnesota law and that the individuals cited could defend themselves under a Minnesota statute. Well, it is an item which most likely can be handled by Federal supremacy. If the Congress decides to act to eliminate any ambiguity that Federal law will control notwithstanding Minnesota law which Federal statute could supercede the decision of the Court of Appeals for the Eighth Circuit.

These are very important items. We are dealing with a multi-billion dollar industry, estimated to bring in on dietary supplements like \$24 billion a year and body-building supplements projected to yield in the range of \$2.5 billion a year. So there are substantial property rights involved. But there are also very substantial health risks involved.

In existing legislation as noted, under the Food and Drug Administration, under controlled substances there are tough penalties. We may need to take a look at what we are going to do here with the exemption which allows these body-building steroids to be sold without preclearance under 1994 legislation.

Now I am pleased to yield to my distinguished colleague, Senior Senator from Utah. This hearing panel is small, but loaded with ex-chairmen of this Judiciary Committee. Senator Hatch.

**STATEMENT OF HON. ORRIN HATCH, A U.S. SENATOR FROM
THE STATE OF UTAH**

Senator HATCH. Thank you, Mr. Chairman. It is nice to be with you as always. We are very close friends and I appreciate being here at this hearing.

There should be a high priority to enforce the laws currently on the books so that no one, a high school football player, a middle-aged dieter, or a major league baseball player may walk into a health food store and purchase a product off the shelf that contains steroids. Today such purchases are illegal, plain and simple. Any company that sells such products is in violation of law and those types of products should be taken off the market immediately, no infrastructure, ands, or buts about it.

So this is an important issue and is equally important that this hearing clear up the abundant confusion and misinformation about what the laws are, how they are being enforced, and which agency is responsible for overseeing and enforcing laws that make anabolic steroids illegal.

It is my hope that we can use this hearing as an opportunity both to educate American consumers, especially teens and athletes about the dangers of steroids and to ensure them that laws do exist to protect them from these dangerous products.

As members of the Subcommittee know, we have worked hard to ensure that the government has adequate authority to take products containing anabolic steroids off the market.

Many of us have been concerned as we begin to see the use of anabolic steroids increase in professional and amateur athletics. That was the primary reason for the enactment of the 1990 Anabolic Steroids Control Act which banned anabolic steroid use in the United States.

Senator Biden and I were the prime sponsors of that bill.

While the 1990 law was successful in deterring potential steroid abuse, new products were being developed to circumvent the reach of Federal law enforcers. And while not technically anabolic steroids, these steroid precursors react in a virtually identical dangerous manner once inside the human body. So we worked closely with the Drug Enforcement Administration and then Senator Biden to update the law and pass the Anabolic Steroid Control Act of 2004.

Mr. Chairman, I recall your being very supportive of this legislation as well and I personally appreciated it. This was not controversial legislation. It passed the Senate unanimously and the House of Representatives passed it by a vote of 408 to 3.

The Anabolic Steroid Control Act of 2004 addressed the abuse of steroids by athletes and also youngsters and teenagers by listing new steroid precursors as controlled substances. The law also gave the DEA the authority to schedule new precursors more easily without the sometimes difficult process of proving the product builds muscle mass.

Importantly the law designated the substance androstenedione as a controlled substance, thus clearing up any ambiguity that this dangerous product could mask as a dietary supplement regulated by the Food and Drug Administration.

Senator Harkin of Iowa and I had spent considerable time urging the government to ban andro, as it is called, and I was very supportive of its listing which thus placed significant controls on its distribution and use including substantial criminal penalties.

Let me take this opportunity to raise one issue that will probably be considered within the context of this hearing. When the 2004 law was considered on the floor, Senators Biden, Kennedy, Durbin and I had a detailed colloquy including discussion of how DHEA, a hormone precursor, which is sometimes marketed as a dietary supplement would be treated under the Anabolic Steroid Control Act. As we recognized, it was not the intent of Congress to stop the use of substances that are legitimately marketed as dietary supplements, or to limit access to substances that are not abused as steroids by athletes or children.

The 2004 law deliberately did not schedule DHEA and as a result legitimate users of DHEA continue to have access to it if it is lawfully marketed. However, the 2004 law does allow the DEA, the Drug Enforcement Administration, if it should find that the product is being abused by athletes, by youngsters, or by teenagers to schedule it as a controlled substance by applying the standards in Section 201 of the Controlled Substances Act including the eight factor analysis listed in Section 201.C of that Act.

But I add that in fact the DEA need not find that DHEA meets each of the eight factors before it can be scheduled. For example, if the DEA considers that DHEA has no or minimal psychic or physiological dependence liability, the DEA may schedule DHEA if the agency concludes, after consideration of the facts and relative importance of other factors, such as the actual or relative potential for abuse, the history and current pattern of abuse, or the scope, duration, and significance of abuse, that it should be scheduled.

So that we would be clear, I asked that the Administration provide its written understanding of that provision. And Administrator Karen Tandy wrote a letter to me stating that the presence of each of the eight factors is not a mandatory prerequisite to scheduling.

Now, Mr. Chairman, I ask unanimous consent that that letter be submitted for the record.

Chairman SPECTER. Without objection, it will be made a part of the record.

[The letter of Administrator Tandy appears as a submission for the record.]

Senator HATCH. Thank you, sir.

If I could take a few more minutes because this is a subject that is very important to me and my home state of Utah, world leader in the manufacture of dietary supplements.

I would like to take a few minutes to discuss briefly the Dietary Supplement Health and Education Act of 1994 known as DSHEA. While the Health Committee has jurisdiction over this bipartisan law, that Senator Harkin and I wrote, it is an important piece of supplement regulatory structure. DSHEA clarified the Food and Drug Administration's regulatory authority over supplements while ensuring that consumers will continue to have access to safe supplements and information about their use. It passed the Senate not once but twice by unanimous consent. The law established a statutory framework for FDA so that these vitamins, minerals, herbal products, amino acids, enzymes and other dietary supplements are generally recognized as foods.

The law "grandfathered" supplements on the market in the United States at the time of enactment. The presumption being that these products had an abundant history of long and safe use. At the same time we wrote a strong safety standard into the law the products that might be harmful could be removed from the market.

As a double safeguard we also gave the FDA an "imminent hazard" authority so the agency can immediately remove from the market a product it suspects to be unsafe, no questions asked. We also included a provision to require manufacturers to submit to the FDA, 75 days prior to marketing, safety information about any new ingredients not previously marketed.

A key principle of the law is that supplements were not subject to premarket approval since the cost and time alone required to see a product through the FDA approval process would sound the death nail for this industry. Most supplement products cannot be patented and there is no incentive for a manufacturer to put its products through this costly and onerous process when any other manufacturer could benefit equally from the research and investment.

Another key provision in the law authorized issuance of good manufacturing practice standards for supplements so that FDA inspectors could make certain the products are being manufactured in compliance with all the safeguards of the law.

Finally, we required that all ingredients be listed on the label and that any claims must be made truthful and not misleading.

The reason I outline these provisions is to illustrate that we took great pains to design a regulatory framework that will assure supplements are manufactured and marketed with consumer safety as the top priority. We provided the FDA with an arsenal of new tools to enforcement the law. Some they have used, others not. And since that time the industry has grown. By some estimates it is a \$20 billion industry today. While critics of the industry have viewed this growth as a negative development, repeatedly stating that the industry is unregulated, is simply the wrong statement. All of these requirements are set out in the law in order to be administered by the regulatory agency, the FDA.

While the great majority of supplement products are used safely, there have been problems with some products. Some of the problems relate to manufacturing, some relate to labeling. I do not see this as a failure in the law. Supplements are regulated under the law. But let me be clear. We all recognize there are bad actors in the supplement industry. These individuals should be subject to swift punishment by the FDA and the Federal Trade Commission. Their products should be removed from the marketplace immediately and the full weight of the law should be brought down on these bad actors. Unfortunately it is no secret that the FDA is a woefully underfunded agency. The agency will be the first to admit that its oversight of the dietary supplement industry is hampered by a lack of resources.

For several years I have worked with Senator Harkin to rectify that shortcoming by requesting that the Appropriations Committees in the House and the Senate provide the FDA with more resources so that it can do a better job regulating the industry. Senator Kohl, Senator Bennett, and Senator Cochran have been very helpful as well in this regard.

One other regulatory authority should be mentioned before I conclude. The situation with the herb ephedra certainly pointed out that the FDA could benefit from earlier warnings about serious problems with supplement and over-the-counter drug products. Senator Durbin was instrumental in pushing this issue forward. We worked together with Senators Harkin, Enzi, and Chairman Kennedy to pass the Dietary Supplement and Nonprescription Drug Consumer Protection Act in 2006 which mandated a system of adverse event reports to the FDA regarding all serious events which are associated with the use of these products.

Finally, I also want to mention that the Government Accountability Office issued a report on the regulation of dietary supplements at the end of January. The GAO report, in my opinion, made some helpful recommendations regarding FDA oversight of these products.

We, in Congress, will continue to evaluate GAO's recommendations on how to improve the regulation of this industry. But one of the important points the report raises is the lack of FDA resources to enforce the laws already on the books. I will continue to work with my colleagues in Congress and the FDA to provide more resources to the FDA for dietary supplement oversight.

Before I conclude I want to stress an extremely important point. Since enactment of DSHEA almost every FDA Commissioner, Henney, McClellan, Crawford, and von Eschenbach on record stating that the agency has enough enforcement authority to regulate dietary supplements. And the current Commissioner, Dr. Margaret Hamburg, in a recent speech to the Food and Drug Law Institute on effective enforcement and benefits to public health mentioned that, "reports have noted that there has been a steep decline in the FDA's enforcement activities." And, "in some cases serious violations have gone unaddressed for far too long. These include violations involving product quality, adulteration, and misbranding. False, misleading, or otherwise unlawful labeling, and misleading advertising."

Furthermore, in providing an example of the FDA stepping up its enforcement activities, Dr. Hamburg cited enforcement actions against companies selling over-the-counter, body-building products that contain anabolic steroid under the guise of dietary supplements. Dr. Hamburg stated in referring to these steroid products, "these are unproven and unapproved drugs not dietary supplements."

In other words, these products are considered "adulterated" and "misbranded" under the Food, Drug and Cosmetic Act. Simply put, under current law, these products are not allowed to be marketed.

I appreciate the Chairman's willingness to listen to my long statement. But as you know, this subject is near and dear to my heart.

I want to welcome our witnesses and thank them for taking the time out of their busy schedules today to join us. I look forward to discussing this important issue with them and of course with my Chairman and, of course, other members of this subcommittee.

Chairman SPECTER. Will the witnesses please raise your right hands?

[Whereupon, the witnesses were sworn en masse.]

Chairman SPECTER. You may be seated. We will proceed now to our first witness who is Mr. Michael Levy, Director of the New Drugs and Labeling Compliance in the Office of Compliance for the Center for Drug Evaluation and Research at the Food and Drug Administration.

Since 2000 he was associate Chief Counsel at one of the branches of FDA. And before that he was an assistant district attorney in the Philadelphia DEA's office. Outstanding academic record, Duke, cum laude, Bachelors Degree; Amherst, Duke, cum laude, law degree, and Amherst College, magna cum laude.

I note your service with the Philadelphia District Attorney's Office.

Mr. LEVY. That's correct, yes.

Chairman SPECTER. So you have obviously had excellent training.

[Laughter.]

Mr. LEVY. Thank you.

Chairman SPECTER. You have the same name as a former Assistant District Attorney.

Mr. LEVY. I do, yes.

Chairman SPECTER. Is he your father?

Mr. LEVY. He is not. No, we are not related.

Chairman SPECTER. You are not related?

Mr. LEVY. Not related.

Chairman SPECTER. Well, I hired him as an assistant DA in 1971. He could qualify. He is now the distinguished United States Attorney for the Eastern District of Pennsylvania.

Thank you for joining us, Mr. Levy. We look forward to your testimony. There is a 5-minute limitation.

Mr. LEVY. OK.

Chairman SPECTER. Which is the standard rule in the subcommittees on the Judiciary.

STATEMENT OF MICHAEL LEVY, DIVISION DIRECTOR OFFICE OF COMPLIANCE, CENTER FOR DRUG EVALUATION AND RESEARCH U.S. FOOD AND DRUG ADMINISTRATION WASHINGTON, DC

Mr. LEVY. OK. Mr. Chairman, and members of the Committee I am Michael Levy, as you mentioned, Director of the Division of New Drugs and Labeling Compliance in the Office of Compliance of FDA's Center for Drug Evaluation and Research.

Chairman SPECTER. As Senator Thurmond used to say, pull the machine a little closer.

Mr. LEVY. OK. With me today is Doctor Vascilios H. Francos, Ph.D., Director of the Division of Dietary Supplement Programs in FDA's Center for Food Safety and Applied Nutrition.

Dr. Francos will assist me in responding to questions pertaining to products marketed as dietary supplements and their regulation under the Federal Food, Drug and Cosmetic Act.

At this point I want to take the opportunity to thank Senator Hatch for his long-standing leadership on dietary supplement issues and specifically the 2004 Anabolic Steroid Control Act and adverse event reporting for dietary supplements.

Senator HATCH. Well, thank you so much.

Mr. LEVY. And thank you to the Subcommittee for the opportunity to discuss FDA's perspective on the issue of steroids and products marketed as dietary supplements.

FDA is very concerned with products containing synthetic steroid ingredients that are marketed as dietary supplements. Body-building products marketed as dietary supplements are commonly found to contain these types of steroids. There is no requirement for the manufacturer of a dietary supplement to provide FDA with evidence of the product effectiveness or safety prior to marketing unless the product contains a substance that was marketed as a die-

tary ingredient before 1994 and that has not been a part of the food supply which the law defines as a "new dietary ingredient."

In addition to the agency's concerns that many of these products have not been clinically studied or demonstrated to be safe, the products are often sold with misleading labeling and they are frequently manufactured without quality controls.

By labeling steroid products as dietary supplements unscrupulous firms can introduce into the marketplace products that contain ingredients that may pose risks to health.

FDA has recently taken action to protect the public from illegal steroids and dietary supplements. In July 2009, for example, FDA issued a public health advisory warning consumers to stop using any body-building products that are represented to contain steroids or steroid-like substances. The public health advisory was issued in response to a cluster of serious adverse event reports submitted to FDA associated with several products containing synthetic steroids and marketed as dietary supplements. Adverse events included serious liver injury, stroke, kidney failure, and pulmonary embolism.

Although the body-building products containing these synthetic steroids were marketed as dietary supplements they were not dietary supplements. Rather, they were unapproved and misbranded drugs that had not been reviewed by FDA for safety and effectiveness.

FDA executed a criminal search warrant and issued a warning letter to American Cellular Labs regarding the illegal manufacture of these products. FDA also, last week, executed a criminal search warrant at the premises of Body-building.com. This search warrants involves an active criminal investigation into the distribution of body-building products marketed as dietary supplements that have been found to contain steroids.

In the past 5 years FDA has sent 28 warning letters to firms that were illegally marketing products marketed as dietary supplements and containing steroids. Currently FDA's civil and criminal enforcement offices are gathering and reviewing additional data about other products that are marketed for body building and that claim to contain steroids or steroid-like substances.

Despite these actions FDA enforcement in this area is challenging. Because FDA generally does not receive information on these products prior to marketing, FDA generally cannot identify violative products before they enter the marketplace. After products enter the market, FDA must undertake a painstaking investigative and analytical process of the products, ingredients, and labeling that often involves laboratory testing to show that they are violative.

Currently the agency struggles to provide effective civil and criminal deterrents to prevent unscrupulous firms from fraudulently marketing these products. We are also unable to effectively prevent the importation of many violative products because of the sheer volume of imports and the agency's inability to do a comprehensive examination of all packages entering the United States.

These challenges make it very difficult to stop the sale of these dangerous products. FDA, however, will continue its efforts to identify and remove illegal steroid products from the marketplace. FDA is committed to doing everything we can to protect the American

public, not only through regulation and enforcement, but also through education, outreach and collaboration with entities outside FDA.

FDA looks forward to working with Congress on this important public health issue and I would be happy to answer any questions.

Chairman SPECTER. Thank you, Mr. Levy.

Our next witness is Mr. Joseph Rannazzisi, Deputy Assistant Administrator for the Drug Enforcement Agency, coordinates major drug investigations and serves as liaison to the pharmaceutical industry.

He has his Bachelors degree in Pharmacy from Butler University, a law degree from Detroit College at Michigan State, registered pharmacist and a member of the Michigan Bar.

Thank you for coming in today and the floor is yours for 5 minutes.

STATEMENT OF JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. RANNAZZISI. Thank you, sir.

Chairman Specter, Senator Hatch, distinguished members of the panel, on behalf of Acting Administrator Michelle Lynhart and the more than 9,400 men and women of the Drug Enforcement Administration I want to thank you for the opportunity to appear today and provide testimony concerning body-building products, hidden steroids and enforcement barriers.

To understand the use of steroid products for body-building and performance enhancement, we must start by discussing testosterone. Testosterone is a hormone that is produced in the body and primarily responsible for the development and maintenance of male sexual characteristics and the promotion of muscle growth. It is a Schedule III controlled substance that has legitimate medical use as a therapeutic agent. It is also used non-medically by body builders, weight lifters, and amateur and professional athletes to perfect body appearance, increase physical performance and gain muscle size and mass.

Over time scientists developed and synthesized compounds or derivatives that were structurally similar to testosterone and prohormones such as androstenedione, andro, a steroid that when ingested is metabolized into testosterone. Androstenedione was sold over the Internet and in health food and nutrition stores as a dietary supplement until 2004. Many, if not all the designer steroids, steroid prohormones and testosterone boosters on the market today are sold as dietary supplements.

In 1990 Congress passed the Anabolic Steroid Control Act which placed 27 anabolic steroids into schedule III of the Controlled Substances Act. Pursuant to the 2004 Act the Congress placed an additional 36 steroids and over-the-counter prohormone dietary supplements into schedule III of the CSA including androstenedione and its derivatives.

Dietary supplements are regulated under amendments to the Federal Food, Drug and Cosmetic Act; added by the Dietary Supplement Health and Education Act of 1994. The Drug Enforcement

Administration has no statutory authority to enforce provisions of DSHEA. But does have statutory authority to investigate the manufacture and distribution of anabolic steroids in the dietary supplement market. With the passage of the Anabolic Steroid Control Act of 2004, Congress refined the definition of the original 1990 law to allow DEA to administratively classify a substance as an anabolic steroid if the substance is both chemically and pharmacologically related to testosterone, not an estrogen, progestin, or codoco steroid and not dyhydroepiandrosterone or DHEA. Using this provision DEA identified substances marketed as anabolic products in the dietary supplement market and then conducts a scientific review, an analysis of the substance to determine if it is related to testosterone and if the substance meets the criteria to be classified as a schedule III anabolic steroid.

The scheduling process requires an interagency review, the publication of a notice of proposed rulemaking and the review of public comments and the publication of a final rule in the Federal Register that provides notice to the public and industry of the scheduling action. This is a lengthy process and there is no method under the current statute to expedite this scheduling process.

DEA is currently in the final stages of the scheduling process for boldione, desoxymethyltestosterone, 19-nor4-4,9(10)-androstadienedione, three substances that are sold and marketed as anabolic steroids in the dietary supplement and found to be chemically and pharmacologically similar to testosterone. DEA is aware of 58 supplements that purportedly contain one or more of these steroids.

The initial notice of proposed rulemaking concerning the scheduling of these substances was published in April of 2008. We anticipate publishing the final rule in the next several months. When finalized, these products would be the first substances scheduled under the 2004 Act. As you can see, the overall time period to perform an anabolic steroid scheduling action may take as long as 2 years to complete. In the time that it takes DEA to administratively schedule an anabolic steroid, several new products can enter the dietary supplement market to take the place of products that have been scheduled. Chemists continue to create new derivative products by substituting and altering the structure of testosterone and then market them as dietary supplements. Often these new formulations have never been clinically tested and the potential adverse reactions in humans are simply unknown.

DEA has also identified products in the dietary supplement market that contain small amounts of schedule III anabolic steroids. The presence of these anabolic steroids is not listed on the label of these products. The companies manufacturing, bottling, and marketing them do not hold controlled substance registrations and the manufacture and distribution of these products violate various provisions of the Controlled Substances Act.

In conclusion, DEA will continue to identify products that are structurally and pharmacologically similar to testosterone that are masquerading as dietary supplements and classify them as controlled substances. We will continue to investigate companies that market and sell dietary supplement products that are adulterated with controlled substances and pursue the appropriate criminal,

civil and administrative remedies to prevent the continued sale of these products.

Again, I thank the Subcommittee for the opportunity to discuss this issue and welcome any questions you may have.

Chairman SPECTER. Thank you very much.

Our next witness now is Mr. Travis T. Tygart, CEO of the U.S. Anti Doping Agency.

Prior to joining the agency Mr. Tygart was an associate in sports law at Holme, Roberts and Owen. A distinguished academic background, Bachelors degree from North Carolina, law degree from Southern Methodist, Order of the Coif.

We appreciate you being here, Mr. Tygart and look forward to your testimony. Five minutes.

STATEMENT OF MR. TRAVIS TYGART, CHIEF EXECUTIVE OFFICER, UNITED STATES ANTI-DOPING AGENCY, COLORADO SPRINGS, COLORADO

Mr. TYGART. Thank you, Mr. Chairman, members of the Committee, Good afternoon.

My name is Travis Tygart and I am the Chief Executive Officer of the United States Anti-Doping Agency, or USADA. On behalf of the millions of participants who demand fair, clean, and safe sport that we represent, I appreciate the opportunity to be here today to discuss these important issues.

USADA has been recognized by Congress as the independent, national anti-doping agency for Olympic sport in the United States. We are greatly concerned about the ease with which products containing steroids can be purchased in America's supplement storefronts. We are equally concerned that some athletes have tested positive for banned drugs because the product they were using were either contaminated or intentionally spiked by manufacturers.

Designer steroids made their leap into America's consciousness in 2003 when the BALCO Doping Conspiracy was revealed. One of the designer steroids found in BALCO was Madol. The story of Madol conforms the alarming migration of designer steroids from underground, clandestine laboratories to mainstream marketing.

Since its discovery, Madol quickly rose from an unknown substance to the signature ingredient in nutritional products readily available in retail supplement stores and over the Internet.

Unfortunately Madol is just one example of a designer steroid that is marketed as an otherwise legitimate supplement to an unsuspecting public. It is estimated that 10 percent or \$2.8 billion is spent annually on performance-enhancing products. Best estimates suggest that there are hundreds to thousands of products currently available that contain one or more of these 20 designer steroids.

It is all too easy for the junior high or college athlete to walk into a local health food store or log onto the Internet and see the glossy labels and the bright bold claims of legal and all natural. He thinks, as we all believe, that because these supplements are readily available that they must be safe and effective. What he does not know is that all it takes for a supplement maker to cash in on the storefront steroid craze is a credit card to import raw materials

from China, the ability to pour powder into a bottle, and a printer to create a label.

What he does not know is that the maker can create a new steroid product, have it on the shelves within a matter of weeks, make unsubstantiated claims, and sell millions of dollars of product before the FDA has the ability to take action.

Unfortunately we don't just have to imagine such an athlete because one is here with us today. His name is Jareem Gunter. I have not known Jareem long, but it doesn't take long to realize that Jareem and others like him are sobering examples of how unscrupulous profiteers are trading the health of our children for the pursuit of quick cash.

Jareem was fortunate to have some God-given athletic ability and to work hard to earn financial assistance to play baseball at a small college. Jareem decided to look for a legal nutritional product to help his workouts. He did his due diligence, even checking the school's prohibited drug list. And he found a product not on that list called "Super Draw." According to court papers, and its advertising materials at the time, Super Draw even invoked the name of Congress to suggest that because Congress had not added it to the Controlled Substance Act that it was 100 percent legal.

Shortly after using Super Draw Jareem started feeling ill and the pain eventually drove him to the emergency room. If he had waited another day, according to the doctor, he might not be alive today, because he suffered acute liver failure. Jareem's pursuit of the American dream was compromised by what he reasonably believed to be a safe and legal product.

I want to thank Jareem for being here today and letting me share his story. Today his health is better, but he is forced to be constantly vigilant looking for the return of the symptoms caused by Super Draw.

He now works with children at a mentoring center, city of Dreams, in the Bay Area, trying to help other kids stay away from drugs and stay off the streets.

Jareem's only mistake was believing that products sold over-the-counter and readily available on the Internet can be assumed to be safe and legal in the United States. Jareem had no way of knowing that a regulatory scheme designed over 15 years ago, for a few companies, selling a limited number of simple vitamins and minerals has been hijacked by unscrupulous manufacturers. He had no way of knowing these companies are exploiting the lack of pre-market regulation to sell magic pills while using the reputation of the legitimate food and vitamin industry to cloak themselves with the appearance of safety and propriety.

Mr. Chairman, we applaud this Committee for holding this hearing today because now is the time to fix this problem. While the recent FDA raids that were earlier referenced are an important step to protect consumers, the current law severely restricts the FDA and its ability to stop, much less slow down the designer steroid gold rush.

Both pre-market and post-market changes are required to give all consumers a truly healthy choice.

The legitimate dietary supplement companies truly concerned about the health and safety of our consumers have nothing to fear

by the proposals that hopefully will be discussed and are presented in my written testimony. You saw it as committed to being part of the solution. And in the weeks to come we will be announcing an effort supported by the National Football League, Major League Baseball, National Basketball Association, and the United States Olympic Committee and many other entities equally concerned about this topic and committed to solving the problem.

We look forward to working with all groups that have a sincere interest in preventing these dangerous products from so easily getting into the hands of our young children.

I would like to finally thank this Committee for its time and its interest in this important public health issue and for inviting me to share USADA's experience about the reality of the market.

Thank you.

Chairman SPECTER. Thank you very much, Mr. Tygart.

We now turn to Mr. Daniel Fabricant, Interim Executive Director and CEO of the Natural Products Association, which is a trade association representing the natural product industry.

Mr. Fabricant has his Bachelors degree in Chemistry from the University of North Carolina; Ph.D. in Pharmacology from the University of Illinois at Chicago.

Thank you for coming in, Mr. Fabricant. Your testimony is next.

STATEMENT OF DANIEL FABRICANT, Ph.D., INTERIM EXECUTIVE DIRECTOR AND CEO, VICE PRESIDENT SCIENTIFIC AND REGULATORY AFFAIRS NATURAL PRODUCTS ASSOCIATION, WASHINGTON, DC

Mr. FABRICANT. Thank you, Mr. Chairman, Senator Hatch. On behalf of the NPA, thank you for the opportunity to be here today. We represent the interests of more than 10,000 retailers, manufacturers, suppliers, and distributors of healthcare products, dietary supplements, and natural personal care as well as our source for the millions of Americans who use supplements each year. I am also a former college athlete and sports nutrition expert, so I have a deep personal understanding of this issue.

First let me say that we welcome this hearing because we share your concerns about illegal steroids. Selling products containing illegal substance is already a crime. Whenever a product containing illegal substance is identified, be they steroids or something else, we are the first to call for throwing the book at the offending party. Anyone caught selling steroids should be prosecuted to the full extent of the law and the natural products industry has worked for years to pass those laws.

We believe that tougher enforcement and prosecution, again, to the fullest extent of the law, are the best ways to stop the criminals. The barriers to enforcement are simple: money, manpower and will.

We fully support strong rules to ensure what is on the label is what is in the bottle. The criminals who illegally sell steroids do not. We fought for additional DEA enforcement ability, especially concerning the passage of the Anabolic Steroid Control Act of 2004. This law gave DEA additional authority and made it easier for them to schedule anabolic chemicals. We have also worked hard for good manufacturing practice regulations, serious adverse event re-

porting and the pre-market, new dietary ingredient notification system as well as other important provisions of the Federal Food, Drug, and Cosmetic Act which are used to regulate the space. We also strongly support the FTC's activities against false and deceptive advertising.

Criminal activity is always a problem. We are not surprised that criminals defy these laws. That's what criminals do. We are not surprised that criminals ignore current legal requirements to notify the government of their intent to sell illegal substances.

So, again, we urge the panel to get tough on criminals. That is why our industry has fought repeatedly for Congress and the Administration to provide the Drug Enforcement Agency, the FDA, the FTC, and other agencies the resources they need to enforce the law. For many years, quite frankly, their budgets were slashed and these resources were lacking.

Over the past 12 months, notably at FDA, Congress has provided a significant infusion of funding which has led to a noticeable increase in activity like the enforcement activity last week that made the new cycle. We welcome this increased government enforcement and support efforts to boost resources further. The criminals who illegally sell steroids do not.

There are additional enforcement measures that under current law could be used. For instance, the FDA sent 28 warning letters to firms that were illegally marketing products containing steroids in the past 5 years. While warning letters are certainly a good start, how many of those letters were followed up with court action which is well within the authority of the FDA to pursue.

Likewise, to our knowledge, DEA has only proposed listing of three additional compounds under the Anabolic Steroid Control Act of 2004 in the past 5 years. These limited enforcement activities are not an effective deterrent and make it far too easy for criminals to stay one step ahead of the law.

One place the agencies might concentrate an increasing effort is on those products marketing themselves with street drug names for steroids. I would also say this to any athlete out there, beware of any product that sounds like an illegal steroid. Because if it is posing as steroid or some steroid-like knock off, chances are, it very well might be. And anyone seeking to buy these illegal products is doing such at a great risk to themselves.

Finally, it is in our best interest to continue to earn the public's trust and anything we can do to separate the legal, safe, healthy supplement industry from the seedy, fly-by-night, and unsafe world of illegal steroids is worthwhile.

Indeed, when any athlete blames an off-the-shelf dietary supplement as the cause for a banned substance being found in their bodies, our industry is always the first one to ask them to name the supplement, name of the manufacturer, and name the store where they bought it. We asked the same question of Donald Fehr who essentially blamed the entire steroids scandal in major league baseball on the legal dietary supplement industry.

Clearly, when it comes to drug testing in athletes we all have more questions than we do good answers.

So, Mr. Chairman, again, we are glad you are holding this hearing. We support efforts to stop the sale of illegal steroids. We

strongly support resources for government agencies to enforcement the law. We stand ready to work with the committee, the government, non-government agencies, and supporting agencies to help identify and remove criminal activity which is the root cause of this tragedy.

Thank you. And, again, I look forward to your questions.

Chairman SPECTER. Thank you, Mr. Fabricant.

Our final witness is Mr. Richard Kingham, partner at Covington and Burling, concentrating on food and drug law, product liability and product safety. Represented many major pharmaceutical manufacturers and biotech companies as well as trade associations. Graduate of George Washington University, law degree from the University of Virginia.

Thank you very much for coming in Mr. Kingham and the floor is yours.

**STATEMENT OF RICHARD KINGHAM, COVINGTON & BURLING,
LLP, WASHINGTON, DC**

Mr. KINGHAM. Thank you, Mr. Chairman and Senator Hatch. Manufacturers of legitimate dietary supplements share the concerns that you have with the distribution of body-building products that contain anabolic steroids. The adverse effects of those products are well-known and those substances should not be available for general use.

It is important to recognize, however, that the vast majority of dietary supplements are in no way implicated by the matters being discussed in this hearing. More than 150 million Americans regularly use legitimate dietary supplements and those products offer significant health benefits to the people who use them.

There is, moreover, and this is the main focus of my presentation, no need to amend existing legislation to deal with anabolic steroids. The Food and Drug Administration and the Drug Enforcement Administration both have ample authority to deal with the problem by making use of existing statutory powers.

Congress has twice amended the Controlled Substances Act to give DEA special power to regulate anabolic steroids. The most recent amendments enacted in 2004 greatly expanded the list of substances subject to regulation under the statute to include metabolic precursors, salts, esters and ethers of listed substances. Congress also authorized DEA to add new substances to the relevant schedule without proof of anabolic effect, thus simplifying the burden for administrative scheduling actions. Persons who traffic illegally and scheduled anabolic steroids are liable to severe criminal penalties.

FDA also has broad powers to prevent distribution of products containing anabolic steroids under existing provisions of the Federal Food, Drug, and Cosmetic Act. Although many of the products that are currently promoted in stores and in the Internet are labeled as dietary supplements. They seldom, if ever, are in compliance with dietary supplement provisions of the law.

FDA has multiple enforcement tools which, in fact, are set out in Mr. Levy's written testimony to this hearing, to deal with products of that type. These include provisions of the Federal Food, Drug, and Cosmetic Act that relate both to drugs and to dietary supplements. Many product, for example, are advertised with

claims that fall within the new drug provisions of the Food and Drug Act and are, for this reason, both misbranded and in violation of statutory provisions that require pre-market approval of new drugs. Others contain new dietary ingredients for which required pre-market notifications have not been made to FDA under the dietary supplement provisions of the statute. Those products are legally deemed adulterated and are liable to the full range of enforcement measures under the statute including seizures, injunctions, and criminal prosecution of responsible persons.

The provisions of the Food and Drug Act governing pre-market submissions for new drugs and new dietary ingredients do not require FDA to prove that a product is unsafe, but only that the required pre-market procedures have not been followed. Thus, the burden of proof on the government is minimal and experience suggests the courts are willing to interpret the provisions of the act liberally to protect the public against unlawful products.

For this reason a warning from FDA backed up with a credible threat to take formal enforcement action is usually sufficient to achieve compliance.

FDA has, as Mr. Levy has stated, issued a number of warning letters to companies that distribute products containing anabolic steroids and it has the capacity to issue more letters and to take formal enforcement actions as appropriate.

The Food and Drug Act also effectively addresses the problem of so-called "designer drugs" that are formulated to circumvent the scheduling provisions of the Controlled Substances Act. Anabolic steroids that are not listed in the relevant schedule will typically be new within the meaning of the provisions of the Food and Drug Act that require prior approval of new drug applications or submission of new dietary ingredient notifications.

Now, as has also been mentioned, and recent reports suggest, that there are some products on the market whose labeling does not declare the presence of anabolic steroids that are detected in laboratory assays. Those ingredients might be surreptitiously added to what would otherwise be lawful products. But those practices are clearly illegal under multiple provisions of existing law.

The Food and Drug Act, for example, prohibits the addition of the deleterious substances to legitimate products. It imposes special requirements for good manufacturing practice for dietary supplements that include controls on contaminants and the ingredients that are added to products and it requires label disclosure of ingredients.

As Dr. Fabricant said, what's in the bottle must be on the label of a dietary supplement.

As with the provisions of the law relating to new drugs and new dietary ingredients, these provisions can be enforced with the full range of sanctions under the law.

For these reasons I do not believe that amendments to the law, especially a pre-market approval requirement would be appropriate. Existing law, if properly enforced, is sufficient to assure protection of the public.

A pre-market approval requirement for these products, which, by the way, they were not subject to prior to 1994, would only add to

the expense of bringing them to the market and increase administrative responsibilities at FDA.

Body-building products constitute less than 10 percent of the market for dietary supplements in the United States. And the products that are the subject of this hearing are a tiny fraction of that market segment. It would be a mistake to alter the carefully crafted regulatory framework for all dietary supplements simply to deal with a small number of outlier products that can be effectively controlled under existing statutory provisions.

Thank you.

Chairman SPECTER. Thank you, Mr. Kingham.

We will now proceed with a 10-minute round of questioning.

Mr. Tygart, in your judgment are the existing laws adequate to protect the public from dietary supplements—represented as dietary supplements which have steroids or steroid substances?

Mr. TYGART. I think clearly no, from our perspective.

Chairman SPECTER. You have Mr. Jareem Gunter, would you have him step forward and let us hear what happened to him.

Mr. Gunter, would you mind stepping forward?

Mr. Tygart has described your experience. Would you tell us what happened to you in your own words?

Mr. GUNTER. Yes. So I went to college in Missouri, Lincoln University, to be exact. And while I was in school I ended up getting sick. I went home for the summer and I found a supplement on line that I thought would be healthy for me or would be something that wouldn't hurt me.

In the beginning of the year our coach comes in with the health instructor that comes in and gives us a list of all the substances that we cannot take. So the list was pretty in depth. I looked at the list and I went to GNC and compared and contrasted things that I could not—that I wasn't able to take. And most things that were at GNC I could not take because it had some—either the supplement was on there or something that was in the supplement was banned from NCAA or conference.

So I went back to the computer and was trying to figure out things I could take. I researched for about three to 4 weeks different products that I could take that would be legal that wouldn't be harmful to me. When I found the product that I took, it was called Super Draw. When I found it I thought I had found a diamond in the rough, something that I felt that wouldn't harm me at all. And also it would be helpful to me.

Chairman SPECTER. Did you take it?

Mr. GUNTER. Yes.

Chairman SPECTER. And did it harm you?

Mr. GUNTER. Yes.

Chairman SPECTER. And in what way did it harm you?

Mr. GUNTER. It actually gave me liver failure. So I was in the hospital for a while.

Chairman SPECTER. Gave you what?

Mr. GUNTER. Liver failure.

Chairman SPECTER. Liver failure?

Mr. GUNTER. Yes. So I was in the hospital.

Chairman SPECTER. How long were you in the hospital?

Mr. GUNTER. It was about 4 years ago, so I—to be exact, it was anywhere between four to 6 weeks I was in the hospital. And it constantly wasn't four to 6 weeks in and out, I was in there for good and couldn't leave.

Chairman SPECTER. And were you advised as to what potential consequences there could have been from taking that supplement of your liver failure?

Mr. GUNTER. So the doctor let me know that throughout my life it could come back at any time. As of right now I am OK. But the doctor told me to be aware of whatever I do just to make sure because it could come back at any time.

Chairman SPECTER. Mr. Levy, you testified that there are problems with misleading labeling, there are no quality controls, you issue warnings and public health advisories, some 28 warnings, you specified. You listed a long line of problems, pulmonary embolism, stroke, kidney failure, liver problems. In the absence of preclearance is there any effective way for the FDA to deal with these problems?

Mr. LEVY. I would answer that by saying that this is a very challenging area in which to regulate because it's difficult to find violative products and it can be difficult to act on those products.

Chairman SPECTER. Did Mr. Tygart accurately describe all that it takes to put one of these dietary supplements on that market?

Mr. LEVY. I don't recall exactly what Mr. Tygart said. Generally ?

Chairman SPECTER. He said you could get a substance—he testified just a few minutes ago; were you listening?

Mr. LEVY. Yes. Yes.

Chairman SPECTER. Well, he testified that you could take a substance, you could put it in a bottle, you could put some liquid in it, then you could get a printer and put a label on it and sell it.

Mr. LEVY. That is . . .

Chairman SPECTER. Did he actually describe the process?

Mr. LEVY. Yes, I think that's quite possible. That probably would not be legal, but, yes, it's possible.

Chairman SPECTER. Well, we know it's not legal and Mr. Kingham and Mr. Fabricant had decried these illegal practices to Senator Hatch. But the question is, how do you safeguard the public against that?

Mr. RANNAZZISI, you described what you have to go through in a very elongated process. Does DEA have any effective way of dealing with this problem considering the description you made as to the lengthy kind of an investigation, the kinds of notice you have to put out, the kinds of public hearings there has to be, and the opportunity for people to substitute materials while you're in that process so you have to start all over again?

Mr. RANNAZZISI. Sir, the process is extremely frustrating because by the time we get something to the point where it will be administratively scheduled, there are two to three substances out there to replace it.

Chairman SPECTER. Never mind whether it's frustrating, is it possible for it to be effective?

Mr. RANNAZZISI. At the present time I don't believe we are being effective as far as controlling these drugs; no.

Senator Specter. Mr. Fabricant, you accurately depict the situation as having or Senator Hatch said, you don't use the same words, "bad actor", but how is it realistically possible given what the Food and Drug Administration has by way of resources to deal with this problem without preclearance?

Mr. FABRICANT. Well, I think you touched on it as a matter of resources. I think all of us at the table and those distinguished members of the Committee were all happy with the recent activity last week. I think that calls directly for the need for more enforcement. That is the critical issue here.

Chairman SPECTER. Well, how about it, Mr. Levy, is it realistic for you to follow these people after the fact? How many of these so-called "bad actors" do you think there are out there?

Mr. LEVY. I think there are quite a few bad actors out there. Is it realistic to follow after every one? No, I don't believe so. So, you know, what we have chosen to do is to try to be strategic in the way we approach enforcement actions and to try to get the biggest bang for our buck, if you will.

Chairman SPECTER. Well, the biggest bang for the fewest bucks may not be a very big bang as big bangs go.

Mr. Tygart, come back to the witness stand. What is the impact on these dietary supplements which have steroids with respect to the younger generation like Mr. Jareem Gunter?

Mr. TYGART. Well, I think it's huge. And while my fellow panelists said it's only 10 percent of the \$28 billion industry or 10 percent of the 150 million consumers, 10 percent is 15 million if my math is right. That's huge. And a lot of those are our kids. Just like Jareem, they are going to stores to buy these to be the best that they can be and pursue their American dream.

Chairman SPECTER. How effective is the professional leagues' anti-doping policy?

Mr. TYGART. The leagues are part of this effort. They haven't yet adopted the world anti-doping code, which we think is the gold standard for anti-doping programs and is what our Olympic athletes—

Chairman SPECTER. They have not?

Mr. TYGART. They have not.

Chairman SPECTER. And why not?

I'm not sure. We wish they would. We frankly think they should if they want the most effective policies in place. But they've decided not to.

Chairman SPECTER. And what problems are caused by the decision by the Court of Appeals for the Eighth Circuit stopping the enforcement by the NFL of the disciplinary action taken against the two athletes?

Mr. TYGART. I think it's potentially big and that it could gut the effectiveness of the programs. If every state's law—

Chairman SPECTER. What were the facts of those cases, if you know?

Mr. TYGART. As I understand them from the Minnesota case, and there was a parallel case down in Louisiana, but there were three Minnesota Vikings that were using an over-the-counter product advertised as a dietary supplement for weight loss.

Chairman SPECTER. Did they have adequate notice that they were doing something which could get them into that kind of trouble?

Mr. TYGART. From what I understand of the facts, they were told, as all of our league-level athletes are told, these products are dangerous.

Chairman SPECTER. And how about with J. Ramero, was he adequately on notice?

Mr. TYGART. I think he was adequately warned.

Chairman SPECTER. Why do you say that?

Mr. TYGART. Well, I know the policies are at that level as well as in our world to notify athletes of the potential risk of positive tests in taking any of these supplements.

Chairman SPECTER. Well, who notifies the athletes—the league?

Mr. TYGART. I would think the league and hopefully the union, if they are there to protect their players, they probably have that same obligation.

Chairman SPECTER. And what were the facts of the Mark McGuire case?

Mr. TYGART. I think it came out publicly that he used andro. I don't know that he received any sanction for his use of androstenedione. And that was obviously before androstenedione was controlled as a schedule III controlled substance which it is now.

Chairman SPECTER. Whether he had a sanction, he declined to testify before a Congressional Committee on the privilege against self incrimination; right?

Mr. TYGART. That's right. That's exactly right.

Chairman SPECTER. Do you think there is any doubt that Congress has the authority to legislate to overrule the Court of Appeals opinion in the Eighth Circuit and enforce those laws?

Mr. TYGART. I think so.

Chairman SPECTER. My red light just went on, so I am going to yield now to Senator Hatch. I am going to observe that time limit. Senator Hatch.

Senator HATCH. This is an interesting hearing. Like everything else, law enforcement can only do so much. But the laws are certainly clear that these type of products are illegal. And we wrote them very carefully so they would be. What it really basically comes down to, are we going to put the funds in to be able to do the work that has to be done?

I think FDA, Mr. Levy, is overburdened as it is, without question. And we treat it like a wicked step-sister around here even though, you know, I passed the FDA Revitalization Act in the early 1990's and yet we are still not finished with that class out there. It didn't even start until around 2000 and I blame Congress for a lot of these things and we don't give you enough support.

But let me go to you, Mr. Rannazzisi. I want to thank you for your testimony here today. In your prepared statement you reference the Anabolic Steroid Control Act of 2004. As you know, I was the prime sponsor—

Mr. RANNAZZISI. Yes, sir.

Senator HATCH [continuing]. Of that legislation with former Senator Biden, now Vice President Biden. In that bill we followed the

recommendations of the DEA to refine the definition of what a steroid is and we followed your advice. The purpose of the amendment, the amended definition was to allow the DEA to administratively classify additional compounds as schedule II anabolic steroids. In preparation for this hearing, I was reviewing your previous testimony before the House Committee on the Judiciary from March of 2004. In that testimony you expressed the support of the DEA for the Anabolic Steroid Control Act of 2004. In speaking for DEA you appealed to Congress to provide a legislative remedy of refining the definition of a steroid.

In your testimony you said, this would, “give us new tools to more quickly and effectively classify new steroids as controlled substances.” And as I stated, Congress did that just 5 years ago. We gave the DEA what you basically asked for. However, I noted in your prepared statement that the DEA is in the final stages of classifying three substances scheduled under the Anabolic Steroid Control Act of 2004. You also stated the DEA is in the process of reviewing three other substances.

Now, can you tell me why 5 years after Congress expanded DEA’s authority only three substances have been scheduled? And I’m puzzled as to why three substances, which by your own testimony, have not been finalized yet, will be the first three scheduled under the Anabolic Steroid Control Act of 2004? Is this also a lack of resources?

Mr. RANNAZZISI. No, sir. If we go back to the 1990 Act, if you remember, the 1990 Act required us to show promotion of muscle growth which was virtually impossible for us. We looked at andro for almost 5 years by independent labs and we still, up until the time the act was passed in 2004, could not show that andro promoted muscle growth. That’s why we asked for the removal of the promotion of muscle growth.

While it made our job a lot easier, it, by all means, was still a very difficult process. The problem is, when we schedule a drug it’s got to be based on scientific evidence. It takes at least six to 8 months just to do the cellular studies required to schedule a drug. We have to show that that drug is not a cortical steroid, it is not a progesterone, and it’s not estrogen. That requires several binding studies—cellular binding affinity studies. These are done by outside labs. It takes a while to get all of this evidence necessary to go through the formal process of scheduling. Plus we have public comment. Plus we have to go through the initial notice of proposed rulemaking. And we have to vet it through all the different agencies. This is not a process that can be done overnight.

My colleagues on the panel make it sound like it’s an easy process. It is far from easy. I think doing those first three will help us streamline the process, but I can’t tell you it is going to be much quicker than it is right now.

Senator HATCH. Does DEA have a memo of understanding with the FDA but to assure that the two agencies are effectively coordinating their activities relative to steroids? Do you work together?

Mr. RANNAZZISI. We do work together. In fact, on several investigations DEA and FDA are working together. We just met with the OIG from FDA that were looking at other products in the pharmaceutical chain. We work together. It is not a question of us not

working together. It is a question of the process, the scheduling process. I think we are working together fine.

Senator HATCH. Why haven't you come to Congress then and let us know that you need changes in the law? I mean, frankly I'm not sure you do. We are always going to have bad actors. We are always going to have people who are criminals. It seems to me there's enough legal authority there to get these bad substances off the marketplace. But I understand that there are some pretty wicked, evil people out there that are constantly coming up with these.

Does FDA tell you when they deny a new ingredient notification that could involve an anabolic steroid?

Mr. RANNAZZISI. If I may, sir, could I just talk to one of my scientists?

Senator HATCH. Sure.

[Pause.]

Mr. RANNAZZISI. No, we don't receive a warning scientist to scientist, no.

Senator HATCH. Do you outsource some of this analysis or do you do it with your own chemists?

Mr. RANNAZZISI. No. Well, the chemical analysis we do. But the studies, the cellular studies, animal studies, that all has to be outsourced. We can't do that. Yes, sir.

Senator HATCH. Do you check with FDA to see if they have received a new dietary ingredient notice for a compound you're looking at possibly listing under the Controlled Substances Act?

Mr. RANNAZZISI. Not in regard to anabolic steroids, sir.

Senator HATCH. Let me ask you, Mr. Levy, on page 11 of your testimony in the first full paragraph, all three examples that you present would be illegal under the 1994 DSHEA law. In every example under DSHEA they would be illegal. Now, FDA has the authority to take those products off the market and tell me why that isn't happening or is it happening? If it isn't, then I want to know what we can do to help you.

I mean, I made it pretty clear, I think, that you don't have the resources to be able to do everything you need to do in these areas. And I blame us for that because we've tried to get you the resources and we just haven't been able to be as successful as I would like us to be.

Mr. LEVY. I would say that I think that we are doing what we can. You know, we have had an agency-wide reemphasis recently on drug safety as a part of this. I think that we have taken our recent actions—I'm struggling to find what three ingredients you are specifically referring to. But I would say that I think that the ingredients that we mentioned in my testimony, we have at some point taken some enforcement action with respect to all of those.

Senator HATCH. Let me ask just a couple of questions to Mr. Fabricant and Mr. Kingham.

Has the Federal Government, specifically the FDA and the DEA reached out to the industry to work in a collaborative manner to address issues associated with products containing synthetic steroid ingredients that are marketed as dietary supplements?

Mr. FABRICANT. Not in any formal manner. There is no memorandum of understanding or agreement in that capacity.

Senator HATCH. Do you work together at all?

Mr. FABRICANT. We do from time to time, but it is on an informal basis and we have notified them of ingredients that are of concern to us that they should be monitoring for.

Senator HATCH. Mr. Kingham, what is your response to the concerns raised by both the FDA and DEA about the difficulties encountered when they try to pull products containing steroids off the market?

Mr. KINGHAM. Well, Senator Hatch, first of all, let me point out, and I think from reading Mr. Levy's testimony, that we agree on this, the products that this hearing is about require some form of submission to FDA before they enter the market, either a new drug appointment or a new dietary ingredient notification. And, moreover, for multiple other reasons are almost always in violation of other provisions of the Federal Food, Drug, and Cosmetic Act.

If people violate existing requirements for new drug application submissions and new dietary ingredient notifications, why would we believe that they would comply with some new pre-market approval requirement that you would put in the law?

The answer is, I think, that the FDA, in particular, has to use the authority it already has to bring severe, serious, informal enforcement actions against violators.

Senator HATCH. Does it have enough authority?

Mr. KINGHAM. I think they do, Senator. I believe they do. And I think looking at Mr. Levy's testimony that he and I agree that the products that we're discussing today are almost invariably clearly in violation of law. The question is whether the law will be enforced.

Warning letters are good, seizure actions are a good thing as well. But eventually if people float the law, I believe that criminal prosecutions may be appropriate.

Senator HATCH. Thank you, sir.

My time is up, Mr. Chairman.

Chairman SPECTER. Thank you, Senator Hatch.

I will now proceed with 5-minute rounds.

Mr. Kingham, your testimony is, documented in the written part submitted, more than 150 million Americans regularly use legitimate dietary supplements. And you say that body-building products constitute less than 10 percent. So by your statistics you have something in the range of 15 million people, somewhat less than 15 million people use body-building dietary supplements. Now, given the facts of life as to what is happening in this field, don't you think it's important that Congress should modify the law to have some preclearance requirements on these body-building supplements?

Mr. KINGHAM. Well, Senator, first of all, what I meant to say and I am sorry if I wasn't clear is that the whole body-building segment of the dietary supplement market is about 10 percent. But, of course, that includes vitamins and minerals and other products that are specifically marketed to body-builders. It is a tiny fraction of the business that comprises the products we are talking about.

Chairman SPECTER. Now, wait a minute. Wait a minute. You have a 150 million people who take supplements?

Mr. KINGHAM. Yes.

Chairman SPECTER. So you have 10 percent, you say, on body-building supplements, that's 15 million people; am I correct?

Mr. KINGHAM. You are absolutely right.

Chairman SPECTER. That's a lot of people at risk.

Mr. KINGHAM. You are correct. But that includes a market segment to which legitimate dietary supplements that are perfectly safe and perfectly appropriate are promoted.

Chairman SPECTER. Well, no doubt about the fact that many are legitimate that are not causing damage.

Mr. KINGHAM. Yes.

Chairman SPECTER. But you still have millions of people being exposed to the problem. Now, I agree with you that more has to be done on the regulators.

Now, let me turn to you Mr. Rannazzisi. You have Super Draw which was on the market which Mr. Jareem Gunter used. In the affidavit issued by your agency says that Super Draw is a synthetic anabolic steroid. But yet Super Draw is not listed on schedule III as a prohibited anabolic steroid; why not?

Mr. RANNAZZISI. It is one of the substances that we are looking at.

Chairman SPECTER. What?

Mr. RANNAZZISI. It is one of the substances that we are looking at. It is out on the market. It is not—

Chairman SPECTER. Wait a minute, what are you looking at? You've got the affidavit which your agency filed, what more is there to look at?

Mr. RANNAZZISI. It still has to go through the scheduling process, sir. It still has to go through the scheduling process.

Chairman SPECTER. Wait a minute. You took an affidavit that it was an anabolic steroid.

Mr. RANNAZZISI. Yeah.

Chairman SPECTER. When you say something that is false in an affidavit filing we may find a criminal case here, but in the wrong direction.

But when you have identified Super Draw as an anabolic steroid and you have a case of a young man who has been hurt, is there any conceivable excuse for your agency not having listed it on schedule III?

Mr. RANNAZZISI. Sir, I can't just list something on schedule III. It still has to go through the scheduling process. It must go through the scheduling process. I don't have the authority just to say, I want this drug scheduled. There's a process through the Administrative Procedures Act—

Chairman SPECTER. You can take an affidavit that it's an anabolic steroid but not put it on schedule III?

Would you like us to change the law to simply the scheduling process?

Mr. TYGART. We would, Senator.

[Laughter.]

Chairman SPECTER. We understand that.

Mr. TYGART. And worse than that—

Chairman SPECTER. We are going to give Mr. Tygart's testimony right under your name if you don't speak up.

[Laughter.]

Mr. RANNAZZISI. I apologize sir.

Chairman SPECTER. Let me turn to you, Mr. Levy. My time is about up and I want to observe the time.

Ethodura was sold as a dietary supplement banned by the FDA in 2004, but the ban occurred 10 years after FDA issued its first advisory and only after FDA had received thousands of reports of adverse effects, including deaths. What possible explanation is there for that kind of a delay?

Mr. LEVY. I am going to turn to Dr. Francos on this.

Chairman SPECTER. Do you want to consult your lawyer?

[Laughter.]

Mr. LEVY. My dietary supplement expert.

Chairman SPECTER. Well, let's come back to you Mr. Tygart, since nobody else seems ready to—

Mr. TYGART. Worse than the fact that it's not in the process of being scheduled, the very same product that was identified by affidavit in that search warrant, certain products in that search warrant were seized. You can still buy that designer steroid over the Internet. We purchased this through Amazon.com and it has the same designer steroid that should be controlled being sold today by other companies.

Chairman SPECTER. Mr. Rannazzisi, we are about to close this hearing, and Mr. Levy, too, you can supplement your answers to the Committee in writing.

Senator Hatch.

Senator HATCH. When you were talking about 10 percent, you didn't mean 15 million people, you meant there might be that many who are taking some sort of dietary supplements and some may even be taking some body-building supplements as well.

Mr. KINGHAM. That's correct.

Senator HATCH. That doesn't mean all 15 million were taking these—

Mr. KINGHAM. No, I don't think so.

Senator HATCH [continuing]. Banned substances or the substances that should be banned?

Mr. KINGHAM. That's right. And the other thing I really want to underscore, it's terribly important, I believe, and I don't think the FDA disagrees, that virtually all the products we are talking about require, already, under current law, some kind of submission to FDA before they enter the market. These people are just breaking the law. They need to be punished. They need to be caught, and the law needs to be enforced. But the law is not the problem. The problem is enforcement.

Senator HATCH. Well, that is my contention. I think we wrote the laws well.

Now, let me ask you—let me see if I can find my notes here—Mr. Tygart, on too many occasions athletes have appeared before the cameras and apologized for testing positive for a banned substance. In some cases the athlete may not have intended to ingest a substance banned by his or her collective bargaining agreement or rules of competition. However athletes sometimes fail to assume personal responsibility when they make a mistake, especially in cases that if they had consulted with their league office or Olympic Committee the issue could have been avoided from the onset.

Now, that does not excuse bad actors in the sports nutrition industry. However, athletes skirting the truth need to be held accountable for their own actions, and I think you certainly have indicated you believe that.

In your prepared statement you stated that the USADA's mission is to, "preserve and protect the health of athletes." Can you explain to me the support USADA provides to athletes when they are considering taking a supplement? For example, is there a dedicated telephone number or a hotline that athletes may call to seek advice on supplements?

I ask this because in a recent case a high-profile athlete failed to call his league's hotline and the result was he tested positive for a banned substance. Now, the league representatives have stated time and time again that had the athlete called the hotline he would have been told not to ingest that product.

Do you have the same system for your—

Mr. TYGART. We do. We are very clear in our educational materials to the millions of athletes that technically fall into our jurisdiction. That given the poor regulation in the dietary supplement market, any product you take from a multivitamin to an anabolic-type product, you run a risk of testing positive.

And, of course, I don't believe every athlete that stands up and says they got it from a supplement. I don't think that's the case. We have had at least two cases, one the Jessica Hardy case, one the Kicker Vinsel case where Kicker Vinsel was taking a multivitamin. And a panel after a full litigated case determined that the multivitamin that he took was what caused his positive test for a steroid. The same in the Jessica Hardy case.

Mr. FABRICANT. May I make a point on the Kicker Vinsel case? I believe it was overturned later on appeal and then settled out of court.

Senator HATCH. OK. Well, Mr. Fabricant, you are also a pharmacist?

Mr. FABRICANT. Pharmacologist. Designing drugs; yes.

Senator HATCH. As I understand it, the report said there were upwards of 100,000 people who may in part lose their lives because of pharmaceuticals in this country. Is that way off the beam?

Mr. FABRICANT. Adverse event reports?

Senator HATCH. No, I'm talking about actually are harmed by ingesting pharmaceuticals that really they shouldn't have taken.

Mr. FABRICANT. I would say that, you know, we worked hard to put the adverse event reporting system in place and we haven't seen any numbers anywhere near that with respect to that.

Senator HATCH. OK. Well, then in dietary supplements do you see any real—and I'm talking about dietary supplements that are legal—do you see any real adverse events?

Mr. FABRICANT. With the legal dietary supplement world we see the system as working. We have had issues, we've had signals, we've had notices, and they've all been acted upon very quickly by industry. We have had recalls—voluntary recalls where the industry acted very responsibly based on only 14 products—14 adverse event reports. You compare that with other industries, other consumer product industries it exceeds 60,000 for them to even take action against a pharmaceutical on the market.

So, you know, for the assertions that the industry isn't tightly regulated, I would advise them to look at just how quickly the supplement world has responded in a short time.

Senator HATCH. Our system is working?

Mr. FABRICANT. Yeah, very well.

Senator HATCH. All right. Now, let me ask you this, Mr.—I am having trouble—

Mr. RANNAZZISI. Rannazzisi.

Senator HATCH [continuing]. Of the 58 dietary supplements mentioned in your testimony that purportedly contain one or more of the three steroids in the final stages of the scheduling process, how many of them are currently on the market? And isn't it true that the FDA has the authority to remove any of those products under the laws that we've passed here?

Mr. RANNAZZISI. Yes, sir. I think our scientists have talked about those substances. Some are, some aren't. We don't know because this is over a period of time.

I have the list of the drugs and the names of the drugs that are on the market or were on the market when we did our checks. And I believe that list was shared to FDA.

I have the brand names. If you would like I could submit it for the record.

Senator HATCH. I think it would be good if you submitted that.

Chairman SPECTER. Well, thank you very much, gentlemen. I am constrained to conclude the hearing by four. Senator Hatch, would you like to make a closing comment?

Senator HATCH. Thank you, Mr. Chairman. As usual you are always courteous and a dear friend.

But let me just say this to you. We have done our very God-level best to try and make sure these laws have the strength in them to be able to be implemented. I still believe that they are well put together. If we had premarket approval the whole industry would be gone and we would all be bereft of what really are very, very good vitamins and minerals, amino acids, and herbal products.

Because to go through the safety and efficacy process of the FDA can cost up to a billion dollars or more and even as many as 15 years. So there is no way anybody in the dietary supplement industry could go through that.

But I think by and large the industry is a highly competent, highly good industry. But it is inexcusable that we permit any of these anabolic steroids to be on the market.

Mr. Tygart, I appreciate what you are trying to do. It is a tough, tough thing because all of us hate to see a star athlete get chewed up, especially in the Olympics. But I hate to see it in professional sports too. And, you know, sometimes it really isn't their fault, many times it is. But I just hope that we all will work together. And if you can give us better ways of amending these laws or making them even better than they are, I would be happy to consider that. But I think there's enough language in the laws, in these various laws that we've passed that I've personally been a proud sponsor of for FDA to do the job, for DEA to do the job, and of course hopefully helpful to you on USADA group as well.

There is no desire on any of our part to have anybody illegally use anything. And we certainly don't want our folks in this country

or any other country to be subject to deleterious substances, which, under the DSHEA law, FDA has an absolute right to take off the marketplace automatically.

So it isn't like the laws aren't there. The question is, I would suggest to all of you—and this is my last sentence—that you really push the Congress to give FDA the resources it needs to do this job. The law is there. All we have to do is have the resources.

Thank you, Mr. Chairman.

Chairman SPECTER. Thank you, Senator Hatch.

The efforts to give FDA more resources on many, many lines has not been successful. I think there are some things that need to be done here, some real questions. And I think the Drug Enforcement Administration needs to answer the question which hasn't been answered here today about why Super Draw was not placed on the schedule III list after it was identified and an affidavit had filed as being an anabolic steroid. And if you need some revision on your listing, let us know. Don't wait for us to come to you.

And the business about ephedra being identified in 2004 with a ban 10 years after the FDA first issued its first advisory and only after the FDA received thousands of reports of adverse effects, including deaths, that's not satisfactory.

When Senator Hatch talks about the legitimate part of the industry, I think it's true, vastly legitimate. But still, if you have 15 million people who were taking supplement with steroids and although some of that is legitimate, we're exposing millions of people to problems. So that from my view, I think we need to look at some preclearance issues here unless we find some way to solve it otherwise.

And the leagues have a question to answer which the Subcommittee is going to put to the leagues. Why haven't you adopted the anti-doping policy? So perhaps the hearing was useful for all the questions which have emerged.

We thank you all and we especially thank Mr. Jareem Gunter and wish him well and wish you all well.

That concludes our hearing.

[Whereupon, at 4 p.m., the hearing was concluded.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

Questions for Daniel Fabricant, Interim Executive Director/CEO, Vice President, Scientific & Regulatory Affairs, Natural Products Association, Washington, D.C. from Senator Orrin Hatch

1.) The Good Manufacturing Process regulations were a long time coming. I know that legitimate companies comply with these requirements. How do these requirements guard against contamination of a dietary supplement with a drug?

Consumers want to be assured that what's on the label is in the bottle – nothing more, nothing less – and the GMP regulation aims to make sure that is the case. We're glad the regulation (21 CFR Part 111) was finally issued in 2007 and we would have been even more pleased if it had come out even sooner.

GMP compliance is the sole responsibility of those domestic and foreign firms who manufacture, label, package or hold dietary supplements in the United States, including those involved with testing, quality control, packaging, labeling and distributing them in the United States. Under the cGMP rule, manufacturers are required to:

- Employ qualified employees and supervisors;
- Design and construct their physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, labeling and holding;
- Use equipment and utensils that are of appropriate design, construction, and workmanship for the intended use;
- Establish and use master manufacturing and batch production records;
- Establish procedures for quality control operations;
- Hold and distribute dietary supplements and materials used to manufacture dietary supplements under appropriate conditions of temperature, humidity, light, and sanitation so that the quality of the dietary supplement is not affected;
- Keep a written record of each product complaint related to cGMPs; and
- Retain records for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.

While many of these provisions in and of themselves can safeguard against contamination of a supplement, the rule also requires a number of specific modalities to protect against contamination. For example:

- Requires testing the identity of every incoming dietary ingredient. This prevents mix-up and the potential for cross-contamination should that firm also manufacture active-pharmaceutical ingredients (APIs) in that facility;
- Requires identification and quarantine of returned dietary supplements until quality control personnel conduct a material review and make a disposition decision;
- Requires reserve samples of dietary supplements to be held in a manner that protects against contamination and deterioration; and
- Requires a qualified person to investigate any "product complaint" that involves a possible failure of a dietary supplement to meet any cGMP requirement, with oversight by quality control personnel.

2.) Please tell me more about how the dietary supplement industry views FDA warning letters, such as the ones issued in July regarding supplements adulterated with steroids.

The industry is very pleased that the agency took action against firms selling unapproved drugs masquerading as dietary supplements. We applaud their efforts and would like to see more enforcement against firms that violate the laws that regulate the dietary supplement industry.

3.) Under current law, any facility that manufactures, packages, or processes a dietary supplement must register with FDA before starting operation. If these products are being made by unregistered firms, that is a violation of the law, and the extensive testing requirements Mr. Levy believes are so burdensome aren't even necessary in these instances. Would you agree?

Yes, if a facility isn't registered or in compliance with other provisions of the FDCA, the agency can certainly take action. As we saw with the raids of the firms that followed the warning letters issued in July of 2009, FDA can and does seize product. If FDA believes it takes too long to build a case, to me that means that they (FDA) need more personnel and resources. But they clearly have the authority to pull product off the shelves and they do. The agency also has an "imminent hazard" clause under DSHEA which means that if they suspect a product is a threat to the public health they can have it removed from the shelves. To declare an imminent hazard the Secretary does NOT have to prove a product is hazardous. As you noted at the hearing and as previous FDA commissioners and heads of CFSAN had testified to, DSHEA gives the agency more than adequate authority to regulate the marketplace.

4.) I appreciate that your testimony indicates your association shares the concern we in Congress have shown about the problem of illegal steroid precursor products, many of which could be threatening young athletes.

Would your association pledge to work with Congress as we consider steps to make these products less available, such as possible amendments to the Controlled Substances Act?

We support efforts to stop the sale of illegal steroids. We strongly support resources for government agencies to enforce the law. We stand ready to work with the Committee, the government, non-governmental organizations, and supporting agencies to help identify and remove criminal activity, which is the root cause of this tragedy, from the system.

Additional Questions

1.) There has been a lot of discussion about the article appearing Sports Illustrated earlier this year. Mr. Kingham and Mr. Fabricant, could I get your reaction to some of the accusations made in the article? I would appreciate hearing your insights.

Unfortunately the intent of the sports illustrated article "What You Don't Know Might Kill You" was to make the dietary supplement industry look as big and as bad as possible, it is a good example of why the authors of it and authors of other such articles may want to check their facts more closely before going to print. For starters, their headline referencing Americans' "\$20 billion obsession" with sports supplements. The truth is that sports supplements account for approximately \$2.5 billion in annual sales, according to the same source they incorrectly cited. That would put the size of this "broad-based juggernaut" as we were called in the article a half million south of the \$3 billion scrapbooking and pen and pencil industries in consumer sales.

Additionally, while it's true that there are 33.5 million consumers of sports supplements, only seven million are regular or heavy ("obsessive?") users, including performance athletes. I wish it stopped there but a great deal more in the story was exaggerated, distorted or just plain wrong. For instance, all dietary supplements must comply with stringent manufacturing and adverse event reporting requirements, in the same manner and magnitude of other industries also regulated by the Food and Drug Administration (FDA), such as prescription drugs and medical devices. And claims made about dietary supplements must be truthful and non-misleading, or the Federal Trade Commission will levy heavy fines, such as it did in 2008 to the tune of \$40 million. Additionally, any new ingredient that is to be marketed as a dietary supplement must first pass FDA scrutiny for safety and label claims. This means that manufacturers are prohibited from creating "novel" ingredients and marketing them as a dietary supplement until safety data have been reviewed.

These requirements represent significant barriers to entering -- and staying -- in the marketplace. With regard to the online article tied to the Sports Illustrated story, titled "FDA Reports," we appreciate that the authors appropriately disclose that "*In most cases, as the FDA reports state, it is difficult or impossible to tell whether the supplement was the cause of a particular consumer's*

ills. Many of the complaining consumers, whose names are redacted, take other medications, have prior health problems, or have their cases closed when they fail to follow up by providing the FDA with medical documentation or contact information for a doctor that examined them." However, these facts did not get in the way of the author first linking a variety of adverse reactions to apparent supplement use. Since most of your readers may not be familiar with adverse event reporting, giving this subject some context would have useful. For instance, in 2008 the FDA received 600 reports from manufacturers regarding adverse experiences potentially related to the use of a dietary supplement. During the same time period, the FDA received more than 490,000 reports from drug manufacturers regarding prescription medications. The industry has long supported legislation requiring reporting of adverse events for dietary supplements as we believe it demonstrates that when used responsibly, these products are overwhelmingly safe. But even without a comparison to prescription drugs, the fact that more than 180 million Americans use supplements safely and effectively every day points to a rather remarkable safety record for any consumer product.

In regard to the story involving a visit by "sports medicine expert" to a GNC store, there are a few items that were really off base in the story. First and foremost, "case reports" are not conclusive scientific evidence or concrete proof of a physiological reaction. In the next paragraph the expert, in examining a particular supplement bottle, states that there is *"no way a normal person can figure out what's in this. I can't tell what's in this."* Apparently Sports Illustrated wasn't aware that by law, the Dietary Supplement Health and Education Act (DSHEA), all dietary ingredients have to be disclosed on the label of a product in the "Supplement Facts" panel. In this particular case, I'm not sure where the confusion lies. It is clear to see from both the product label and company's website that Glycerol-Phosphoplexx is a proprietary blend of Glycerol Stearate, Calcium Glycero Phosphate, Magnesium Glycero Phosphate, Sodium Glycero Phosphate, Potassium Glycero Phosphate. So consumers and experts alike will know exactly what is in the product, per the letter of the law.

Lastly, and perhaps most troubling coming from a publication like Sports Illustrated, is the fact that pain-relief creams - or any type of cream for that matter, are NOT dietary supplements. A dietary supplement by the legal definition is intended for ingestion in pill, capsule, tablet, or liquid form; it cannot, therefore, be a topical product. While it may have added more drama to the story, citing adverse events and anecdotes related to topical products in a story about dietary supplements is at best misleading to the millions that read Sports Illustrated.

2.) What is your response to the concerns raised by both the FDA and the DEA about the difficulties encountered when the agencies try to pull products containing steroids off the market?

There are additional enforcement measures under current law that are available and could be used. For instance, the FDA sent 28 warning letters to firms that were illegally marketing products containing steroids. Warning letters are a good start, but how many of those were followed by court action, which is well within the authority of the FDA to pursue? Likewise, to

our knowledge, the DEA has only proposed the listing of three additional compounds under the Anabolic Steroid Control Act of 2004 -- just three compounds in five years. These limited enforcement activities are not an effective deterrent and make it far too easy for criminals to stay one step ahead of the law. More enforcement is needed. We always advocate for greater resources for the agencies to do just that.

3.) Has the federal government, specifically, the FDA and the DEA reached out to the industry to work in a collaborative manner to address issues associated with products containing synthetic steroid ingredients that are marketed as dietary supplements?

While we fought for stronger Drug Enforcement Agency rules, especially the passage of the Anabolic Steroid Control Act of 2004. This law gave DEA additional authority, made it easier to schedule chemicals as anabolic steroids, and increased penalties and fines for criminal activity. No formal collaborative efforts are in place at present between the industry and the agencies. We have certainly through the years sent emails to FDA on potentially troubling websites and advertisements on products that we believe should be investigated further. We have also provided FDA with the insights of potential areas of adulteration. As you can see from the attached email communication (titled Sibutramine NPA 2007), we, NPA, brought Sibutramine to the agency's attention a few years ago. Since that time the agency has sent over 50 warning letters to firms that were illegally marketing Sibutramine as a dietary supplement. However, no formal collaborative efforts are in place at present.

4.) In Mr. Tygart's testimony, he makes several suggestions on how to address the problems the Subcommittee is discussing today. Has the industry reviewed his recommendations? Are there areas of agreement?

We have reviewed his recommendations, while we appreciate his passion for the issue, with respect to food and drug law, most of his suggestions are unsubstantiated and really add little to address or deter criminal activity. Criminal activity is always a problem, it is not specific to the dietary supplement industry. While I will leave it to others to quantify, the vast majority of athletes use legal dietary supplements safely and responsibly on a daily basis. Enforcement is the key to assure the consumer in the marketplace.

For example, Mr. Tygart recommends a pre-market process for dietary supplements. However, he fails to recognize that we already have such a process in place for new dietary ingredients (NDI). The NDI process, is a pre-market process, it is described in great detail on the FDA website <http://www.fda.gov/Food/DietarySupplements/ucm109764.htm>. But criminals are already skirting this pre-market process, so we think it's unlikely that criminals will comply with any new regulations requiring them to tell the government when they are about to break the law. They don't comply with the NDI process as it stands now.

Questions for Daniel Fabricant, Interim Executive Director/CEO, Vice President, Scientific & Regulatory Affairs, Natural Products Association, Washington, D.C. from Senator Arlen Specter

1.) How best can we achieve the balance between free and open markets for dietary supplements while keeping all consumers safe from contaminated and unsafe products?

To me that indicates that the current framework allows for such a balance. Two points need to be made to clarify. Steroids are not dietary supplements. If we're talking about steroids and dietary supplements were talking about two different things. Secondly, just because a steroid or other product is marketed as a dietary supplement, that doesn't make it so. Unfortunately, there have been companies that have operated outside of the law by masquerading steroids as dietary supplements. This has unfortunately tarnished the legitimate industry.

As Sen. Hatch pointed out at the hearing, previous FDA commissioners and heads of CFSAN have testified in front of congress that DSHEA gives them adequate authority to regulate dietary supplements to ensure that the American consumer is safe. To me, that indicates that the current framework allows for such a balance. Built into DSHEA are important safeguards for consumers that increased the FDA's authority and enforcement powers over dietary supplements. Because of it FDA has the power to strictly regulate what is stated on a supplement label and what is in the supplement through the GMPs (21 CFR Part 111) which were authorized by DSHEA. Furthermore as we saw in the raids leading up to the hearing FDA can and will remove any products from commerce that pose a risk to public health. Additionally the agency can also impose substantial sanctions, including criminal prosecution on those who violate the law.

2.) Given that many dietary supplement companies are importing their ingredients from India and China how can a company conduct its business to assure the products it sells are not contaminated?

Consumers want to be assured that what's on the label is in the bottle – nothing more, nothing less – and the GMP regulation aims to make sure that is the case. We're glad the regulation (21 CFR Part 111) was finally issued in 2007 and we would have been even more pleased if it had come out even sooner.

GMP compliance is the sole responsibility of those domestic and foreign firms who manufacture, label, package or hold dietary supplements in the United States, including those involved with testing, quality control, packaging, labeling and distributing them in the United States. Under the cGMP rule, manufacturers are required to:

- Employ qualified employees and supervisors;

- Design and construct their physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, labeling and holding;

- Use equipment and utensils that are of appropriate design, construction, and workmanship for the intended use;

- Establish and use master manufacturing and batch production records;

- Establish procedures for quality control operations;

- Hold and distribute dietary supplements and materials used to manufacture dietary supplements under appropriate conditions of temperature, humidity, light, and sanitation so that the quality of the dietary supplement is not affected;

- Keep a written record of each product complaint related to cGMPs; and

- Retain records for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.

While many of these provisions in and of themselves can safeguard against contamination of a supplement, the rule also requires a number of specific modalities to protect against contamination. For example:

- Requires testing the identity of every incoming dietary ingredient. This prevents mix-up and the potential for cross-contamination should that firm also manufacture active-pharmaceutical ingredients (APIs) in that facility;

- Requires identification and quarantine of returned dietary supplements until quality control personnel conduct a material review and make a disposition decision;

- Requires reserve samples of dietary supplements to be held in a manner that protects against contamination and deterioration; and

- Requires a qualified person to investigate any "product complaint" that involves a possible failure of a dietary supplement to meet any cGMP requirement, with oversight by quality control personnel.

With regards to imported ingredients, a big part of being GMP compliant is in qualifying your supplier, with that stated, in 2006 the association opened a branch office in Beijing, the Peoples Republic of China. The goals of that office are twofold. The first, which ties in to our overall mission is to grow the marketplace for natural products in China, the second is that with so much of the industry dominated by commodity ingredients originating from China, we wanted to play

a role in strengthening the supply chain. While some Chinese suppliers are currently undergoing NPA GMP certification, with much of the recent press on the heels of melamine in pet foods, diethylene glycol in toothpaste, and tainted milk protein materials all originating from China, the association wanted to have the ability to display transparency not only for manufacturing practices but also for ingredients. The program is in response to industry efforts to maintain product quality and reliability as competition to supply ingredients and raw materials to the industry grows. In 2007, the association launched another industry first by offering a program for testing Chinese raw materials for purity and composition. While testing materials in China is nothing new, instead of having to rely either on tests provided by China or on postshipment tests, US manufacturers can test the quality of Chinese raw materials prior to shipment, and members have access to a database of suppliers' test results for consideration when making contractual decisions. The association's program also offers suppliers a competitive edge as well as a chance to demonstrate the quality of their products. How the program works is detailed in Figure 23.1. The NPA has a contract with United States Pharmacopocia (USP) to test dietary supplement raw ingredients. The tests may be used to confirm the identity, strength, and purity of the ingredient, or they may be limited to searching for the presence of contaminants. USP scientists in Shanghai, China, perform the tests for the NPA in most cases. In some instances in which USP does not have highly specialized equipment to run some tests, such as microbiological evaluations, USP will subcontract these test to laboratories that USP has inspected and audited.

While the program does not have the storied past of TruLabel or the GMP certification program it has enjoyed much of the same success in its brief history. Recently, the program along with the NPA GMP certification program was featured in the July 2008 Action Update Plan of the Presidential Working Group on Import Safety. Both programs were cited as private sector engagement highlights that help strengthen and secure the supply chain. Another example of the success of the program is that in October 2007, the Association was awarded a grant from the United States Department of Commerce (USDOC), receiving both financial and collaborative support from USDOC through the department's Market Development Cooperator Program in large part due to this initiative. This is just one example of the many that our industry takes to assure the quality of imports.

3.) Do you support any of the regulatory fixes included in Mr. Tygart's written statement?

We have reviewed his recommendations, while we appreciate his passion for the issue, with respect to food and drug law, most of his suggestions are unsubstantiated and really add little to address or deter criminal activity. Criminal activity is always a problem, it is not specific to the dietary supplement industry. While I will leave it to others to quantify, the vast majority of athletes use legal dietary supplements safely and responsibly on a daily basis. Enforcement is the key to assure the consumer in the marketplace.

For example, Mr. Tygart recommends a pre-market process for dietary supplements. However, he fails to recognize that we already have such a process in place for new dietary ingredients

(NDI). The NDI process, is a pre-market process, it is described in great detail on the FDA website <http://www.fda.gov/Food/DietarySupplements/ucm109764.htm> . But criminal are already skirting this pre-market process, so we think it's unlikely that criminals will comply with any new regulations requiring them to tell the government when they are about to break the law. They don't comply with the NDI process as it stands now.

4.) Do you have suggested fixes of your own?

As I stated at the hearing, I believe this is a regulatory problem not a legislative matter. The key is more enforcement. For that to take place FDA and DEA need to have appropriate resources. While the resources have increased recently, greater resources are needed to ensure effective regulation of the vast amounts of products they regulate. Additionally, I believe more communication in a formal structure between the agencies (FDA and DEA) and, the industry will yield some real world regulatory thoughts on the topic that should help all at the table deal with the matter more effectively. Lastly as we stated in our testimony, we support efforts to stop the sale of illegal steroids. We strongly support resources for government agencies to enforce the law. We stand ready to work with the Committee, the government, non-governmental organizations, and supporting agencies to help identify and remove criminal activity, which is the root cause of this tragedy, from the system.

Daniel Fabricant

From: David Seckman [dseckman@nnfa.org]
Sent: Wednesday, October 31, 2007 12:45 PM
To: Daniel Fabricant
Subject: Fw: Follow-up

Sent from my Verizon Wireless BlackBerry

-----Original Message-----

From: "Elder, David K." <david.elder@fda.hhs.gov>

Date: Wed, 31 Oct 2007 11:11:37

To: "David Seckman" <dseckman@naturalproductsassoc.org>

Subject: RE: Follow-up

David - thanks again for this and we've begun looking deeper into the sibutramine issue. We are conducting surveillance and identifying potential targets for sampling and analysis. I can't say what they are at this point but I wonder if any of your industry reps or scientific advisors have any particular brand names or mfr/dist names in mind that we should be sure to consider when identifying our potential targets. If they don't, or if you'd prefer not to identify specific products, I understand and we'll continue our work.

I enjoyed the meeting last week. I'm sorry I had to connect by phone but couldn't avoid it due to other meetings before and after.

Thanks.

David Elder

From: David Seckman [mailto:dseckman@naturalproductsassoc.org]
Sent: Friday, October 05, 2007 10:37 AM
To: Elder, David K.
Subject: Follow-up

David --

I wanted to follow up on our conversation where you asked me if we could provide you with some insights and ideas on areas of possible adulteration and illegal products coming into the country in the form of dietary supplements. Our group meet late last week and I wanted to provide you with the attached paper. We are particularly concerned with illegal products marketed as dietary supplements that were intentionally adulterated with analogues of the active pharmaceutical ingredients sildenafil, tadalafil, vardenafil. This problem was first observed as early as 2001 in Asia (Takako, M., Sutemi, S., Kiyoko, K., Fusako, I., Jyunichi, N., Hisashi, K. and Ichiro, Y. 2001. Identification system for sildenafil in health foods. Yakugaku Zasshi 121: 765-769.; Tseng, M. C. and Lin, J. H. 2002. Determination of sildenafil citrate adulterated in a dietary supplement capsule by LC/MS/MS. J. Food Drug Anal. 10: 112-119.; and Shin, M. H., Hong, M. K., Kim, W. S., Lee, Y. J. and Jeoung, Y. C. 2003. Identification of a new analogue of sildenafil added illegally to a functional food marketed for penile erectile dysfunction. Food Addit. Contam. 20: 793-796.) With that in mind, the

enclosed paper in addition to some informal discussion with some industry representatives who maintain an active presence in Asia have mentioned the potential for the illegal distribution of products marketed as dietary supplements for weight control/ fat loss intentionally adulterated with pharmaceutical analogues, specifically the active pharmaceutical ingredient sibutramine (trade name meridia).

I hope this information is helpful to you and are the type of products/ingredients that the agency will want to focus on. On another topic, I wanted to let you know that I have e-mailed Dr. Bracket requesting a meeting the week of October 22nd - 26th to discuss our testing of raw ingredient program with USP in China. Per your suggestion I asked for all of the individuals you included in your e-mail to me be invited to the meeting. Thanks again and let me know what more we can do for you and your team. And, I look forward to seeing you at the above mentioned meeting soon.

David R. Seckman
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October 20, 2009

BY ELECTRONIC MAIL AND HAND DELIVERY

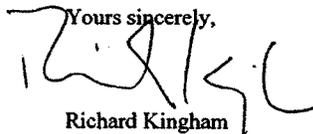
Sarah Guerrieri
Hearing Clerk
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Ms. Guerrieri:

This is in response to Senator Specter's letter dated October 6, 2009, and Senator Leahy's letter dated October 7, 2009, which requested answers to supplemental questions in relation to my testimony at the September 29 hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers." My answers are set out in the attachments to this letter.

Please let me know if anything further is required.

Yours sincerely,



Richard Kingham

Attachments

October 20, 2009

Answers from Richard Kingham, Covington & Burling LLP, to Questions
from Senator Specter in Relation to the Hearing on "Body Building Products and Hidden
Steroids: Enforcement Barriers"

1. How best can we achieve the balance between free and open markets for dietary supplements while keeping all consumers safe from contaminated and unsafe products?

Answer

The current provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) are adequate to achieve this balance. The Act provides the Food and Drug Administration (FDA) and other federal law enforcement authorities with a range of effective remedies against dietary supplements and other products that are unsafe within the meaning of the statute, that contain new dietary ingredients for which required premarket submissions have not been made, or that are deemed to be "new drugs" for which approved new drug applications (NDAs) are required. Enforcement measures available under the FDCA include seizures of unlawful products, injunction proceedings against companies that distribute them, and criminal prosecutions of companies and responsible individuals. Criminal liability does not require proof of intent, negligence, or other *mens rea* and can be imposed on any individual who stands in a responsible relationship to an enterprise that commits a violation. In addition, FDA may take informal measures to enforce the law, including issuance of warning letters and consumer alerts. As was stated in my testimony, products of the type that were the subject of the recent hearing will ordinarily be unlawful under one or more provisions of the FDCA and therefore liable to any or all of the available enforcement measures. The problem is thus not with the provisions of the law, which are more than adequate to protect consumers, but with the enforcement priorities and resources of the federal government. Congress should send a clear message to FDA that it wishes the existing law to be vigorously enforced, and provide FDA with the resources necessary to carry out its statutory duties.

2. Would it help to address the problems raised in this hearing if FDA had recall authority for dietary supplements found to be unsafe?

Answer

Historically, FDA has almost always been able to secure voluntary product withdrawals and recalls, relying in part on the threat of adverse publicity and formal enforcement actions. If the agency vigorously pursues the enforcement measures currently available to it, it should not require formal recall power. I understand, however, that Congress is currently considering including such power in the FDCA in respect of all food products as part of the pending food safety legislation. If such power is granted to FDA, it will presumably apply to dietary supplements that are unsafe or otherwise in violation of the FDCA, in the same manner that it would apply to other foods.

3. Mr. Tygart, in his written statement, suggested some regulatory fixes for the problems addressed in the hearing. Which ones, if any, do you support?

Answer

For the reasons set out in my testimony, I believe the main problem is one of resources and priorities for enforcement of existing legal authority. New legal requirements are unlikely to be effective unless the federal government enforces them. Set out below are responses to Mr. Tygart's proposals, in the order in which they are made on pages 10-11 of his prepared statement:

- It might be feasible to require registration of dietary supplement manufacturers, perhaps coupled with submission of product labels, in a manner similar to the submissions made for drug products under section 510 of the FCDA. As under section 510, these submissions should not require any form of premarket approval, but would provide FDA with current information on products in the marketplace. Such submissions would be in addition to submissions that are already required under bioterrorism legislation and under the FDCA with respect to structure/function claims for dietary supplements.
- There is no reason to require submission of master formulas (which are typically regarded as trade secrets), because appropriate composition information is contained in ingredient declarations that are currently required on product labels.
- There is no need to amend the current provisions relating to premarket submissions for new dietary ingredients to deal with the issues presented by anabolic steroids. Old anabolic steroids will typically be within the list of substances in Schedule III under the Controlled Substances Act, while new anabolic steroids of synthetic origin will require new dietary ingredient submissions under the provisions of the FDCA.
- There is no need to amend the FDCA to create new requirements for data substantiation files for dietary supplements. Current FDA regulations require companies to make submissions to the Agency certifying that the claims about the effects of dietary supplements on the structure or functions of the body are adequately substantiated, and the Federal Trade Commission has long held that it is an unfair practice, in violation of the FTC Act, to make a product performance claim for which prior substantiation does not exist.
- No amendments to the FDCA are needed to hold distributors and retailers of dietary supplements responsible for the products they sell, because the FDCA already imposes such responsibility on these entities.
- Additional rules are not needed for reporting of adverse events associated with dietary supplements. Existing rules require reports of serious adverse events, whether or not they are actually caused by a supplement, and FDA has very limited resources to deal with this small number of reports. If all events were required to be reported, FDA would be swamped, and serious events could be lost in the background noise of minor product

complaints. Under current law, manufacturers are required to keep records of all adverse event complaints, whether serious or not, and make them available to FDA on request, so the agency can obtain full information on all events associated with specific products when it believes that information is required.

- FDA does not need additional authority to deal with marketing of products for which required premarket submissions have not been made. Failure to make such submissions subjects the products to seizure actions and the companies and individuals that market them to injunctions and criminal prosecution (under a strict liability standard). These are the same enforcement powers FDA currently uses to protect against marketing drugs for which required premarket submissions are not made. They give the agency more than adequate power, provided that the power is actually used and the agency commits necessary resources to enforcement.
- There is not currently a case that amendments are required to the scheduling provisions of the Controlled Substances Act (CSA). Congress only recently amended the CSA, at the Drug Enforcement Administration's request, to simplify the findings required for scheduling of anabolic steroids. It does not appear that DEA has committed the resources necessary to make full use of the powers it already possesses. Before any amendments are considered, Congress should make a detailed inquiry to determine why DEA has not made effective use of its existing powers.
- In the absence of effective action by DEA, there is in principle no reason why Congress should not update Schedule III of the CSA to include new anabolic steroids, provided that the listed substances actually meet the scheduling criteria contained in the Act. But it is a matter for considerable concern that DEA rulemaking procedures are so inefficient that Congress can enact amendments to the statute faster than the agency can take administrative action.
- There is no need to enact new provisions relating to advertising claims for anabolic steroids. Under existing law, as interpreted by FDA in warning letters and other enforcement actions, claims of the type with which the hearing was concerned will almost always be "drug" claims within the meaning of the FDCA, subjecting products to enforcement action for lack of an approved new drug application. False or unsubstantiated claims of steroidal effect will also be subject to action under the misbranding provisions of the FDCA and the enforcement provisions of the FTC Act. It would be entirely inappropriate to enact a general prohibition on claims that dietary supplements (or other foods) affect the structure or function of the body. FDA has long permitted such claims for many foods (e.g., "calcium helps build strong bones"), and there is no conceivable reason to deprive consumers of truthful information of this kind.

4. Do you have suggested fixes of your own?

Answer

Existing law is more than adequate to protect consumers against illegal anabolic steroids. The real problem is lack of enforcement. Congress must send a clear message to DEA and FDA to enforce the law, and must give those agencies and other federal law enforcement authorities the resources they need to do their jobs.

October 20, 2009

Answers to Questions from Senator Hatch to Richard Kingham, Covington & Burling LLP, in Relation to Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"

1. Does FDA already have the authority to move against dietary supplements contaminated with drugs, including steroids? Please describe the range of enforcement tools available to the agency?

Answer

Yes, FDA has broad powers to act against products marketed as dietary supplements that are contaminated with anabolic steroids and other drugs. If anabolic steroids are not listed in the ingredient declarations, such products will be misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). Contaminated products would also most likely be in violation of FDA regulations establishing requirements for current good manufacturing practice (cGMP) for dietary supplements and thus be deemed to be adulterated under the FDCA. Depending on the circumstances, such products would often be classified as new drugs, for which approved new drug applications (NDAs) are required under the FDCA, or would contain new dietary ingredients for which premarket notifications are required under the law. Failure to comply with the NDA requirement is an offense under the FDCA and also renders the product misbranded for lack of adequate directions for use; failure to comply with the requirement for premarket notification of a new dietary ingredient renders the product adulterated under the FDCA. FDA and the Department of Justice can use a wide range of enforcement measures to punish and prevent violations of the FDCA, including seizures of violative products, injunction actions against companies and individuals that market such products, and criminal prosecutions of companies and responsible individuals. Criminal liability can be imposed under the FDCA on any person who stands in a responsible relation to a violation of the act, without proof of intent, negligence, or other *mens rea*. Federal courts have also used their injunction powers under the FDCA to require disgorgement of profits resulting from sale of violative products. In addition, FDA can take a variety of informal enforcement measures, including issuance of warning letters and other correspondence, as well as consumer alerts and other forms of publicity. Using the threat of adverse publicity and formal enforcement action, FDA can induce companies to recall violative products from the market.

2. Isn't it true that all manufacturers currently have the legal responsibility to list all dietary supplement ingredients on the label?

Answer

Yes, under the FDCA and FDA regulations, the label for a dietary supplement must declare all dietary supplement ingredients. Failure to comply with this requirement renders the product misbranded and subjects the product and persons responsible for selling it to the full range of enforcement measures identified above.

3. Mr. Levy of the FDA states in his testimony that many of these adulterated body-building products may be manufactured without quality controls. This seems to me to be in violation of the Good Manufacturing Practices Regulation. Would you agree, and if so, does FDA have the authority to pursue enforcement actions?

Answer

Yes. FDA's regulations governing current good manufacturing practice for dietary supplements, set out in 21 CFR Part 111, contain detailed requirements for personnel, manufacturing facilities, production and process control systems and quality assurance, control of components, packaging, and labels, master manufacturing records, batch production records, laboratory operations, manufacturing operations, packaging and labeling operations, holding and distributing products, handling of returned products, complaints, and recordkeeping. Products that are not manufactured in accordance with these requirements are deemed to be adulterated under the FDCA, subjecting the products and persons responsible for their manufacture to the full range of legal sanctions identified above.

4. I also welcome your informed viewpoint on food and drug issues. I think you have done a good job in identifying the many tools FDA has to regulate dietary supplements.

The testimony of FDA's Mr. Levy concludes that there are many regulatory challenges which preclude his agency from being able to identify and remove illegal steroid products from the market.

Would you care to comment on the challenges Mr. Levy outlined in his testimony in any greater detail for the record? Do you see these as legal challenges or more as administrative challenges?

Answer

In my view, existing law is more than adequate for FDA to take effective action against marketing of unlawful dietary supplement products, including the anabolic steroid products that were the subject of the hearing. As noted in my answer to Question 1, these products will typically violate any of several provisions of the FDCA, subjecting the products and persons responsible for marketing them to a wide range of sanctions, including strict criminal liability. The challenge is therefore a matter of law enforcement resources and priorities rather than lack of legal powers.

In particular, there is no need to adopt additional provisions relating to premarket notification or approval of dietary supplements. Most of the products that were the subject of the hearing appear to have been marketed in violation of existing requirements for approval of NDAs or premarket notification of new dietary ingredients. In the absence of tough enforcement policies, it is unlikely that a new requirement for premarket submissions would be any more effective than the requirements under existing law.

FDA has many resources at its disposal to discover violative products in the marketplace. Investigators can take samples of products sold in retail outlets, and FDA can monitor the Internet and make test purchases of suspicious products. A major source of information is complaints from law-abiding manufacturers, who often submit detailed reports to FDA concerning products that appear to have been introduced to the market in violation of the FDCA. In my experience, FDA has often been slow to act in response to such reports, even when repeated requests are made for enforcement action. In recent years, the agency has also made sparing use of the formal enforcement measures at its disposal, except in the most egregious cases, relying instead on warning letters and other informal communications.

FDA is not entirely to blame for this situation. For many years, Congress has failed to appropriate sufficient funds for enforcement of federal laws governing foods, including dietary supplements. Until recently, the relevant part of FDA's budget actually declined from year to year, after allowing for inflation. The result was a steady decrease in the number of field and headquarters personnel dedicated to enforcement of laws relating to food safety and labeling. In the FY 2009 budget, Congress began to redress this deficiency, responding in part to a substantial effort by coalitions including trade associations of FDA-regulated industries. But more resources are needed, coupled with a clear mandate from Congress for vigorous enforcement of the FDCA.

5. Mr. Kingham, the associations who testified at the hearing indicate that they share the concern we in Congress have shown about the problem of illegal steroid precursor products, many of which could be threatening young athletes.

Would the association you represent pledge to work with Congress as we consider steps to make these products less available, such as possible amendments to the Controlled Substances Act?

Answer

The Council for Responsible Nutrition (CRN), for which my firm acts as a legal adviser, is fully committed to working with Congress on actions necessary to prevent the sale of illegal anabolic steroid products. The first priority, as outlined above, is effective enforcement of existing law. It is my understanding, however, that CRN would support reasonable amendments to the Controlled Substances Act if they are needed to provide additional power for the federal government to protect consumers, including young athletes, from illegal anabolic steroids.

October 20, 2009

Answers from Richard Kingham, Covington & Burling LLP, to Questions from Senator Hatch for Kingham and Fabricant Relating to Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"

1. There has been a lot of discussion about the article appearing in *Sports Illustrated* earlier this year. Mr. Kingham and Mr. Fabricant, could I get your reaction to some of the accusations made in the article? I would appreciate hearing your insights.

Answer

In my view, the article exaggerates the scope of the problem presented by illegal anabolic steroids and misstates the legal status of those products and the enforcement powers available to federal agencies to control their sale. Any use of illegal anabolic steroids is a matter for great concern, given the well-known adverse effects of those products. But the article suggests that the sports nutrition industry is much larger than it actually is, and fails to recognize that products containing illegal anabolic steroids comprise a tiny fraction of the products in that sector. The article also wrongly suggests that the Dietary Supplement Health and Education Act of 1994 (DSHEA) effectively deregulated dietary supplements and deprived FDA of enforcement powers. In fact, DSHEA established a detailed and comprehensive regulatory regime that currently includes requirements for premarket notification of new dietary ingredients, full ingredient declarations on product labels, mandatory good manufacturing practice, mandatory notification to FDA about claims that a product or ingredient is intended to affect the structure or function of the body, and more than adequate power for FDA to act against products that are adulterated, misbranded, or unsafe within the meaning of the law. In addition, the statute leaves intact FDA's power to act against products that fall within the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) governing drugs, including requirements for premarket approval of new drug applications (NDAs). Products of the type that were the subject of the recent hearing will almost always be in violation of one or more provisions of the FDCA. Such products and persons responsible for selling them will be subject to the full range of formal and informal enforcement actions under the statute, including seizures, injunctions, criminal prosecutions, warning letters, and other measures. I am attaching to this submission a detailed response to the *Sports Illustrated* article that was posted on the Internet website of the Council for Responsible Nutrition.

2. What is your response to the concerns raised by both the FDA and the DEA to the difficulties encountered when agencies try to pull products containing steroids off the market?

Answer

My response to Question 4 in the list of questions from Senator Hatch directed specifically to me, which accompanies this submission, contains a detailed answer to this question. In my view, FDA and DEA, working together, have ample authority to control the sale of illegal anabolic

steroids. With respect to products containing ingredients that are listed in Schedule III under the Controlled Substances Act, DEA has extensive enforcement powers, including the potential to seek severe criminal penalties. DEA also has the power to add new substances to Schedule III in accordance with simplified findings established by the Anabolic Steroid Control Act of 2004. As for other products of the type addressed in the hearing, FDA and the Department of Justice have a wide range of enforcement powers at their disposal under the FDCA. The problem is therefore not lack of legal authority but rather lack of effective enforcement of existing laws.

3. Has the federal government, specifically the FDA and the DEA, reached out to the industry to work in a collaborative manner to address issues associated with products containing synthetic steroid ingredients that are marketed as dietary supplements?

Answer

I am not personally aware of such efforts on the part of the federal agencies.

4. In Mr. Tygart's testimony, he makes several suggestions on how to address the problems the Subcommittee is discussing today. Has the industry reviewed his recommendations? Are there any areas of agreement?

Answer

I can offer my personal views as a lawyer to who advises regulated companies. For the reasons set out in my testimony, I believe the main problem is one of resources and priorities for enforcement of existing legal authority. New legal requirements are unlikely to be effective unless the federal government enforces them. Set out below are responses to Mr. Tygart's proposals, in the order in which they are made on pages 10-11 of his prepared statement:

- It might be feasible to require registration of dietary supplement manufacturers, perhaps coupled with submission of product labels, in a manner somewhat similar to the submissions made for drug products under section 510 of the FCDA. As under section 510, these submissions should not require any form of premarket approval, but would provide FDA with current information on products in the marketplace. Such submissions would be in addition to submissions that are already required under bioterrorism legislation and under the FDCA with respect to structure/function claims for dietary supplements.
- There is no reason to require submission of master formulas (which are typically regarded as trade secrets), because necessary information is contained in ingredient declarations that are currently required on product labels.
- There is no need to amend the current provisions relating to premarket submissions for new dietary ingredients to deal with the issues presented by synthetic anabolic steroids. Old anabolic steroids will typically be within the list of substances in Schedule III under the Controlled Substances Act, while new anabolic steroids of synthetic origin will require new dietary ingredient submissions under the provisions of the FDCA.

- There is no need to amend the FDCA to create new requirements for data substantiation files for dietary supplements. Current FDA regulations require companies to make submissions to the Agency certifying that claims about the effects of dietary supplements on the structure or functions of the body are adequately substantiated, and the Federal Trade Commission has long held that it is an unfair practice, in violation of the Federal Trade Commission Act, to make a product performance claim for which prior substantiation does not exist.
- No amendments to the FDCA are needed to hold distributors and retailers of dietary supplements responsible for the products they sell, because the FDCA already imposes such responsibility on these entities.
- Additional rules are not needed for reporting of adverse events associated with dietary supplements. Existing rules require reports of serious adverse events, whether or not they are actually caused by a supplement, and FDA has limited resources even to deal with this relatively small number of reports. If all events were required to be reported, FDA would be swamped, and serious events could be lost in the background noise of minor complaints. Under current law, manufacturers are required to keep records of all adverse event complaints, whether serious or not, and make them available to FDA on request, so the agency can obtain full information on all events associated with specific products whenever it is required.
- FDA does not need additional authority to deal with marketing of products for which required premarket submissions have not been made. Failure to make such submissions subjects the products to seizure actions and the companies and individuals that market them to injunctions and criminal prosecution (under a strict liability standard). These are the same enforcement powers FDA currently uses to protect against the sale of drugs for which required premarket submissions are not made. They give the agency more than adequate power, provided that the power is actually used and the agency commits necessary resources to enforcement.
- There is not currently a case that amendments are required to the scheduling provisions of the Controlled Substances Act (CSA). Congress only recently amended the CSA, at the Drug Enforcement Administration's request, to simplify the findings required for scheduling of anabolic steroids. It does not appear that DEA has committed the resources necessary to make full use of the powers it already possesses. Before any amendments are considered, Congress should make a detailed inquiry to determine why DEA has not made effective use of its existing powers.
- In the absence of effective action by DEA, there is in principle no reason why Congress should not update Schedule III of the CSA to include new anabolic steroids, provided that the listed substances actually meet the scheduling criteria contained in the Act. But it is a matter for considerable concern that DEA rulemaking procedures are so inefficient that Congress can enact amendments to the statute faster than the agency can take administrative action.

- There is no need to enact new provisions relating to advertising claims for anabolic steroids. Under existing law, as interpreted by FDA in warning letters and other enforcement actions, claims of the type with which the hearing was concerned will often be “drug” claims within the meaning of the FDCA, typically subjecting products to enforcement action for lack of an approved new drug application. False or unsubstantiated claims of steroidal effect will also be subject to action under the misbranding provisions of the FDCA and the enforcement provisions of the FTC Act. It would be entirely inappropriate to enact a general prohibition on claims that dietary supplements (or other foods) affect the structure or function of the body. FDA has long permitted such claims for many foods (e.g., “calcium helps build strong bones”), and there is no conceivable reason to deprive consumers of truthful information of this kind.

Attachment



Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

Contact: Season Solorio, 202-204-7682

CRN RESPONDS TO SPORTS ILLUSTRATED ARTICLE

WASHINGTON, D.C., May 19, 2009 – In response to a recent article in the May 18 issue of *Sports Illustrated* magazine, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement.

Statement from Steve Mister, president and CEO, CRN:

Sports Illustrated's article "What You Don't Know Might Kill You," (May 18, 2009) starts by referring to sports nutrition supplements as a "\$20 billion obsession," portraying the industry as eight times larger than it is. Now it's true that more than 150 million Americans take dietary supplements annually, and that 72 percent of physicians recommend supplements—products that include vitamins, minerals, botanicals, sports nutrition, weight management, and specialty supplements. The entire dietary supplement industry has U.S. sales of approximately \$24 billion, with vitamin sales alone representing approximately \$10 billion of the total market. But the sports nutrition supplements that are the focus of this article represent sales somewhere closer to \$2.5 billion. While that smaller figure is not nearly as dramatic as the \$20 billion figure which teases the story, it is important, from a factual standpoint, to point out that the estimate in the article for sports nutrition products includes not just dietary supplements, but a whole range of conventional food products and drinks that are marketed for weight loss as well.

Ironically that inflated figure seeks to portray a problem that, if it exists at all, represents only a very small portion of companies in the supplement industry not representative of the mainstream companies that manufacture products that consumers choose to include in their cadre of personal healthcare options.

Further, the article is surprisingly one-sided and suffers from an unfortunate lack of understanding of the Dietary Supplement Health and Education Act (DSHEA)—both in terms of what the law did, and what it allows the Food and Drug Administration (FDA) to do. Contrary to Dr. David Kessler's statements, and to common misunderstandings about the law, rather than shifting the safety burden to FDA, DSHEA actually provided FDA with new enforcement authority not previously available. Dietary supplements were regulated as a category of food prior to DSHEA and continue to be regulated as a category of food today. Further, FDA never had legal pre-market approval authority for dietary supplements—DSHEA did not change that fact.

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The article inaccurately suggests that dietary supplements are exempted from the entry requirements and regulatory scrutiny that apply to all other FDA-regulated products, including food and drugs. That is simply not so. According to the article, DSHEA “razed virtually every barrier to entry into the marketplace.” With that premise, the extreme examples the article describes appear to be a product of DSHEA, when in fact, they more likely result from FDA’s lack of enforcement of that law over the past 16 years, starting with Dr. Kessler’s decision to allow FDA to turn its back on supplement regulation once DSHEA—a bill he strongly opposed—was enacted.

DSHEA was passed by Congress following an outpouring of letters received from consumers urging the legislative body to keep intact consumers’ freedom of choice when it came to supplements. This consumer activism was fueled consumers’ concerns that FDA was inappropriately looking to stretch its regulatory muscle to the point where it would be impossible for companies to bring new products to market, and could also have pulled products off the shelves without any scientific rationale or safety reason. But consumers made it quite clear that they wanted to play a proactive role in their healthcare regimen, and that FDA’s precautionary principle approach was not going to be tolerated.

Once the law passed, the folklore that the law “took away” FDA’s authority began, but in reality, DSHEA gave the Agency new tools for enforcement. In actuality, FDA chose to sit on its collective hands, refusing to take advantage of the new tools it now had, even ignoring the simplest requirements from Congress to issue new Good Manufacturing Practices (GMPs) specific to dietary supplements.

Whether due to a lack of resources, a lack of interest, or a lack of political will, following the passage of DSHEA, FDA failed to enforce the regulations that DSHEA put on the books. It wasn’t until Dr. Mark McClellan became FDA Commissioner in 2002 that the Agency emerged from its fog of inertia concerning the dietary supplement industry and began to look at and use some of the additional authority provided to it by DSHEA.

Beginning with Dr. McClellan’s tenure, FDA began to open the toolbox, and actively find ways to use the authorities granted it under DSHEA. In the past five years or so, the industry and the Agency have both come a long way: with industry lobbying for GMPs that are supplement-specific and FDA finally issuing these rules; with industry urging for passage of a mandatory reporting system for serious adverse events, and FDA getting the system up and running; and with FDA taking strong enforcement action—ranging from warning letters to significant fines to product seizures against companies that manufacture unapproved drugs masquerading as dietary supplements.

The article’s description is not how we—and responsible companies in the industry—understand the laws and regulations at all. To begin with, because dietary supplements are regulated as a category of food, in every respect they get at least the same levels of scrutiny accorded to any

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kinds of food—from breakfast cereals to canned soup—and in many respects they get even more.

Under current law, any facility that manufactures, packages, or processes a dietary supplement must register with FDA before starting operation. Extensive regulations specify that these products carry a “Supplement Facts” box on their labels alerting consumers to the contents of the product, and failure to comply with these rules makes the supplement “adulterated” (in other words, subject to FDA seizure and prosecution). With respect to the claims one can make for these products, there are still more requirements in the law: If you want to make a claim about how the product affects the structure or function of the body, you must provide FDA with the exact wording of those claims within 30 days after beginning marketing of the product; for claims that the product may reduce the risk of certain diseases, you must get FDA approval before using these claims at all; and any claims that a product treats, cures, prevents or mitigates a disease are prohibited altogether. In addition, if you plan to bring a new ingredient to market that was not already sold as a food or dietary supplement prior to 1994, you must notify FDA of the new dietary ingredient and provide evidence that the product can reasonably be expected to be safe at least 75 days *prior* to marketing. Once a company begins manufacturing dietary supplements, it is subject to the GMP regulations that were issued in 2007 and the requirement to report serious adverse events to FDA within 15 days of being notified, a law enacted in 2006. When FDA chooses to enforce these requirements, they offer considerable market barriers to screen out bad actors.

The article also insinuates that anabolic steroids and pro-hormone ingredients are lawfully marketed under the law and that enforcement to remove these products from the market is left to the Drug Enforcement Agency (DEA) to “keep up” with the ever evolving list of new metabolites and analogs of these anabolic steroids. That’s simply not true. Under DSHEA, most of these substances are not even legal dietary ingredients, i.e., they cannot be legally included in dietary supplements, period. DSHEA further provides that a dietary supplement containing a “new dietary ingredient (NDI)” that is marketed without complying with the NDI notification process is adulterated under the Act, and it further provides that any food (including supplements) that is adulterated is subject to a range of penalties including seizure, fines and imprisonment for the manufacturer. Completely independent of DEA’s jurisdiction in this area, FDA has clear and powerful authority to address supplements that contain performance-enhancing drugs or anabolic steroids. These various new chemical cocktails are illegal under DSHEA simply because no NDI has been filed for them or because they are not legal dietary ingredients in the first place. But curiously, we are not aware that FDA has ever initiated an enforcement action because a dietary supplement failed to comply with the NDI notification requirements. Just as the evasion of tax laws were ultimately used to bring down many notorious gangsters of old, the NDI provisions of the law offer a convenient and effective way to get anabolic steroids and human growth hormone and their related analogs out of the supplement aisle once and for all—and this can be accomplished under DSHEA when the FDA chooses to act.

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Unfortunately, readers are left with no way to distinguish legitimate sports nutrition products from the ones without sufficient safety profiles and quality assurance. Every industry has its outliers, the underbelly that ignores the laws, cuts corners in manufacturing and puts profits ahead of long-term confidence of their consumers. This industry is no exception, but that is not the fault of the law itself. No law works unless it is enforced.

The supplement industry, including sports nutrition supplements, has a strong safety profile, and consumers value the benefits these products can provide. The entire supplement industry sells billions of bottles of products in a year, and yet for the first full year that the mandatory serious adverse event reporting system for supplements was in existence, FDA received only 1,080 total adverse event reports, 672 of which were considered serious. Compare these numbers to the pharmaceutical industry where hundreds of thousands of serious adverse events are received each year. In 2008 alone, FDA received over 526,000 adverse event reports related to drugs and biologic products, over 300,000 of which were considered serious, including close to 50,000 deaths. In the period from 1969 through 2002, a total of 75 FDA-approved drugs were removed from the market due to safety concerns. The American Association of Poison Control Centers reported that in 2007 the category of analgesics alone was associated with over 6,300 adverse reactions, compared with just over 3,100 for *all* dietary supplements (including vitamins, minerals, multivitamins, amino acids, botanicals, etc...).

But numbers for serious adverse events must be placed within context, and it should be recognized that while adverse events allow FDA to determine potential patterns or problems with a specific product or product category, they are not necessarily causally related to products. Even with a strong safety record for supplements, consumers would be wise not to buy supplements in back-rooms or ones advertised to be "legal" versions of otherwise illegal substances, and they should be wary of products that make claims that sound too good to be true.

Some critics who call for a revision of DSHEA are cavalier in their approach: suggesting that pre-market approval of all products is the answer. But pre-market approval provides no guarantee of safety, as we've seen with pharmaceutical products that have been "approved" only to be later withdrawn due to safety concerns. Further, it is not reasonable to believe that FDA has the resources to manage a pre-market approval system for dietary supplements, nor is it necessary to ask for one: the provisions in place under the law—when enforced—provide the Agency with appropriate authority to protect consumers while still allowing them access to the variety of beneficial products they are requesting.

The article also fails to place any responsibility on the highly-paid professional athletes to know what they put in their bodies and the rules imposed on them by their leagues. Some substances (even caffeine and certain cold medicines) are banned by some professional sports organizations for their potential to provide an artificial "edge" to paid athletes; that doesn't mean the product is unsafe for everyone else.

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Whatever the law, the “burden” for consumer safety should always rest between a combination of industry responsibility and regulatory body enforcement. The article leaves the reader with the misimpression that the industry is suffering from a weak legal framework to govern bad actors and outliers—and that simply is not true. Now that FDA has set its regulatory mind to enforcing the law, it has the ability under the law to weed out bad actors—those who are not abiding by regulations. FDA’s job is to protect the public, and we urge Congress to provide sufficient budgetary funds for the Agency to do its job, rather than wasting time and tax-payers’ money with re-writing laws unnecessarily.”

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Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements, CRN members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN’s Code of Ethics. Visit www.crnusa.org.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

The Honorable Arlen Specter
Chairman
Subcommittee on Crime and Drugs
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

NOV 05 2009

Dear Chairmen Leahy and Specter:

Thank you for providing the Food and Drug Administration (FDA or the Agency) the opportunity to testify at the September 29, 2009, hearing entitled, "Body Building Products and Hidden Steroids: Enforcement Barriers," before the Senate Committee on the Judiciary, Subcommittee on Crime and Drugs. Michael Levy, J.D., Director, Office of Compliance, Center for Drug Evaluation and Research, testified on behalf of the Agency.

We are responding to your letters of October 6, 2009, and October 7, 2009, that you sent in follow up to the hearing. We have included FDA's responses to the questions from each Member on the following, separate pages. Each question is restated in bold, followed by our responses.

Senator Arlen Specter

- 1. Did Mr. Travis Tygart in his testimony before the Senate Judiciary Subcommittee accurately describe the process of what it takes to get a dietary supplement on the market?***

In his written testimony, Mr. Tygart described the process of introducing a dietary supplement to market as follows:

"It is what this consumer does not know that is the reason we are all here today. What he or she does not know is that all it takes to cash in on the storefront steroid craze is a credit card to import raw products from China or India where most of the raw ingredients come from, the ability to pour powders into a bottle or a pill and a printer to create shiny, glossy labels."

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), a manufacturer or distributor does not need to obtain FDA approval of a dietary supplement before it is marketed. Therefore, as a generalization of the process for developing and marketing a dietary supplement,

*Denotes questions to which the Center for Food Safety and Applied Nutrition within FDA provided responsive information

**Denotes questions to which the Office of Criminal Investigation within FDA provided responsive information.

Mr. Tygart's description is correct; in most cases, a firm would only need to obtain raw material, manufacture and package the finished dietary supplement, and correctly label the package. There is no statutory requirement for the firm to get FDA approval of that product or its packaging before marketing it. However, for dietary supplements containing certain new dietary ingredients (NDI) not present in the food supply, the manufacturer or distributor would be required to submit

a premarket notification to FDA with the information, on the basis of which the firm has concluded that the dietary supplement will be reasonably expected to be safe.

2. Absent premarket clearance by the FDA for dietary supplements, are there effective ways for the FDA to deal with the problem of anabolic steroids being sold as body building dietary supplements?

FDA's ability to adequately address the enormous and expanding challenge of products that are marketed as dietary supplements but that contain active ingredients in FDA-approved drugs, analogs of approved drugs, and other compounds such as anabolic steroids that do not qualify as dietary ingredients, is limited. By merely labeling products as dietary supplements, unscrupulous firms can easily introduce into the marketplace products that contain ingredients that may pose risks to health, because there is no requirement for the manufacturer of a dietary supplement to provide FDA with evidence of the product's effectiveness, and the manufacturer also need not provide FDA with evidence of ingredient safety prior to marketing, unless the product contains an NDI that has not been part of the food supply as an article used for food (in a form in which the food has not been chemically altered).

FDA's regulation of these products is particularly challenging given the seemingly endless volume of potentially violative products and the painstaking process required to prove that a violation exists. By way of example only, a quick Internet search for "buy bodybuilding dietary supplements" yields close to 500,000 hits, indicating that a huge amount of resources would need to be dedicated to seek out all of the violative firms and products for this one category of products alone.

After identifying one of numerous potentially violative products, an in-depth analysis begins that includes examining labeling claims and ingredients. Because the law permits dietary supplements to bear truthful and nonmisleading claims about effects on the structure or function of the body ("structure/function claims"), determining whether a product is violative often must go beyond a superficial examination of a product's labeling. For example, some androgenic claims may be allowable structure/function claims if they are not false or misleading.

FDA often must also analyze the ingredients of a product to determine whether that specific product is violative. Although not the case with all body-building products, sometimes the active ingredient is undeclared on the labeling and FDA must conduct a laboratory analysis of the product. Even if the labeling of a particular dietary supplement identifies an ingredient we suspect renders the product violative, the process required to confirm a violation is in-depth and extremely time-consuming. With respect to steroids, there are not only many known steroids but also a variety of different names for each ingredient. In addition, manufacturers often misname an ingredient or use a nickname. FDA often must use a steroid expert to identify potentially dangerous ingredients.

When an ingredient that may render a product violative is adequately identified, FDA must then determine whether the ingredient is a dietary ingredient through an extensive search of the scientific literature. Once we determine whether the ingredient is a dietary ingredient, an examination of the product's other ingredients, labeling, and other promotional material is required to determine its proper regulatory status (e.g., unapproved new drug, adulterated dietary supplement).

Even if FDA concludes that regulatory action is warranted against a steroid product marketed as a dietary supplement, FDA must determine the location of the company marketing the violative product and the most responsible parties, before the Agency can proceed with a Warning Letter, civil enforcement action, or criminal investigation. This task is often difficult when a company is knowingly violating the law and does not want to be found. Further, taking regulatory or enforcement action against a firm does not necessarily prevent the firm from committing further violative acts; e.g., if FDA sends a firm a Warning Letter or even seizes product, the firm can easily market the same violative product under a different product name and labeling, or through a different distribution channel or Web site.

Thus, protecting the public from just one violative and dangerous product, much less an entire category of violative products is immensely challenging. The approach FDA must generally take—tackling products one by one—is unsustainable and ineffective in protecting the public from a growing problem.

3. How often have dietary supplement firms complied with the 75 day premarket requirement for filing substantiation reports for products which contain a new dietary ingredient?*

Under Section 413(c) of the FD&C Act (21 U.S.C. 350b(c)), the term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States before October 15, 1994. A dietary supplement that contains a new dietary ingredient is deemed to be adulterated under section 402(f) of the Act unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, or
2. There is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the firm submits to FDA the information which is the basis on which it has concluded that a dietary supplement containing an NDI is reasonably expected to be safe (21 U.S.C. 350b(a)(1)-(2)).

Since the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103-417) in October 1994, FDA has received 600 NDI notifications submitted pursuant to 21 U.S.C. 350b(a)(2) and 21 *Code of Federal Regulations* (CFR) 190.6. The numbers of

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submissions received vary from year to year; FDA received 55, 82, and 65 in FY 2009, 2008, and 2007, respectively.

FDA has not undertaken a systematic survey of the marketplace in order to attempt to determine the number of dietary supplement products on the market that contain NDIs for which a notification to FDA is required but for which no notification has been submitted. However, anecdotal observations of products marketed on the Internet, in conventional retail venues, or promoted at industry trade shows suggest that substantial numbers of such products are being marketed.

4. What are the penalties for ignoring this filing requirement and have these penalties been enforced? Please provide details of FDA's enforcement actions for ignoring this filing requirement.*

Under the Act, a dietary supplement containing an NDI for which a notification is required is adulterated if the required notification is not submitted at least 75 days prior to introduction or delivery for introduction into interstate commerce. FDA can initiate an injunction action or criminal prosecution against parties marketing violative products, or a seizure action against the products themselves.

FDA has not taken enforcement action against significant numbers of dietary supplements that contain NDIs for which notifications were not submitted. This circumstance derives primarily from the fact that FDA's limited enforcement resources have been directed to compliance activities that have a higher priority and involve an immediate public safety hazard, such as actions against dietary supplements that contain undeclared active pharmaceutical ingredients; e.g., sildenafil (Viagra) analogs or weight-loss drugs.

In 2004, FDA sent Warning Letters to 23 firms marketing dietary supplements containing the steroid androstenedione. The letters alleged that the products were adulterated because they contained an NDI for which a notification was required and no such notification had been submitted to FDA (copies of these Warning Letters can be found at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm081774.htm>).

In cases involving dietary supplements containing only synthetic steroids as active ingredients, rather than allege that the products are adulterated because they contain an NDI for which a notification is required but was not submitted, FDA has generally charged that such products were unapproved drugs because they were intended to affect the structure or function of the body and could not be legally marketed as dietary supplements, because the synthetic steroids were not dietary ingredients (See Warning Letters at Tab A). To be a dietary supplement, a product must contain at least one dietary ingredient (See 21 U.S.C. 321(ff)(1)), and to the best of FDA's knowledge, no synthetic steroid currently being marketed is a dietary ingredient. In cases where the Agency does not have enough information to determine conclusively whether a steroid in a dietary supplement is a dietary ingredient (e.g., because the steroid may be a constituent of a plant rather than synthetically derived), FDA has generally alleged in the alternative that if the substance is a dietary ingredient, it is an NDI for which a notification is required (See LG Sciences seizure complaint and consent agreement at Tab B) and, accordingly, the dietary supplement containing the ingredient is adulterated.

5. Does the FDA have subpoena power to request a dietary supplement firm's substantiation files? Would having subpoena power to request those files be helpful?*

FDA does not have the authority to subpoena information that a firm may possess that substantiates the safety of its products or that substantiates any labeling claims about the products' purported benefits, safety, or other product attributes. FDA could only compel a firm to produce such information as part of the discovery process in a court proceeding.

At this time a determination has not been reached on whether having the ability to compel dietary supplement firms to disclose the types of information described above would be useful to FDA.

6. What are your top recommendations for tightening the regulations on dietary supplements without over burdening the manufacturers that manufacture and sell the good and safe products?

FDA's enforcement challenges are discovering the violation in a huge universe of dietary supplements, proving the violation, and effectively deterring future bad actors. After products enter the market, FDA must undertake intensive investigative and analytical processes to show that they are violative. Each enforcement action involves a collaborative effort by FDA chemists, laboratory staff, lawyers, physicians, and investigators that can span many months.

We cannot comment at this time on specific proposals for regulatory fixes. However, we would be happy to work with this Subcommittee and provide technical assistance if the Subcommittee wishes to make a formal legislative proposal.

7. Mr. Tygart, in his written statement, suggested some regulatory fixes for the problems addressed by this hearing. Which one, if any, do you support?

FDA agrees with Mr. Tygart that enforcement against illegal dietary supplements that contain steroids is very difficult, and would like to highlight key points of his testimony. FDA shares Mr. Tygart's concern in protecting populations, such as young athletes, law enforcement, fire department, and military personnel, particularly when these steroid supplement products are sold with false and misleading claims. As evidenced by Mr. Jareem Gunter's testimony at the hearing on September 29, these products can easily deceive young athletes with claims of being "legal" and "all-natural."

Mr. Tygart aptly characterizes the relative ease with which unscrupulous companies can enter the supplement marketplace. A violative steroid-containing, body-building product can be on a store shelf right next to a legitimate body-building product manufactured and distributed by a responsible, compliant supplement company. An average consumer has no way to distinguish between a responsible company and a bad actor. In his testimony, Mr. Tygart states that companies are "exploiting the lack of premarket regulation to sell magic powders and pills in a bottle, while using the reputation of the health food and vitamin industry to cloak themselves with the appearance of safety and respectability." This exploitation is detrimental to both consumers and to dietary supplement firms that invest in developing and marketing quality products.

We cannot comment at this time on Mr. Tygart's proposals for regulatory fixes. However, we would be happy to work with this Subcommittee and provide technical assistance, if the Subcommittee wishes to make a formal legislative proposal.

Senator Orrin G. Hatch

- 1. Has the FDA ever used the imminent hazard authority provided to the Agency through the DSHEA law? When we were writing this law back in 1994, we included this authority to make sure that the FDA's hands were not tied should a serious problem be discovered.***

Section 402(f)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) (21 U.S.C. 342(f)(1)(C)) states that a dietary supplement or dietary ingredient is adulterated if "the Secretary declares [it] to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration."

FDA regulations define the term "imminent hazard" as follows:

(a) "Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The *imminent hazard* may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an *imminent hazard* of such occurrence exists."

(b) "In exercising his judgment on whether an *imminent hazard* exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury." (21 CFR 2.5)

FDA has never made a recommendation to the Secretary to invoke the imminent hazard authority for dietary supplements.

- 2. In your testimony, you state that the FDA is very concerned with products containing synthetic steroid ingredients that are marketed as dietary supplements. Isn't it true that products containing synthetic steroid ingredients that are marketed as dietary supplements today are prohibited from being on the market through the DSHEA law? Doesn't the DEA have the authority, too, to remove that product if it contains anabolic steroids? The industry believes that products that contain anabolic steroid[s] marketed as dietary supplements should be removed from the market immediately. Isn't it true that DSHEA prohibits these products from being marketed?**

DSHEA does not specifically or necessarily prohibit dietary supplements from containing anabolic steroids. It is only in two situations that DSHEA would prohibit the marketing of a steroid-containing product as a dietary supplement. First, if an anabolic steroid was approved as a new drug or authorized for investigation as a new drug, for which substantial clinical investigations whose existence has been made public were instituted before the steroid was marketed as a dietary supplement or as a food, a product containing the steroid cannot legally be

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marketed as a dietary supplement (See 21 *United States Code* (U.S.C.) 321(ff)(3)(B)). Second, if an anabolic steroid in a dietary supplement is not a dietary ingredient as defined in section 201(ff)(1) of the Act (21 U.S.C. 321(ff)(1)) and the product contains no other dietary ingredients, DSHEA prohibits the product from being a dietary supplement. However, some types of anabolic steroids (e.g., those made from plant material or animal tissue) may be dietary ingredients because they fit within one of the categories of dietary ingredients defined in section 201(ff)(1) of the Act.

Determining whether a steroid is a dietary ingredient is an arduous task. When FDA identifies a potential steroid ingredient, either because it was declared on the product's label as an ingredient or not declared but found as a result of laboratory testing, we must determine what the substance is.

In some cases, we cannot identify a substance that has been listed on a product label because it has been given a nickname or named incorrectly (either intentionally to confuse and mislead consumers or unintentionally because of a misunderstanding of steroid nomenclature), or because it is a novel steroid that has not been previously identified. In those cases, we must consult experts, either from within or outside FDA, to assist us in identifying the steroid ingredient. Once the steroid ingredient has been identified, FDA staff must do an extensive search of scientific literature to gather the information needed to determine whether it is a dietary ingredient.

Once FDA determines whether a steroid in a product is a dietary ingredient, an examination of the product's ingredients, labeling, and other promotional material is also required to determine the product's regulatory status and the violations that may apply to it. For products that contain a steroid that is not a dietary ingredient, depending on the product's other ingredients and the claims made for it, the product may be an unapproved new drug or it may be a dietary supplement that is adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)) because the steroid ingredient is an unapproved food additive. On the other hand, if FDA determines that the steroid in fact meets the definition of a "dietary ingredient," the Agency must also determine whether a premarket notification would be required for the dietary ingredient. If a premarket notification was required but not submitted at least 75 days before marketing, the product would be considered an adulterated dietary supplement (See 21 U.S.C. 342(f)(1)(B), 350b(a)).

If a product is an unapproved new drug or an adulterated dietary supplement, the product may not be marketed for consumption in the United States. However, DSHEA does not prohibit all products containing steroids from being marketed as dietary supplements, and determining whether a product that contains a steroid is being illegally marketed under the Act alone is a time-consuming task, even if the legality of the product under other statutes, such as the Controlled Substances Act, is not considered.

3. **I would like to add that the action that your Agency took to protect the public from illegal steroids in dietary supplements was made possible through a law that Congress passed in 2006 to require serious adverse event reporting to the FDA. I was the sponsor of that legislation along with Senators Durbin, Enzi, Kennedy and Harkin. When the FDA issues its Warning Letters to companies illegally marketing products containing anabolic steroids, aren't these companies in violation of laws currently on the books? Could you please explain to me the specifics of current law for products containing these steroids? And why is the FDA's ability to solve problems associated with products**

containing illegal substances limited, especially since I have had four former FDA Commissioners tell me that the FDA has sufficient authority to regulate dietary supplements?

The law Congress passed in 2006 (the Dietary Supplement and Nonprescription Drug Consumer Protection Act) requires dietary supplement manufacturers and distributors to submit serious adverse event reports to FDA. We note that the action FDA took to protect the public from illegal steroid-containing products marketed as dietary supplements by American Cellular Laboratories was initiated as a result of voluntary adverse event reports FDA received from medical professionals. To date, American Cellular Laboratories has not submitted any adverse event reports to FDA.

When FDA issues Warning Letters to companies that are illegally marketing products containing anabolic steroids, these companies are indeed in violation of existing law. However, these violations are difficult to detect and prove, which makes it difficult for FDA to expeditiously address the enormous and expanding challenge of products marketed as dietary supplements that contain active ingredients in FDA-approved drugs or analogs of approved drugs. By merely labeling products as dietary supplements, unscrupulous firms can easily introduce into the marketplace products that contain ingredients that may pose risks to health, because there is no requirement for the manufacturer of a dietary supplement to provide FDA with evidence of the product's effectiveness, and the manufacturer also need not provide FDA with evidence of ingredient safety prior to marketing, unless the product contains an NDI that has not been part of the food supply as an article used for food (in a form in which the food has not been chemically altered).

FDA is in a reactive posture with respect to these types of products—a position that is particularly challenging, given the endless volume of potentially violative products and the painstaking process that is often required to prove that a violation exists. By way of example only, a quick Internet search for “buy bodybuilding dietary supplements” yields close to 500,000 hits, indicating that a huge amount of resources would need to be dedicated to seek out all the violative firms and products for this one category of products alone.

After identifying one of numerous potentially violative products, an in-depth analysis begins that includes examining labeling claims and ingredients. Because the law permits dietary supplements to bear claims about effects on the structure or function of the body (“structure/function claims”), determining whether a product is violative often must go beyond an examination of a product's labeling. For example, many androgenic, weight loss, and sexual enhancement claims are allowable structure/function claims.

Accordingly, FDA often must analyze the ingredients of a product to determine whether that specific product is violative. Although not the case with all products, sometimes the active ingredient is undeclared on the labeling and FDA must conduct a laboratory analysis of the product. Even if the labeling of a particular dietary supplement identifies an ingredient we suspect renders the product violative, the process required to confirm a violation is in-depth and time-consuming. Using the steroid example, there are not only many known steroids, but also a variety of different names for each ingredient. Also, manufacturers often misname an ingredient or use a nickname.

When an ingredient that may render a product violative is identified, FDA must then determine whether the ingredient is a dietary ingredient through an extensive search of the scientific literature. Once we determine whether the ingredient is a dietary ingredient, an examination of the product's other ingredients, labeling, and other promotional material is required to determine its proper regulatory status (e.g., unapproved new drug, adulterated dietary supplement).

If FDA concludes that regulatory action is warranted against a product marketed as a dietary supplement, FDA must first determine the location of the company marketing the violative product and the most responsible parties. This task is often difficult when a company is knowingly violating the law and does not want to be found. Further, taking regulatory or enforcement action against a firm does not necessarily prevent the firm from committing further violative acts. For example, if FDA sends a firm a Warning Letter or even seizes product, the firm can easily market the same violative product under a different product name and labeling, or a different distribution channel or Web site.

Thus, protecting the public from just one violative and dangerous product, much less an entire category of violative products is immensely challenging. The approach FDA must generally take—tackling products one by one—is unsustainable and ineffective in protecting the public from a growing problem.

- 4. Does the FDA and the DEA work together on these pressing issues associated with the illegal marketing of products containing anabolic steroids? It seems that there would be a lot of overlap between the two agencies. Is there coordination on these types of cases? And what type of outreach has the FDA pursued with the dietary supplement industry on this issue? Have there been any collaborations between the Agency and the industry? If so, will you take a few minutes to talk about those discussions?***

FDA's Office of Criminal Investigations (OCI) recognizes the need to coordinate with DEA on these types of investigations, particularly because some of these products contain controlled substances specifically listed in the Controlled Substances Act as anabolic steroids. OCI aggressively investigates the distribution of illegal dietary supplements containing synthetic "designer" steroids and recognizes the risks these products pose to consumers. OCI remains actively engaged with DEA to pursue these types of investigations. This strong partnership was highlighted during Operation Raw Deal (See DEA-issued press release, dated September 24, 2007, for additional information on this joint DEA-OCI operation (<http://www.usdoj.gov/dea/pubs/pressrel/pr092407.html>)).

The Agency has recently met with industry stakeholders, including the American Herbal Products Association, the Natural Products Association, the Consumer Healthcare Products Association, and the Council for Responsible Nutrition, on the use of steroids in dietary supplements. FDA has also issued many Warning Letters to companies marketing such products in the past five years. These letters are posted on FDA's Web site (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>) and are widely read by dietary supplement companies and the lawyers who advise them. In addition, in 2004, 2006, and 2009, the Agency issued press releases to publicize its enforcement activities concerning body-building products containing steroids and to inform consumers, industry, and health professionals about the risks of these products.

5. Could you walk me through the process of how the FDA considers a New Dietary Ingredient (NDI) for approval after it is submitted to the Agency by a dietary supplement manufacturer?*

FDA does not approve NDIs; however, FDA does review NDI notifications to determine whether there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. Upon receipt of incoming correspondence at FDA's Center for Food Safety and Applied Nutrition (CFSAN), an FDA Consumer Safety Officer (CSO) inspects the material to see if it is intended to be an NDI notification under 21 CFR 190.6. If so, the notification is filed for review, which starts the clock for the 75-day period during which the notifier may not market a dietary supplement containing the NDI.

Next, the CSO looks more carefully through the notification to see whether it complies with the administrative requirements of 21 CFR 190.6, the regulation implementing the NDI notification provision of the FD&C Act (21 U.S.C. 350b(a)(2)), which was enacted as part of DSHEA, and which gives FDA the authority to review the submission. Approximately 10 percent of submissions do not comply with 21 CFR 190.6. The most common reasons for noncompliance are notifications that include foreign language publications that have not been completely or accurately translated into English and notifications that make reference to published material but fail to provide reprints or photocopies of the published material. If the notification does not meet the requirements of 21 CFR 190.6, the Agency attempts to contact the notifier, by telephone if possible, to arrange for an amendment to complete the notification.

After review by the CSO, copies of the notification are distributed to employees with appropriate expertise to review the contents of the notification. The expertise needed for review varies somewhat based on the notification. Generally, a chemist and a toxicologist are assigned. Notifications with clinical studies may also be reviewed by a medical officer. Notifications for substances derived from plants are evaluated by botanists. Notifications with live microbial ingredients (e.g., probiotics) are evaluated by a microbiologist. Each member of the multi-disciplinary ad hoc team assigned to the notification provides a preliminary evaluation specific to his/her expertise. The evaluation is based on the material in the notification, publicly available information about the ingredient or similar ingredients identified through a literature search, and any relevant information from previous submissions from other notifiers for the same ingredient or for similar ingredients. At the conclusion of this preliminary review, the ad hoc team then comes together to provide a unified response based on the entire notification and any other relevant information that was uncovered during the preliminary review.

In parallel to its internal scientific review, CFSAN contacts FDA's Center for Drug Evaluation and Research (CDER) to see whether the ingredient might be excluded from use as a dietary supplement because the ingredient was approved as a new drug or authorized for investigation as a new drug for which substantial clinical investigations, whose existence has been made public, have been instituted. Under section 201(f)(3)(B) of the FD&C Act, added by DSHEA, such articles may not be sold as dietary supplements unless the ingredient was marketed as a dietary supplement or food before it was approved or authorized for investigation as a new drug. Because there is no requirement that the holder of an effective investigational new drug application (IND) disclose the fact that clinical trials for which information is publicly available are in fact

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authorized by FDA as investigations of new drugs, CFSAN must rely on confidential information from CDER to begin this analysis.

During review of a notification, FDA staff frequently have questions about the data and information that have been submitted. If these questions are significant enough to affect whether the NDI will reasonably be expected to be safe when used under the conditions described in the notification, FDA may present the questions to the notifier during the 75-day review period, usually during a telephone conference with FDA scientific staff to discuss the scientific issues raised during the FDA review. Administrative and other issues may also be discussed. Responses to these questions frequently arrive in the form of amendments to the notification. Simple responses generally do not affect the length of time it takes FDA to reach a conclusion regarding the information in the notification. However, sometimes responses that contain a substantial amount of new information are received. In order to have sufficient time to review this new information, FDA is authorized to reset the filing date of the notification when it receives a substantive amendment to an NDI notification (See 21 CFR 190.6(d)). Resetting the filing date starts a new 75-day review period.

On or before the 75th day after filing, FDA contacts the notifier to inform the notifier of the conclusions reached during the FDA review of the notification. This is done by letter, with a courtesy copy sent by fax, if fax contact information was provided. After receiving the response letter, some notifiers take advantage of the reminder in the letter to identify to the Agency material in the notification that the notifier considers to be confidential commercial information or trade secrets. On the 90th day after filing, the notification and the FDA response letter are forwarded to the CFSAN Freedom of Information Act (FOIA) staff, who review the material, redact any information that is protected from disclosure under FOIA, and forward a redacted copy to the FDA Division of Dockets Management. The Division of Dockets Management posts the redacted notification and response letter on Regulations.gov, where they are publicly available in docket FDA-1995-S-0039.

6. In your example of the products marketed by American Cellular Labs, Inc., you indicated that the company marketed that product by saying it was a potent anabolic and had low androgenic activity? Isn't such a product already illegal under current law?

The products listed in the American Cellular Labs, Inc. Warning Letter violate the FD&C Act but not solely, because they are marketed as being anabolic and having low androgenic activity. Unfortunately, FDA cannot always take an enforcement action against this type of product merely by looking at the product's marketing claims. For example, claims about enhancing muscle bulk may be allowable function structure claims as long as the claims are not false or misleading. The American Cellular Labs, Inc. body-building products were found to be violative because FDA analyzed each ingredient and determined that the products did not contain any dietary ingredients.

The enforcement challenge is not that these products do not violate the FD&C Act; rather, it is the way the FD&C Act must be enforced—discovering and proving the violation in a huge universe of dietary supplements. Because FDA generally does not receive information on these products prior to marketing, FDA usually cannot identify violative products before they enter the marketplace. After products enter the market, we must undertake intensive investigative and

analytical processes to show that they are violative. Each enforcement action involves a collaborative effort by FDA chemists, laboratory staff, lawyers, physicians, and investigators that can span many months. To find these potentially violative products, FDA staff must search the Internet, gyms, and retail stores. A quick Internet search for “buy bodybuilding dietary supplements” yields close to 500,000 hits, indicating that a huge amount of resources would need to be dedicated to seek out all the violative firms and products, even in this limited product category. Mr. Andrew Shao, Vice President for Science and Regulation at the Council for Responsible Nutrition, estimated that in 2007, \$2.8 billion was spent on products claiming to build muscle or enhance athletic performance. FDA’s arduous investigative and enforcement processes make it difficult for the Agency to monitor and control such a large industry.

After FDA finds a potentially violative body-building product, an in-depth analysis begins. FDA scientists must identify the potential steroid ingredient on the label. There is a vast array of known steroids (over 7,000), all variations of the same basic steroid chemical skeleton. There are also a variety of different names for each ingredient. For example, PubChem lists 60 known synonyms for the controlled substance androstenedione. Some of these include Androtex; Andro; 4-Androstenedione; 4-Androstene-3,17-dione; Fecundin; Androst-4-ene-3,17-dione; delta-4-Androstenedione; 17-Ketotestosterone; 3,17-Dioxoandrost-4-ene; Androstenedione (JAN); Androsten-3,17-dione; delta-4-Androsten-3,17-dione. Because of the multiplicity of steroids and steroid names, FDA must often use a steroid expert to sort through the labeled ingredients and identify potentially dangerous ingredients.

At times, the ingredient may not be listed on the labeling of the finished product, or the ingredient may be misnamed (e.g., parts of the chemical structure name are missing). When this occurs, FDA must send the products to one of our laboratories for analysis. FDA laboratories use scientific expertise and sophisticated instruments to identify the presence of synthetic steroids. Determining the molecular weight may be a useful first step to identifying a chemical compound; however, there could be 20 steroids with the same molecular weight, each representing a unique chemical compound. There are so many different steroid compounds that in many instances reference standards, which are needed for the laboratory to conclusively identify the chemical, are not available.

When the chemical is adequately identified, FDA must then determine whether the ingredient is a dietary ingredient through an extensive search of the scientific literature. Often, it is an entirely novel compound without any published scientific literature. Once we determine whether the steroid ingredient is a dietary ingredient, an examination of the product’s other ingredients, labeling, and other promotional material is also required to determine its proper regulatory status (e.g., unapproved new drug, adulterated dietary supplement).

If FDA concludes that regulatory action is warranted against a product, the Agency must first determine the location of the company and the most responsible parties. Often, there is no physical address listed for the company, only a post office box, phone number, or e-mail address. The companies are often not registered at their state’s secretary of state or have outdated registrations. FDA spends a significant amount of time tracking down the locations of these companies because many of them do not want to be found.

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Only after this long process can FDA begin work on an enforcement action to protect the public from one firm's anabolic steroid or steroid-like products.

7a. How many serious adverse events were reported on an annual basis before the 2006 AER (adverse event reports) legislation was signed into law? Since the 2006 AER law has been implemented, has the FDA seen an increase in the number of serious adverse events?*

The number of serious adverse events reported to FDA markedly increased after the 2006 AER legislation (the Dietary Supplement and Nonprescription Drug Consumer Protection Act) became effective on December 22, 2007. The number of reports received went from 350 reports in calendar year 2007 to 1,107 reports in calendar year 2008.

Table 1 below lists the number of dietary supplement adverse event reports FDA received each year for the past five years. CFSAN staff searched the CFSAN Adverse Event Reporting System (CAERS) Oracle database for reports of adverse events associated with dietary supplements that were received during calendar years 2004 through 2008. Dietary supplement adverse event reports are stored in CAERS after they are received through FDA's MedWatch reporting program. Table 1 also shows the number of adverse events that were reported to FDA as serious each year and the corresponding percentage of serious adverse events for the year. The proportion of reporters to CAERS who characterized the adverse event(s) related to dietary supplement(s) as serious varied across the five years, with no specific trend observed. The highest year for proportion of reporters characterizing the adverse event as serious occurred in 2008, with 78.7 percent of reports characterized as serious.

There are several limitations of making inferences from passive surveillance systems such as CAERS, even with the advent of mandatory reporting. Among these limitations are that CAERS receives a small and unknown percentage of all adverse event reports, and that reported association of a product with an illness does not necessarily prove causation.

YEAR	Total Number of Cases Per Year	Number of Cases Adverse Event Complaint (AEC) Serious as Reported	Percentage of Cases Where AEC Serious as Reported
2004	657	483	73.5%
2005	491	364	74.1%
2006	317	213	67.2%
2007	350	213	60.9%
2008	1,107	871	78.7%

7b. If so, what is the protocol for the FDA to follow up with these companies once a serious AER [is received?]*

The medical reviewers in CFSAN's Division of Dietary Supplement Programs evaluate the adverse event reports for dietary supplements on a case-by-case basis and document their clinical reviews in FDA's CAERS database, where dietary supplement adverse event data are stored. FDA reviewers evaluate the seriousness of the adverse events and their relationship to the suspected dietary supplement. When the initial review indicates that the safety concern is serious enough and the data are strong, FDA then considers appropriate action to protect consumers or, if the information is not definitive enough to support regulatory action, initiates an in-depth analysis. If the level of concern is categorized as relatively low based on the professional judgment of FDA reviewers, FDA continues to monitor the safety signals generated by adverse event reports.

If the initial review indicates that a specific dietary supplement may present a health risk to consumers, FDA would initiate an in-depth review. This process includes, but is not limited to an intensive literature search and review; requesting additional information from academic institutions, individual experts, and industry; consulting experts inside FDA or, if necessary, outside FDA; and preparing a safety review.

The safety review informs Agency compliance and policy staff in considering what Agency action may be warranted. Depending on the seriousness of the injury, the certainty of the relationship to a particular dietary supplement or dietary ingredient, and other factors, a number of actions are available to FDA. These actions include issuing a Warning Letter, initiating a seizure or injunction action, requesting that a firm recall implicated product, issuing consumer alerts or other public warnings, working with state and local public health authorities to recall or embargo implicated products, or issuing a regulation to prevent the marketing of an unsafe dietary supplement or dietary ingredient. More than one of these tools may be used for any given situation.

7c. How does the relatively new adverse event reporting system for dietary supplements assist FDA's enforcement efforts against dangerous products?*

The serious adverse event reporting requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act resulted in an increase in the number of adverse event reports about dietary supplements. The law also mandated that product labels accompany adverse event reports to FDA. These two new requirements have assisted FDA as follows: 1) the higher number of reports enables reviewers and statisticians to better detect unusual reporting patterns from clusters of adverse event reports, which can provide evidence to help FDA determine associations between products and adverse health effects; and 2) product labels allow for better characterization of the products and their ingredients than would result from voluntary consumer reports where the product may not be as clearly described. Better description and characterization of products associated with adverse events support FDA's investigation and enforcement efforts.

7d. What can be done, in your opinion, to encourage more people to report serious AERs?*

Increased outreach to health professionals, industry and consumers to aid in their awareness of where to report, how to report, and how FDA uses their reports could encourage more people to

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report serious AERs. Product labels that provide information about where to report adverse health effects may also encourage more people to report serious adverse events.

8. What percentage of the FDA's annual budget is spent investigating the safety of dietary supplements?

FDA's FY 2010 budget for Dietary Supplement Safety is approximately 0.5 percent of our total annual budget, including user fees.

9a. What type of challenges does the FDA encounter when investigating products with synthetic substances?*

FDA cannot identify violative products before they enter the marketplace. The Agency must go through a detailed investigative and analytical process to show that products are violative after they enter the market; we face struggles to provide an effective criminal deterrent to persons who market these products with the intent to defraud or mislead, and we are unable to effectively prevent the import of all violative products.

Body-building products that contain synthetic steroids continue to be a challenging area for FDA. The marketing of most such products as dietary supplements places FDA in a position where it must identify the products and the firms that market them after the products have already been introduced into the marketplace. To find products with synthetic steroid ingredients, FDA staff must search the Internet, gyms, and retail stores. A quick Internet search for "buy bodybuilding dietary supplements" yields close to 500,000 hits, indicating that a huge amount of resources would need to be dedicated to seek out all of the violative firms and products in this category. Mr. Andrew Shao, Vice President for Science and Regulation at the Council for Responsible Nutrition, estimated that in 2007, \$2.8 billion was spent on products claiming to build muscle or enhance athletic performance. FDA's arduous investigative and enforcement processes make it difficult for the Agency to monitor and control such a large industry.

After FDA finds a potentially violative body-building product, an in-depth analysis begins. First, FDA scientists must identify the potential steroid ingredient on the label. There is a vast array of known steroids (over 7,000), all variations of the same basic steroid chemical skeleton. There are also a variety of different names for each ingredient. For example, PubChem lists 60 known synonyms for the controlled substance androstenedione. Some of these include Androtex; Andro; 4-Androstenedione; 4-Androstene-3,17-dione; Fecundin; Androst-4-ene-3,17-dione; delta-4-Androstenedione; 17-Ketotestosterone; 3,17-Dioxoandrost-4-ene; Androstenedione (JAN); Androsten-3,17-dione; delta-4-Androsten-3,17-dione. Because of the multiplicity of steroids and steroid names, FDA must often use a steroid expert to sort through the labeled ingredients and identify potentially dangerous ingredients.

At times, the ingredient may not be listed on the labeling or the ingredient may be misnamed (e.g., parts of the chemical structure name are missing). When this occurs, FDA must send the products to an FDA laboratory for analysis. FDA laboratories use scientific expertise and sophisticated instruments to identify the presence of synthetic steroids. Determining the molecular weight may be a useful first step to identifying a chemical compound; however, there could be 20 steroids with the same molecular weight, each representing a unique chemical compound. There are so many

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different steroid compounds that in many instances reference standards, which are needed for the laboratory to conclusively identify the chemical, are not available.

Lastly, in order to take regulatory action, FDA must determine the location of the company and the most responsible parties. Often, there is no physical address listed for the company, only a post office box, phone number, or e-mail address. The companies are often not registered at their state's secretary of state or have outdated registrations. FDA spends a significant amount of time tracking down the locations of these companies because many of them do not want to be found.

When firms selling violative products are identified, FDA uses both criminal and civil enforcement powers to address the problem of steroid products marketed as dietary supplements. FDA has used its civil enforcement authority through the issuance of Warning Letters to firms and by pursuing a seizure action, if warranted. However, these actions have a limited deterrent effect on unaffected firms and very often involve only one or two violative products. These factors limit the Agency's reach, given the size of the marketplace and the limited resources available.

Criminal investigations can present legal challenges to law enforcement because some dietary supplements contain novel synthetic steroids that are not specifically listed as anabolic steroids under CSA. In such cases, only misdemeanor violations of the FD&C Act may apply, unless there is evidence of intent to defraud or mislead; a requirement for establishing a felony violation of the FD&C Act. If a dietary supplement contains a novel synthetic steroid that is not a controlled substance under the CSA and the product is accurately labeled, it may be difficult to establish a felony violation of the Act.

FDA also faces the challenge of determining the regulatory classification of steroid products marketed as body-building supplements. Although these steroid products are typically represented as dietary supplements, the products often do not meet the definition of dietary supplement under the Act. For example, if an anabolic steroid was approved as a new drug or authorized for investigation as a new drug, for which substantial clinical investigations whose existence has been made public were instituted before the steroid was marketed as a dietary supplement or as a food, a product containing the steroid cannot legally be marketed as a dietary supplement (See 21 U.S.C. 321(ff)(3)(B)). In addition, if an anabolic steroid in a dietary supplement is not a dietary ingredient, as defined in section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)) and the product contains no other dietary ingredients, the product does not meet the definition of a dietary supplement and may not be marketed as such. However, some types of anabolic steroids (e.g., those made from plant material or animal tissue) may be dietary ingredients because they fit within one of the categories of dietary ingredients defined in section 201(ff)(1) of the FD&C Act.

To be a dietary supplement, a product must contain at least one dietary ingredient (See 21 U.S.C. 321(ff)(1)). A dietary ingredient is defined as a vitamin, a mineral, an amino acid, an herb or other botanical, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.

Some types of steroids may be dietary ingredients because they are either:

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- a dietary substance for use by man because the substance has a history of use as a food or food ingredient;
- a constituent of a “dietary substance” (e.g., the steroid is present in a food such as animal meat or organs used as food);
- a constituent of a plant or botanical (e.g., plant-derived ecdysteroids, phytosterols, saponins, etc.); or
- a metabolite of a substance that is a dietary ingredient.

Therefore, these steroids could be extracted and purified for use as dietary ingredients. However, steroids that are dietary ingredients because they are a constituent of another dietary ingredient are only dietary ingredients if they are extracted and purified from the parent material. FDA believes that synthetic versions of otherwise eligible steroids are not dietary ingredients. This conclusion results directly from the language of the dietary ingredient definition; that is, a synthetic substance that was never a part of a dietary ingredient cannot be understood to be a “constituent” of that dietary ingredient. Rather, it is a synthetic copy of the constituent. Because we believe that most steroids that are being marketed as dietary supplements are synthetically produced, most are not dietary ingredients. To the best of FDA’s knowledge, no synthetic steroid currently being marketed is a dietary ingredient.

FDA faces many challenges when it considers whether a particular steroid-containing dietary supplement violates the Act. Determining whether a product violates the Act is a time-consuming process that requires staff to search scientific literature. In cases where we cannot identify the steroid ingredient in a product marketed as a dietary supplement (e.g., because the ingredient is named incorrectly or is a novel steroid not previously identified in dietary supplements) or are unable to locate information in the scientific literature, we must consult an expert, either inside or outside FDA, to determine what it is.

Once FDA determines whether a steroid in a product is a dietary ingredient, an examination of the product’s other ingredients, labeling, and other promotional material is required to determine the product’s regulatory status and the violations that may apply to it. For products that contain a steroid that is not a dietary ingredient, depending on the product’s other ingredients and on the claims that are made for it, the product may be an unapproved new drug, or it may be a dietary supplement that is adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)) because the steroid ingredient is an unapproved food additive. On the other hand, if FDA determines that the steroid meets the definition of a dietary ingredient, the Agency must also determine whether a premarket notification would be required for the dietary ingredient. If premarket notification was required, but not submitted at least 75 days before marketing, the product would be considered an adulterated dietary supplement (See 21 U.S.C. 342(f)(1)(B), 350b(a)).

9b. When a product contains such a substance, isn’t it true that since it is adulterated or an unapproved drug, that it is illegal to market that product?*

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In the great majority of cases, a product that contains a synthetic steroid is either an unapproved drug or an adulterated dietary supplement. It is a prohibited act under the FD&C Act to market an adulterated dietary supplement or unapproved drug. See previous response and response to Question #4 for the factors FDA considers in determining whether a product containing a synthetic steroid is an unapproved drug or an adulterated dietary supplement.

9c. When the FDA cannot identify a substance listed on the label, why wouldn't it contact the product manufacturer?*

There is no statutory bar to FDA's contacting a product manufacturer when a question is raised about an ingredient in one of the manufacturer's products. However, as a practical matter, FDA's experience has been that this approach is not useful in most situations because of legal limitations such as our inability to compel the firm to disclose information to FDA, and the fact that such contact provides advance notice to the firm of a possible enforcement action. Such advance notice may interfere with FDA's ability to collect evidence in subsequent inspections or searches.

10. Why did FDA take 13 years to issue the dietary supplement Good Manufacturing Practices regulations? Do you think they are helpful?*

In drafting the current Good Manufacturing Practice (cGMP) regulations for dietary supplements, FDA made an extensive effort to be thorough in its regulatory approach and attentive to the many possible impacts on such a varied commodity so frequently purchased by the American public. The aim of the regulations is to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, improper packaging and labeling, and contamination with substances such as natural toxins, bacteria, pesticides, glass, and heavy metals. The history of the rule shows that we carefully considered all comments and were inclusive in our outreach to ensure all stakeholders were able to participate in the process.

To minimize disruptions to small business operations, this rule has a three-year phase-in based on firm size. We are now in the second stage where firms of 20-500 employees are subject to the rule. By June 2010, firms of fewer than 20 employees will also have to comply with the cGMP regulations. Because of the phasing in of the rule's obligations based on firm size, most firms have only recently (June 2009) become subject to the regulations. Given that fact, we do not yet have sufficient inspection data to draw firm conclusions as to whether the cGMP regulations are having their expected impact by ensuring that dietary supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled.

11a. Did the manufacturers of the products at issue here submit pre-market notifications, as required by current law? If not, aren't the products considered adulterated and FDA can take action under current law?*

FDA has not received NDI notifications for most steroid-containing products currently being marketed as dietary supplements. In many cases, this may be because the steroids are not dietary ingredients as defined in section 201(ff)(1) of the FD&C Act. If the steroids in some of these products are in fact dietary ingredients, however, FDA believes that most or all of them would be NDIs for which a notification is required. The fact that no such notification has been submitted to FDA would result in products containing such NDIs being adulterated dietary supplements whose

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marketing would violate the FD&C Act. FDA could take enforcement action against such products if an investigation established evidence of the violations of law.

11b. Has FDA ever initiated an enforcement action because a dietary supplement failed to comply with the new dietary ingredient notification requirements?*

FDA has alleged that a dietary supplement is adulterated under section 402(f)(1)(B) of the FD&C Act (21 U.S.C. 342(f)(1)(B)) in three instances to date. In March 2004, FDA alleged in Warning Letters to 23 firms marketing androstenedione-containing supplements that, assuming that the firms had a basis to conclude that androstenedione was a dietary ingredient, it appeared to be an NDI for which a notification was required. The same charge was used in an August 19, 2009, Warning Letter to the firm EFT, Inc. for the products Perform Plus #3006, Cellprotect I, and Cellprotect II, because they contained either humic and fulvic acids or 4-androsten-3,17-dione. FDA also used this charge in a seizure action against two steroid-containing products marketed as dietary supplements by LG Sciences, LLC (See seizure complaint and consent decree at Tab B). The case ended in a consent decree that condemned the seized products and ordered their destruction.

12. In your testimony, you indicate that FDA is unable to prevent the importation of products that violate the Food Drug and Cosmetic Act. Doesn't this suggest that FDA needs to do a better job exercising its existing authorities before taking on new responsibilities?

Products containing steroids may be either produced domestically or imported. When made domestically, it has been our experience that investigations have determined that the bulk ingredients have been imported for encapsulation, bottling, labeling and distribution. FDA works closely with U.S. Customs and Border Protection to monitor imports. Under section 801(a) of the FD&C Act (21 U.S.C. 381), imported dietary supplements and drugs are subject to review by FDA at the time of entry through U.S. Customs. Products that do not appear to comply with FDA laws and regulations are subject to refusal of admission into the United States. Violative products must be brought into compliance (if feasible), destroyed, or re-exported. Shipments of violative dietary supplements and drugs, however, frequently enter the United States through the international mail facilities and courier services. Such shipments can be extraordinarily difficult to effectively address and prevent because of their sheer volume and FDA's limited resources, which prevent the Agency from performing a comprehensive evaluation of all incoming packages.

With regard to your question about new responsibilities, FDA is mindful of its obligation to use its existing authority well. Accordingly, the Agency will continue to use its available resources to detect imported steroid products and bulk ingredients that violate the FD&C Act and prevent them from being marketed to consumers in the United States.

13. Please go into more detail about the regulation of health claims for supplements on packaging and in advertising.*

Health claims are claims in the labeling of a dietary supplement or other food that expressly or by implication characterize the relationship of a food substance to a disease or health-related condition. An example of a health claim is "Adequate calcium throughout life, as part of a well-

balanced diet, may reduce the risk of osteoporosis" (See 21 CFR 101.72). FDA regulates health claims in supplement labeling; the Federal Trade Commission regulates such claims when they appear in supplement advertising. There are two ways by which FDA exercises its oversight in determining which health claims may be used in labeling for a dietary supplement:

1. **Health Claims Authorized by Regulation.** The FD&C Act provides for FDA to issue regulations authorizing health claims for dietary supplements and other foods based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition. The Agency uses the significant scientific agreement standard to determine whether the substance/disease relationship is well-established.
 2. **Qualified Health Claims.** As a result of court decisions interpreting the First Amendment to the U.S. Constitution, FDA reviews qualified health claim petitions and issues a letter of enforcement discretion when the Agency's review of the scientific literature shows that there is credible scientific evidence supporting the claim, but the quality and strength of the scientific evidence fall below the standard for FDA to issue an authorizing regulation. Qualifying language is included with the claim to describe the limitations in the evidence supporting the claim and to convey any other information necessary to prevent the claim from misleading consumers.
- 14a. Could you please describe for the Committee in as much detail as possible how the Food and Drug Administration works with the Drug Enforcement Administration in investigating and addressing possible sale of illegal steroid and steroid precursor products? Do you have any formal interagency agreement in this area? If so, please provide a copy for the Committee.****

FDA's OCI continues to aggressively investigate the distribution of products containing synthetic steroids, and recognizes the risks these products pose to consumers. OCI remains actively engaged with DEA to pursue these types of investigations. This strong partnership was highlighted during Operation Raw Deal. See DEA-issued press release, dated September 24, 2007, for additional information on this joint DEA-OCI operation at <http://www.usdoj.gov/dea/pubs/pressrel/pr092407.html>. OCI recognizes the need to coordinate with DEA on these types of investigations, particularly because some of these products contain controlled substances specifically listed in the CSA as anabolic steroids.

FDA currently has two Memorandums of Understanding (MOUs) with DEA at Tab C. They are available at <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116001.htm> and <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116210.htm>.

The first MOU, which was signed in 1974, establishes a working arrangement for the operation and activities of a DEA/FDA Liaison Staff created to carry out the objectives of the CSA. The MOU states that the staff shall coordinate efforts to facilitate exchange of pertinent information necessary to controlled substances decisions. The second MOU, signed in 1976, is unrelated to the current topic of steroids in dietary supplements and pertains to narcotic treatment centers.

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In addition, FDA is a member of the Interagency Committee on Drug Control (ICDC), established in the early 1970s as a forum to discuss problem areas in drug control that transcend the boundaries of individual Agency responsibilities. The purpose of the group is to help facilitate the exchange and coordination of information among agencies. The ICDC includes representations from the Office of National Drug Control Policy (ONDCP), DEA, FDA and National Institute on Drug Abuse (NIDA). Please find attached (Tab D) a copy of the charter.

14b. The Commissioner has stated that it is her priority to improve enforcement against illegal steroid products masquerading as dietary supplements. Please outline the steps your Agency is taking to follow through on this commitment.

In late July, FDA executed a search warrant on American Cellular Labs, Inc., and sent a Warning Letter to the firm for marketing and distributing body-building products containing synthetic steroid substances. This action was followed by the execution of a search warrant on Bodybuilding.com, a large online distributor of body-building products on the Internet. The Bodybuilding.com search warrant named over 60 products marketed as dietary supplements that contained one or more of five different steroids—“Madol,” “Tren,” “Superdrol,” “Androstenedione,” and “Turinabol.”

In addition to these actions, FDA continues to use available resources to monitor the marketplace for potentially illegal products. FDA obtains information from inspections of dietary supplement manufacturers and distributors, the Internet, consumer and trade complaints, laboratory analyses of selected products, and adverse events that are reported to the Agency.

When a violative product is investigated, FDA must conduct scientific and labeling analyses of the ingredients, conduct a legal review, discover the firms’ locations, and, when appropriate, take action. Because of the complexity of this process, it may take the Agency many months to complete an investigation and take an action against a violative firm.

If FDA thinks that there is a violative product that should be immediately removed from the market, the Agency must rely on the responsible firm to take such action. Recalls of dietary supplements and drugs are voluntary actions taken by manufacturers or distributors. FDA is not authorized to require recalls of dietary supplements or drugs. If the firm is willing to conduct a recall, FDA works with the firm on recall strategy and implementation. If the firm is not willing to remove dangerous products from the market and is unwilling to voluntarily cease distribution, FDA considers its enforcement tools, including seizure, injunction, and criminal sanctions.

FDA will continue to closely monitor the safety of steroid products marketed as dietary supplements. We are committed to doing everything we can to protect the American public, not only through regulation and enforcement, but also through education, outreach, and collaboration with entities outside FDA. While FDA has made it a priority to improve enforcement against bad actors, our resources are limited. We intend to focus on taking action against those products that pose the greatest health risk to the most vulnerable populations. We hope that industry will also continue to make it a priority to help consumers better distinguish bad actors from responsible supplement companies.

14c. How many possible illegal steroid or steroid precursor products have come to the attention of your Agency? How many of those have you acted on?

Because FDA generally does not receive information on these products prior to marketing, FDA generally cannot identify violative products before they enter the marketplace. However, based on consumer complaints, reported adverse events, and Internet searches, FDA believes that illegal steroid products are a widespread problem. In the search warrant executed on bodybuilding.com on September 25, 2009, FDA seized over 60 different steroid products. This involved one distributor and five different steroid compounds. In the recent American Cellular Laboratories case, FDA identified eight violative steroid products.

14d. If a person becomes aware of such a product, what is the best way to bring it to the attention of the FDA? Would the FDA investigate such a complaint?

FDA welcomes and encourages reports from consumers and health care professionals alerting the Agency to problems with products regulated by FDA. These reports help FDA ensure that products on the market are safe and properly manufactured, labeled and stored. In each case, the information is evaluated to determine how serious the problem is and what follow-up is needed. Top priority is given to products that have caused or may cause a serious illness, injury, or a life-threatening situation. Although FDA cannot respond to every complaint individually, the Agency will evaluate every complaint received.

A person can contact FDA through our Web site in a number of different ways: Report any criminal behavior to: <http://www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm> Report any safety issues or adverse events to FDA's MedWatch: <http://www.fda.gov/Safety/MedWatch/default.htm>. To report unlawful sales of medical products on the Internet, visit Reporting Unlawful Sales at: <http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>.

15. In a February 21, 2009 FDA Consumer Health Information notice, the FDA stated that since 2004, it has identified several products that claim to be dietary supplements for treating erectile dysfunction and enhancing sexual performance.

Some of these products were found to contain the active ingredient or a substance similar to the active ingredient in Viagra or Levitra. Both Viagra and Levitra were approved by the FDA, went through the premarket drug approval process and, today, may only be sold to consumers with a doctor's prescription.

However, this did not stop unscrupulous companies from marketing these products even though they were in clear violation of the Federal Food, Drug and Cosmetic Act. Similarly, products containing anabolic steroids that are marketed as dietary supplements are adulterated and misbranded. These anabolic steroid products are also in a clear violation of the law. Therefore, requiring the premarket approval of these products will not prevent unscrupulous companies from breaking the law. In my opinion, the better solution is to strengthen the enforcement activities of the FDA and DEA. Mr. Levy and Mr. Rannazzisi do you agree?

FDA will continue to closely monitor the safety of steroid products marketed as dietary supplements. We are committed to doing everything we can to protect the American public, not only through regulation and enforcement, but also through education, outreach, and collaboration with entities outside FDA. While FDA has made it a priority to improve enforcement against bad actors, our resources are limited. Therefore, we intend to focus on taking action against those products that pose the greatest health risk to the most vulnerable populations.

Generally, FDA's challenge in regulating these products, is in the way the law must be enforced—discovering the violation in a huge universe of dietary supplements, classifying and proving the violation, and effectively deterring future bad actors. After products enter the market, we must undertake intensive investigative and analytical processes to show that they are violative. Each enforcement action involves a collaborative effort by FDA chemists, laboratory staff, lawyers, physicians, and investigators that can span many months.

16. In his testimony, Mr. Tygart talks about a product called Superdrol. I have done a little research on this product and am having trouble understanding why it wouldn't be taken off the market through the laws currently on the books? The advertisements I have seen make muscle-building claims and tout it as an anabolic steroid.

Most products containing the ingredient known as "Superdrol," which is the synthetic steroid methasteron, violate the FD&C Act. However, these products do not violate the law solely because they are marketed with muscle-building claims and are touted as anabolic steroids. Unfortunately, looking at the marketing claims is only part of the analysis. Certain muscle-building claims can be claims that the ingredient affects the structure or function of the body. These types of claims are allowed for dietary supplements under the FD&C Act as long as they are not false or misleading. However, such claims are not allowed for drugs without FDA approval of a new drug application. Whether a product marketed as an anabolic steroid with muscle building claims will be regulated as a dietary supplement or a drug depends on whether the steroid ingredient is a dietary ingredient under 21 U.S.C. 321(ff)(1) and, if not, whether the product contains any other dietary ingredients. The Anabolic Xtreme Superdrol product that was the subject of FDA Warning Letters to the manufacturer and distributor in 2006 contained Superdrol, which is not a dietary ingredient. See <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075812.htm>; <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075813.htm>. The product contained no other dietary ingredients, and therefore it could not be a dietary supplement because a dietary supplement is defined as a product that, among other things, contains one or more dietary ingredients (See 21 U.S.C. 321(ff)(1)). Because Anabolic Xtreme Superdrol was intended to affect the structure and function of the body by building muscle, was not a dietary supplement and was not FDA-approved as a drug for building muscle, it was an unapproved new drug whose marketing violated the FD&C Act. However, because of the complex, fact-based nature of the legal analysis, FDA must evaluate each Superdrol-containing product individually to determine whether it violates the FD&C Act and, if so, under what provisions.

Because FDA generally does not receive information on steroid body-building products prior to marketing, FDA cannot identify violative products containing Superdrol before they enter the marketplace. After products enter the market, we must undertake intensive investigative and analytical processes to show that they are violative. Each enforcement action involves a

Page 24 – The Honorable Patrick J. Leahy and Arlen Specter

collaborative effort by FDA chemists, laboratory staff, lawyers, physicians, and investigators that can span many months.

17. **As I reviewed the testimony of both the DEA and the FDA, both agencies argued that it takes a great deal of time to build a case against a product in order to take it off the market. In other words, the way I interpreted your statements – you are both saying that you cannot just pull a product off the market. But isn't it true that for the vast majority, if not all of these products, they would require an NDI (new dietary ingredient) notification to FDA? If they are marketing a supplement and haven't filed, FDA can take the product off the market because it is misbranded. If the company has filed an NDI, the FDA may still reject it, as the Agency has in over half of all NDI notifications.***

Based on FDA's experience to date with the steroids used in products marketed as dietary supplements, the Agency believes that the number of steroid ingredients that would require an NDI notification is very small because the great majority of such ingredients are synthetic steroids that do not meet the definition of a dietary ingredient. If a substance is not a dietary ingredient, by definition it is not an NDI (See 21 U.S.C. 350b(c)).

When FDA identifies a product being marketed as a dietary supplement that contains what appears to be a steroid, the Agency needs to seek information that will enable us to answer the following questions, among others:

1. Is the substance a dietary ingredient as defined in section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1))
2. If so, is it an NDI for which a notification is required?

Finding and evaluating information to answer these two questions takes time and resources. But, once that information is in hand, FDA has no regulatory tool that would enable us to compel a firm to remove its products from the market by administrative fiat. Rather, the tool available to us to remove a product if it contains a steroid that isn't a dietary ingredient (and that results in the product being an adulterated dietary supplement or unapproved new drug), or that is an NDI for which a notification was required but not submitted (meaning that the dietary supplement containing an NDI is adulterated) is to file a civil seizure or injunction case in federal court.

If a company submits an NDI notification to FDA, and FDA determines that the substance is not a dietary ingredient or FDA believes that the scientific evidence does not establish a reasonable expectation of safety, FDA's remedy to stop the marketing of a product containing the subject ingredient would be to file a seizure or injunction action in federal court. In most cases, this would happen after the product had been introduced into interstate commerce because FDA seldom knows whether or when a firm that has received an FDA letter objecting to an NDI notification intends to market its product.

It is important to note that NDI notifications are just that; they are not applications requiring FDA approval. A firm that submits a notification meeting the requirements of 21 CFR 190.6 may market its product 75 days later. At that point, the burden is on FDA to take action. If the Agency

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concludes that there is no history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, the Agency's only option to stop the marketing of the supplement is to initiate enforcement action and convince a court that the product violates the FD&C Act. This is because FDA's mere statement in a letter responding to a notification that the Agency believes a product is violative does not constitute a binding legal determination that the product is unlawful and may not be marketed. Rather, it is a statement of FDA's judgment of the information before it.

Thank you again for the opportunity to testify. Please let us know if there are further questions.

Sincerely,



Jr Jeanne Ireland
Assistant Commissioner
for Legislation

Enclosures

Inspections, Compliance, Enforcement, and Criminal Investigations**Legal Gear 08-Mar-06**

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Legal Gear
815 N. Second Street, Suite #109
Brighton, MI 48116

Dear Sir/Madam:

This letter relates to your product Methyl 1-P®, containing the synthetic steroids 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone. The product label and your Internet website at <http://www.legalear.com> list 6-alpha-methyl-etiocholene-3,17-dione as an ingredient, and analysis of this product revealed that it is also contains another steroid not declared as an ingredient, 17a-hydroxyprogesterone. The product label and your website state that this product contains an "anabolic agent." Further, your website includes statements about this product such as the following:

- "[E]ven more potent at building muscle than many illegal anabolics!"
- "[T]he only legal choice for people wanting to build serious mass and gain massive strength"

The product label and your website represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredients used in the product, 6-alpha-methyl-etiocholene-3, 17-dione

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075814.htm>

11/4/2009

and 17a-hydroxyprogesterone, are not vitamins, mineral, amino acids, herbs, or other botanicals, or dietary substances for use by man to supplement the diet by increasing the total dietary intake, nor are they concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient described above. Rather, both of these ingredients are synthetic steroids. Consequently, 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone are not "dietary ingredients" as defined in Section 201(ff)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle and increasing strength. Based on these claims, FDA considers Methyl 1-P® to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as a safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505(a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These includes liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violation concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain 6-alpha-methyl-etiocholene-3, 17-dione or 17a-hydroxyprogesterone. Failure to promptly correct the violations may result in FDA enforcement action without further action. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332,333, and 334].

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075814.htm>

11/4/2009

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, Rockville, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Inspections, Compliance, Enforcement, and Criminal Investigations**Anabolic Resources LLC 08-Mar-06**

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

MARCH 8, 2006

WARNING LETTER

Mr. Mike Keplinger
Anabolic Resources LLC
170 S William Dillard Drive
Gilbert, AZ 85233

Dear Mr. Keplinger:

This letter relates to your product Anabolic Xtreme Superdrol, containing the synthetic steroid methasteron. The product label and your Internet website, <http://www.anabolicx.com>, state that this product is "anabolic" and list methasteron as an ingredient. Further, your website includes statements about this product such as the following:

- "Many people have packed on pounds of lean mass and increased their strength while using this potent supplement"
- "The average user will gain between 6-10 pounds in as little as three weeks."

Although Anabolic Xtreme Superdrol is not currently available on your website, where it is marked "Discontinued," it is still being distributed in interstate commerce with a label that lists your firm name and website. The product label and your website represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredient used in the product, methasteron, is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient described above. Rather, it is a

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075812.htm> 11/4/2009

synthetic steroid. Consequently, methasteron is not a "dietary ingredient" as defined in Section 201(ff)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle, increasing strength, and inducing weight gain. Based on these claims, FDA considers Anabolic Xtreme Superdrol to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 (a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain methasteron. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 341].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075812.htm>

11/4/2009

Anabolic Resources LLC 08-Mar-06

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that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition.

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075812.htm>

11/4/2009

Inspections, Compliance, Enforcement, and Criminal Investigations

Supplementstogo.com, LLC 08-Mar-06



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Mr. Joe Godar
Supplementstogo.com, LLC
5130 Crookshank Road
Cincinnati, OH 45238

Dear Mr. Godar:

This letter relates to your firm's marketing of the product Anabolic Xtreme Superdrol, containing the synthetic steroid methasteron. The product label and your Internet website, <http://www.supplementstogo.com>, state that this product is "anabolic" and list methasteron as an ingredient. Further, your website includes statements about this product such as the following:

- "Many people have packed on pounds of lean mass and increased their strength while using this potent supplement"
- "The average user will gain between 6-10 pounds in as little as three weeks."

The product label and your website, from which this product may be ordered, represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredient used in the product, methasteron, is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract or combination of any dietary ingredient described above. Rather, it is a synthetic steroid. Consequently, methasteron is not a "dietary ingredient" as defined in

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075813.htm>

11/4/2009

Section 201(ff) (1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle, increasing strength, and inducing weight gain. Based on these claims, FDA considers Anabolic Xtreme Superdrol to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 (a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain methasteron. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 334].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to correct the violations described above, and an explanation of each step to ensure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products

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Supplementstogo.com, LLC 08-Mar-06

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that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075813.htm>

11/4/2009

Inspections, Compliance, Enforcement, and Criminal Investigations**Affordable Supplements 08-Mar-06**

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Affordable Supplements
7011 West Central, Suite 117
Wichita, KS 67212

455 Whitney Street
Northborough, MA 01532

Dear Sir/Madam:

This letter relates to your firm's marketing of the product Legal Gear Methyl 1-P®, containing the synthetic steroids 6-alpha-methyl-etiocholene-3,17-dione and 17ahydroxyprogesterone. The product label and your Internet website at <http://www.affordablesupplements.com> list 6-alpha-methyl-etiocholene-3,17-dione as an ingredient, and analysis of this product revealed that it also contains another steroid not declared as an ingredient, 17a-hydroxyprogesterone. The product label and your website state that this product contains an "anabolic agent." Further, your website includes statements about this product such as the following:

- "[C]apable of building huge muscle and without any side effects"
- "[S]olid gains in mass with limited side effects."
- [T]he only legal choice for people wanting to build serious mass and gain

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075815.htm>

11/4/2009

massive strength."

The product label and your website, from which this product may be ordered, represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredients used in the product, 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone, are not vitamins, minerals, amino acids, herbs or other botanicals, or dietary substances for uses by man to supplement the diet by increasing the total dietary intake, nor are they concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient described above. Rather, both of these ingredients are synthetic steroids. Consequently, 6-alpha-methyl-etiocholene-3,17--dione and 17a-hydroxyprogesterone are not "dietary ingredients" as defined in Section 201 (ff) (1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1), and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle and increasing strength. Based on these claims, FDA considers Legal Gear Methyl-1-P® to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505(a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain 6-alpha-methyl-

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075815.htm> 11/4/2009

Affordable Supplements 08-Mar-06

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etiocholene-3,17-dione or 17a-hydroxyprogesterone. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 334].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, Rockville, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075815.htm>

11/4/2009

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

United States of America,)	
)	
Plaintiff,)	No. 2:08-cv-11395
)	
v.)	Honorable NANCY G. EDMUNDS
)	
605 cases, more or less,)	Magistrate DONALD L. SCHEER
of an article of food, each case containing)	
12/135 Capsule Bottles, et al.,)	
Bottles, et al.,)	
)	
Defendants.)	

AMENDED COMPLAINT FOR FORFEITURE

To the Honorable Judge of the United States District Court for the Eastern District of Michigan.

Now comes the United States of America by Terrence Berg, Acting United States Attorney for the Eastern District of Michigan, and shows to the Court:

NATURE OF THE ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of food, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 301 *et seq.*

2. That there are at Brighton, Michigan, in the possession of LG Sciences, 6150 Whitmore Lake Road, or elsewhere within the jurisdiction of this Court, articles of food, as described in the caption, which articles were shipped in interstate commerce from outside the State of Michigan.

JURISDICTION AND VENUE

3. That plaintiff brings this action *in rem* to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the court with jurisdiction over seizures brought under the Act.

4. That this Court has *in rem* jurisdiction over the articles because they are located in the Eastern District of Michigan. An arrest warrant *in rem* is not necessary upon the filing of this amended complaint, however, as the articles at issue remain subject to the judicial restraining order issued by this Court on April 2, 2008. *See* Supplemental Rule G(3)(b)(iii).

5. That venue is proper in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the articles are located at LG Sciences, 6150 Whitmore Lake Road, Brighton, Michigan.

BASIS FOR FORFEITURE

6. The articles are labeled as dietary supplements and contain the substance 1,4,6-etioallocholan-dione, which is identified on the label as a dietary ingredient; however, this substance does not meet the statutory definition of a dietary ingredient under the Act, 21 U.S.C. § 321(ff), in that it is not a vitamin, mineral, herb or other botanical, amino acid, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient described above.

7. That the articles are adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C., as follows:

a. The articles are adulterated under § 342(a)(2)(C), in that they (all lots) contain 1,4,6-etioallocholan-dione, an unapproved food additive which is unsafe within the meaning of 21 U.S.C. § 348. Any substance, other than a dietary ingredient, which is intentionally added to a dietary supplement must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety under the conditions of intended use, or is otherwise exempt from the food additive definition in 21 U.S.C. § 321(s). The substance 1,4,6-etioallocholan-dione is not generally recognized as safe, nor is it exempt from the food additive definition in 21 U.S.C. § 321(s). Therefore, it is not approved for use as a food additive.

b. In the alternative, should the Court find that 1,4,6-etioallocholan-dione is a dietary ingredient under U.S.C. § 321(ff) and not an unsafe food additive, the articles are adulterated under § 342(f)(1)(B), in that they (all lots) contain this substance. The substance 1,4,6-etioallocholan-dione is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

c. The articles called "Formadrol Extreme XL" are adulterated under § 342(f)(1)(B) in that they are labeled as a dietary supplement and contains 4-etioallocholen-3,6,17-trione. This substance is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

8. That by reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation.

FACTS

9. The U.S. Food and Drug Administration (FDA) issued a Warning Letter to Legal Gear, Brighton, Michigan, on March 8, 2006. The letter stated that the firm's product, Methyl 1-P®, contained the synthetic steroids 6-alpha methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone. The product was labeled as a dietary supplement, however, the ingredients were not dietary ingredients. The product did not contain any dietary ingredients and so did not meet the definition of a dietary supplement. The Warning Letter stated that, because the product made claims to affect the structure or function of the body, it was a drug. Because the product was not approved for the uses set out in the labeling, it was a new drug. Legal Gear was advised that continued distribution of the drug, for which there is no approved application, is a violation of the law. The firm discontinued distribution of Methyl 1-P® and recalled the product from the marketplace. The firm was also advised in the Warning Letter that it was responsible for ensuring that all products it markets comply with the Act and its implementing regulations.

10. Legal Gear is an alternative name for DOX, LLC, Brighton, Michigan. The company also uses the name LG Sciences. In March 2006, Eric Marchewitz was the President and Managing Member and he signed the firm's recall letters for Methyl 1-P®.

11. LG Sciences, LLC was organized on June 23, 2006. The Manager of LG Sciences, LLC is Eric Marchewitz.

12. In July 2006, Legal Gear sold its inventory and formulations to a newly created company, LG Sciences, LLC, Brighton, Michigan, at the same address.

13. Legal Gear's web site, www.legalgear.com, redirects the visitor to www.lgsciences.com.

14. FDA conducted a follow-up investigation to the March 2006 Warning Letter to determine if the firm was operating in compliance with the Act. The FDA Investigator confirmed that Methyl 1-P® is no longer being distributed by either Legal Gear or LG Sciences, LLC.

15. Currently, LG Sciences is distributing at least three products labeled as dietary supplements with a component, 1,4,6-etioallocholan-dione, which to FDA's knowledge is not a dietary ingredient. If 1,4,6-etioallocholan-dione is a dietary ingredient, however, it is a new dietary ingredient. The three products known to contain 1,4,6-etioallocholan-dione are Methyl 1-D XL, Methyl 1-D, and Formadrol Extreme XL capsules. In addition, the product Formadrol Extreme XL is labeled to contain 4-etioallocholen-3,6,17-trione, which is a new dietary ingredient.

16. The substance 1,4,6-etioallocholan-dione is also known as "1,4,6-androstatrien-3,17-dione" or "ATD." ATD is used in body building products to control estrogen synthesis.

17. During the inspection conducted on October 11-30, 2007, FDA sampled the lots on hand at LG Sciences, of Methyl 1-D XL, Methyl 1-D, and Formadrol Extreme XL capsules. Analyses by FDA's Forensic Chemistry Center confirmed the presence of ATD in all three

products. FDA's analyses also confirmed the presence in the Formadrol Extreme XL product of 4-etioallocholen-3,6,17-trione, a substance also known as "6-OXO."

18. Despite the warning provided in the March 2006 Warning Letter of the need to ensure that all products marketed by the firm comply with the Act and its implementing regulations, the firm has continued to market products in violation of the Act.

We request that process issue against the articles; that all persons having any interest in the articles be cited to appear herein and answer the allegations in the complaint; that this Court decree the condemnation of the articles and grant plaintiff the costs of this proceeding against the claimant of the articles; that the articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff have such other and further relief as the case may require.

Respectfully submitted,

TERRENCE BERG
Acting United States Attorney

/s/ Carolyn Bell Harbin
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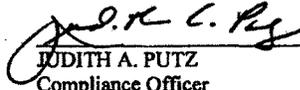
JENNIFER ZACHARY
Associate Chief Counsel
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Office of the General Counsel
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Rockville, MD 20857
(301) 827-9572

VERIFICATION

I, JUDITH A. PUTZ, Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, have read the foregoing Amended Complaint for Forfeiture in this action and state that its contents are true and correct to the best of my knowledge, information, and belief.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

This 6th day of November, 2008.



JUDITH A. PUTZ
Compliance Officer
Food and Drug Administration

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

United States of America,)	
)	
Plaintiff,)	No. 2:08-cv-11395
)	
v.)	Honorable NANCY G. EDMUNDS
)	
605 cases, more or less,)	Magistrate DONALD L. SCHEER
of an article of food, each case containing)	
12/135 Capsule Bottles, et al.,)	
Bottles, et al.,)	
)	
Defendants.)	

CONSENT DECREE OF CONDEMNATION AND DESTRUCTION

On April 2, 2008, Plaintiff, the United States of America, by its undersigned attorneys, filed a Complaint for Forfeiture in this Court against the defendant articles of food ("Articles"), which alleged that the Articles are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 334(a)(1).

On April 2, 2008, the United States Marshal for this District seized the Articles at 6150 Whitmore Lake Road, Brighton, Michigan, pursuant to the Warrant for Arrest issued by this Court. On April 11, 2008, LG Sciences, LLC ("LG Sciences"), through its attorney, intervened and filed a Verified Statement of Interest, asserting an ownership interest in the Articles. On May 8, 2008, LG Sciences answered the Complaint for Forfeiture.

On November 10, 2008, Plaintiff filed an Amended Complaint for Forfeiture ("Amended Complaint"), which alleges that the seized Articles are: (1) adulterated within the meaning of the Act, 21 U.S.C. §§ 342(f)(1)(B) and 348(a), in that all lots contain 1,4,6-*etioallocholan-dione* ("ATD"), which is either an unapproved food additive or a new dietary ingredient for which inadequate information exists to provide reasonable assurance that it does not present a

significant or unreasonable risk of illness or injury; (2) adulterated within the meaning of the Act, 21 U.S.C. § 342(f)(1)(B), in that the seized lots of Formadrol XL contain 4-etioallocholen-3,6,17-trione ("6-OXO"), which is a new dietary ingredient for which inadequate information exists to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury; and (3) by reason of the foregoing, the Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334(a)(1). On December 12, 2008, LG Sciences answered the Amended Complaint, denying Plaintiff's allegations. LG Sciences is the sole claimant in this action.

WHEREAS LG Sciences has appeared and, before any testimony has been taken, agreed to the entry of this Consent Decree without contest, on the motion of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334. Venue is proper in this district under 28 U.S.C. § 1395(b).
2. The Amended Complaint states a claim for relief against the Articles under the Act.
3. LG Sciences affirms that it is the sole owner of the Articles, that no other person has an interest in the Articles, and that it will indemnify and hold Plaintiff harmless should any party or parties hereafter file or seek to file a statement of interest, or to intervene in this action and obtain or defend any part of the Articles subject to this Consent Decree.
4. The Amended Complaint alleges that the Articles are adulterated.
5. LG Sciences denies those allegations in the Amended Complaint, and solely in a compromise to resolve this proceeding the Articles are to be destroyed as set forth below.
6. The Articles are therefore condemned and forfeited to the Plaintiff.

7. Pursuant to 21 U.S.C. § 334(e), LG Sciences shall pay to the United States all court costs and fees, storage, and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed, date, as set forth in paragraph 19 of this Consent Decree. LG Sciences shall pay these costs in full within fifteen (15) days of receiving written notice from the Food and Drug Administration ("FDA") of such costs.
8. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) days of the entry of this Consent Decree, LG Sciences shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety ("Bond") in the amount of fifty thousand dollars (\$50,000.00) in a form acceptable to the Clerk of this Court, to be applied to Lot 1 (as described in Subpart A of Paragraph 11 of this Decree) and held for application to succeeding Lots 2-26 (as described in Subparts B-C of Paragraph 11 of this Decree), payable to the United States of America, and conditioned on LG Sciences abiding by and performing all of the terms and conditions in this Consent Decree.
9. After paying the costs pursuant to paragraph 7 and posting the Bond as specified in paragraph 8, LG Sciences shall give written notice to FDA at the Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207, that LG Sciences, at its own expense, is prepared to destroy the Articles, pursuant to 21 U.S.C. § 334(d), under the supervision of a duly authorized representative(s) of the United States Department of Health and Human Services ("FDA representative"). LG Sciences's notice shall specify the proposed time, place, and method of destruction of the Articles.
10. LG Sciences shall not commence destroying the Articles until it has received written authorization to commence with the destruction from an FDA representative. All Articles shall be destroyed at LG Sciences's expense under the supervision of an FDA representative.

LG Sciences shall pay to the United States all costs incurred in supervising the destruction of the Articles, at the rates specified in paragraph 19 of this Consent Decree.

11. Upon receiving notice from the United States Attorney for this District or FDA that LG Sciences is authorized to commence destroying the Articles, the United States Marshal for this District shall release the appropriate Lot of Articles (as described in Subparts A-C, below) to the custody of LG Sciences for the sole purpose of destroying the Articles pursuant to the destruction plan described in paragraphs 8 and 9 of this Consent Decree. The schedule for release of the Articles is as follows:

A. The Articles in Lot 1, consisting of approximately 1/26 of the Articles (by value), to be further designated by the FDA representative, shall be released to LG Sciences for the sole purpose of destroying the Articles.

B. If and only if LG Sciences complies with all of the terms of this Consent Decree with respect to Lot 1, the Articles in Lot 2, consisting of approximately a second 1/26 of the seized Articles (by value), to be further designated by the FDA representative, shall be released to LG Sciences for the sole purpose of destroying the Articles.

C. Lots 3-26, each consisting of approximately 1/26 of the seized Articles (by value), each to be further designated by the FDA representative, shall be released in succession, if and only if LG Sciences complies with all of the terms of this Consent Decree with respect to each preceding Lot (as described in Subpart B), to LG Sciences for the sole purpose of destroying the Articles.

12. LG Sciences shall at all times, until the Articles have been destroyed, retain the Articles intact for examination, inspection, or sampling by an FDA representative, and shall maintain all

records or other proof necessary to establish the identity of the Articles to the satisfaction of an FDA representative.

13. LG Sciences shall not cause the Articles or any part thereof to be disposed of in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory (as defined in the Act) in which the articles are disposed. LG Sciences shall furnish duplicate copies of evidence of disposition of the articles, if requested by an FDA representative.

14. Within thirty (30) days of entry of this Consent Decree, LG Sciences shall complete the destruction of the Articles under the supervision of an FDA representative. Within fifteen (15) days of LG Sciences's completion of the destruction of the Articles, an FDA representative will send LG Sciences an invoice for the costs of supervising such destruction, and LG Sciences shall pay those costs within ten (10) days of receiving the invoice.

15. The United States Attorney for this District, upon being advised by an FDA representative that the preceding conditions of this Consent Decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be canceled and discharged.

16. If LG Sciences fails to abide by and perform all of the terms and conditions stated in this Consent Decree, then the Bond shall, on motion of Plaintiff in this proceeding, be forfeited in its entirety to Plaintiff and judgment entered in favor of Plaintiff.

17. If LG Sciences breaches any term or condition of this Consent Decree, then LG Sciences shall, at its own expense, immediately return the Articles to the United States Marshal for this District or otherwise dispose of them pursuant to an order of this Court. Following return of the seized articles, the United States Marshal shall destroy the articles and make due return to this Court regarding their disposition. In the event that return of the Articles becomes necessary

pursuant to this paragraph, LG Sciences shall be responsible for all costs of storage and disposition that are incurred by Plaintiff. LG Sciences shall pay such costs within ten (10) days of receiving written notice from an FDA representative of these expenses.

18. If LG Sciences does not avail itself of the opportunity to repossess and destroy the Articles in the manner provided in this Consent Decree, the United States Marshal for this District shall retain custody of the seized articles and destroy them, and make due return to this Court regarding their disposition. LG Sciences shall pay all costs associated with storage and disposition of the seized articles incurred by Plaintiff. LG Sciences shall pay such costs within ten (10) days of receiving written notice from an FDA representative of these expenses.

19. LG Sciences shall reimburse Plaintiff for the costs of supervising LG Sciences's compliance with the terms of this Consent Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Consent Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Consent Decree is signed by the parties, these rates are: \$81.61 per hour and fraction thereof per representative for inspection work; \$97.81 per hour or fraction thereof per representative for analytical or review work; \$0.585 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

20. LG Sciences shall abide by the decisions of FDA regarding destruction of the Articles, which shall be final. All decisions specified in this Consent Decree shall be vested in the

discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a Court of any FDA decision rendered pursuant to this Consent Decree shall be conducted without any discovery by either party and shall be based exclusively upon the written record that was before FDA at the time the decision was made.

21. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED:

s/Nancy G. Edmunds
Nancy G. Edmunds
United States District Judge

Dated: May 11, 2009

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on May 11, 2009, by electronic and/or ordinary mail.

s/Carol A. Hemeyer
Case Manager

We hereby consent to the foregoing Decree.

For Defendants:

LG SCIENCES, LLC

s/ Warren D. Hopper
WARREN D. HOPPER,
Its: Authorized Representative

s/ Thomas W. Cranmer
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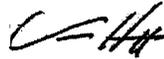
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We hereby consent to the foregoing Decree.

For Defendants:

LG SCIENCES, LLC



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About FDA**MOU 225-74-8013****Memorandum of Understanding****Between
The Drug Enforcement Administration****and****The Food and Drug Administration****Purpose:**

To outline the working arrangements for the operation and activities of the DEA/FDA Liaison Staff established for dealing with related objectives in carrying out DEA and FDA responsibilities under the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act.

I. Objectives and Structure.

The Drug Enforcement Administration and the Food and Drug Administration have established liaison staffs for dealing with related objectives in carrying out their responsibilities under the Controlled Substances Act and the Federal Food, Drug and Cosmetic Act. This Memorandum outlines the working arrangements being followed in the interest of the public so that each agency will discharge its responsibilities as effectively as possible.

The DEA/FDA Liaison Staffs will serve as a focal point for interagency coordinative management of investigative, consultant, scientific, compliance, and legal efforts, involving controlled substances or substances which are being investigated which may be controlled. The Liaison Staffs will also serve in assisting the Administrator and the Commissioner in the development and evaluation of policy.

DEA and FDA shall have the following type of representation on the liaison staff:

- a. Liaison Officer,
- b. Representative from legal office,
- c. Compliance representative,

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d. Science representative,

Other personnel may attend meetings on an as-needed basis.

II. Name and Address of Participating Agencies.

Drug Enforcement Administration
Department of Justice
Washington, DC 20537.

Food and Drug Administration
Department of Health, Education, and Welfare
5600 Fishers Lane
Rockville, MD 20857

III. Liaison Officers.

A. For DEA:

Mr. Ernest A. Carabillo, Jr.
Chief
Special Programs Division
Drug Enforcement Administration
14th and I St. N.W.
Washington, DC 20537
(202) 382-4344.

B. For FDA:

Mr. Thomas W. Brown
Director
Compliance Coordination and Policy Staff (HFC-13)
Office of the Associate Commissioner for Compliance
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-3470.

IV. Operations.

A. Meetings will be held every 2 months on the second Tuesday of the month. The Liaison Officers may reschedule the meeting or convene additional meetings as

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necessary. The host agency will prepare the minutes of meetings, which will be circulated to staff members by the Liaison Officer.

B. The Liaison Staff will limit its discussions to substantive matters in the area of controlled substances involving FDA (not HEW) and DEA.

C. Unresolved policy matters and problems will be referred for discussion at the periodic liaison meetings between the Administrator and the Commissioner.

D. Liaison Staff activities between agencies will be coordinated through the Offices of the Agency's Liaison Officer.

E. Important regulatory developments in both agencies will be promptly communicated to the Agency's Liaison Officer. Regular and frequent exchange of scientific, planning, and regulatory information should take place between officials and professional staffs.

F. The staff shall coordinate efforts to facilitate exchange of pertinent information necessary to controlled substances decisions.

G. The staff shall establish means to clarify and facilitate operating procedures necessary for controlled substances decisions, including, but not limited to, the following interagency cooperative efforts:

- i. Transmittal of and access to necessary documents.
- ii. Access to and knowledge of abuse information.
- iii. Staff level working groups and informal exchanges between such groups.
- iv. Location and production of expert witnesses.
- v. A unified policy concerning publicity releases.
- vi. Procedures to avoid duplication of efforts.

H. The agencies shall informally notify each other in advance of formal proposals to schedule drugs. Additionally, the agencies shall when possible, informally transmit data supporting scheduling decisions in advance of a formal transmittal.

V. Period of Agreement.

This agreement, when accepted by both parties, will have an indefinite period of performance, and may be modified by mutual consent of both parties or may be terminated by either party upon a thirty (30) day advance written notice to the other.

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VI. Authority.

This agreement is entered into under the authority of the Economy Act approved June 30, 1932, as amended, 31 U.S.C. 686.

**Approved and Accepted
for the Drug Enforcement
Administration**

Signed by: Frederick M. Garfield
Director of Research and Technology

Date: July 1, 1974

**Approved and Accepted
for the Food and Drug
Administration**

Signed by: Sam D. Fine
Associate Commissioner for Compliance

Date: June 21, 1974

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About FDA**MOU 225-76-3009**

Memorandum of Understanding
Between
The Drug Enforcement Administration
and
The Food and Drug Administration

I. Purpose

This Memorandum of Understanding outlines the working arrangements between the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) regarding the approval or denial procedures for narcotic treatment programs (hereinafter referred to as treatment programs) and the cooperative efforts of both agencies in any denial or revocation of approval by FDA, or denial or revocation of registration by DEA initiated against these treatment programs. Treatment programs under this agreement include all programs that use any narcotic drug for the treatment of narcotic addiction.

II. Background.

The methadone regulation in Section 310.505 (21 CFR 291.505)* requires that prior approval by FDA be obtained before a treatment program may receive shipments of methadone. Before FDA may give such approval, it must consult with DEA to determine if the applicant is in compliance with the Controlled Substances Act of 1970 (CSA) and the Narcotic Addict Treatment Act (NATA) of 1974. Prior approval of the State authority is also required, except programs wholly operated by an agency of the U.S. Government.

* Recodified to 21 CFR 310.505.

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The NATA of 1974 amended the CSA by requiring that all treatment programs appropriately register with DEA. DEA may not register an applicant without consulting FDA in order to determine if the program meets the medical standards established by the Secretary of Health, Education, and Welfare.

Both agencies have the authority to deny or revoke approval of a treatment program independently of each other, or at the recommendation of the other agency or a State authority, for violation of laws or regulations governing the operations of such programs.

DEA and FDA will continue to work in close cooperation to prevent treatment programs from beginning operations without the required approvals of both agencies, to coordinate any denial or revocation proceedings, and to provide for the disposition of the narcotics if a program's approval or registration is revoked.

III. Substance of Agreement.

a. Each agency shall obtain prior approval of the other before a new application for a treatment program is approved by FDA or registered by DEA. Before FDA may give approval, prior approval by the appropriate State authority is necessary, except in the case of a program wholly operated by the U.S. Government.

b. The agencies shall notify each other of any denial or revocation of approval or registration of treatment programs when such action is initiated and shall keep each other informed of the outcome of such action.

c. Investigations of treatment programs by either agency that reveal suspected violations of the regulations promulgated by the other agency shall be promptly report to that agency.

d. When one agency recommends denial or revocation of approval or registration to the other, the recommending agency shall provide the other agency with all necessary reports, documents, and testimony for successful completion of the action.

e. Both agencies shall cooperate with each other in terminating illegally operating programs and in seizing or accepting surrender of the program's drug supply, as

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well as the supplies of other programs terminated for any reason.

f. FDA shall obtain DEA approval prior to approving treatment program requests for:

1. Alternate dispensing sites;
2. Alternate methods of distribution;
3. Exceptions that involve storage of methadone at locations not approved for that purpose by either FDA or DEA, e.g., jail facilities or wholesalers who only store methadone for a program;
4. Establishment of medication units.

g. FDA shall consult with DEA before approving program-wide, as opposed to individual patient, requests for additional take-home medication not provided for by the regulation.

h. The agencies shall hold periodic meetings to discuss resolution of procedural problems related to mutual enforcement activities.

i. In the forum of the Federal Methadone Treatment Policy Review Board (composed of designated representatives from the Drug Enforcement Administration, Food and Drug Administration, National Institute on Drug Abuse, and the Veterans Administration) DEA and FDA will discuss with each other, and other members of the Board, any proposed new regulations, regulation changes, or any significant interpretative modification with regard to treatment programs that will impact on the other agency.

IV. Liaison Officers.

For DEA:

Mr. Ronald W. Buzzeo
Chief
Regulatory Investigations Section
Compliance Investigation Division
1405 "I" St. N.W.
Washington, DC 20537

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingM...> 11/4/2009

MOU 225-76-3009
(202) 382-4217.

For FDA:

Mr. Buddy F. Stonecipher
Director
Div. of Methadone Monitoring (HFD-340) Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20857
(301) 443-3414.

V. Period of Agreement.

When accepted by both agencies, the agreement will have an effective period of performance from the date of signature with no expiration date. It may be modified by mutual consent of both parties or may be terminated by either party upon thirty (30) days advance written notice to the other.

At such time as the Secretary delegates authority and responsibility pursuant to the Narcotic Addict Treatment Act of 1974, this agreement will be amended to reflect any changes which may be appropriate.

Effective date. This Memorandum of Understanding became effective on May 27, 1976.

**Approved and Accepted
for the Drug Enforcement
Administration**

Signed by: Peter B. Bensinger
Administrator
Drug Enforcement Administration

Date: May 27, 1976

**Approved and Accepted
for the Food and Drug
Administration**

Signed by: A.M. Schmidt
Commissioner

Date: May 20, 1976

**Approved and Accepted
for the Food and Drug
Administration**

Signed by: Sam D. Fine
Associate Commissioner for Compliance

Date: July 2, 1976

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingM...> 11/4/2009



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

February 9, 1981

Office of the Secretary
Food and Drug Administration
Rockville, MD 20855

MEMORANDUM

TO: Acting Commissioner of Food and Drugs *MW*
 Director, National Institute on Drug Abuse
 Administrator, Drug Enforcement Administration

FROM: Joseph A. Levitt, Chairman
 Interagency Committee on Drug Control

SUBJECT: Committee Charter

Please find attached a copy of the proposed Charter for the Interagency Committee on Drug Control ("ICDC"). This Charter was unanimously endorsed by the ICDC at our February meeting, and I therefore forward it to your attention with the Committee's recommendation for your ratification.

The Charter, as drafted, continues past practice in designating the ICDC as primarily a discussion and coordination forum. The major change in the Charter is that each agency's delegation will now report directly to a surrogate appointed by each respective agency head. It is my understanding that this will be Dr. Crout for FDA, Mr. Lawrence for NIDA, and Mr. Haislip for DEA. I view this change as a very positive one which will make the ICDC more accountable for its actions as well as ensure coordination between the staff and policy-making levels of each agency regarding matters brought before the Committee.

I would ask that you reach your decision on the Charter, if at all possible, before our next ICDC meeting which is scheduled for Thursday, March 5, 1981. If you have any questions, please call me at extension x34033 (outside line 443-4033). I look forward to working closely with you and members of the three agencies on drug control matters of mutual concern.

Joseph A. Levitt
Joseph A. Levitt

cc: Dr. Crout
Mr. Lawrence
Mr. Haislip

Charter should be approved

concur *non concur*

M. Haislip

CHARTER

1-12-81

Interagency Committee on Drug Control (ICDC)

History

The Special Action Office for Drug Abuse Prevention (SAODAP) was created in 1972 to focus the resources of the Federal Government to significantly reduce the incidence of drug abuse in the United States within the shortest possible time period, and to develop a comprehensive, coordinated long-term Federal strategy to combat drug abuse. Under SAODAP direction, a committee was formed to coordinate efforts among those agencies involved in drug scheduling and control.

The Interagency Committee on Drug Control (ICDC) was formed and first met on November 15, 1973, to provide an informal forum for discussing important problem areas in drug control, under the CSA of 1970 and international conventions, that transcended the responsibilities of the individual agencies: the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA). In addition, the ICDC was needed to support the efforts of the heads of the member agencies in formulating broad policies for drug control and resolving major questions in the coordination of scheduling recommendations. In this way, it was intended that the entire drug control community would be kept abreast

of the activities of each agency's staff and advisory committees, and activities of each unit could be properly coordinated.

During its first two years, the ICDC was active in efforts to evaluate the impact of drug control regulations on drug abuse; to study the use of identifying logos on scheduled drugs; to initiate approaches toward encouraging good prescribing practices; to develop methodologies for measuring the abuse potential of drugs; to establish reasonable procedures for setting production quotas for drugs; and numerous other functions. The general working procedure for the Committee was for it to serve as a forum for coordination of each agency's response to the various issues arising in the drug control area. Members of the Committee were responsible for mobilizing the appropriate groups within each respective agency to carry out whatever work was necessary.

On June 30, 1975, the statutory authority of SAODAP expired. The NIDA Director recommended to the DEA Administrator and FDA Commissioner that although the ICDC was created to function under SAODAP direction, there was a need for an interagency forum of this type. It was additionally recommended that the chairmanship be rotated among the three agencies. Therefore, the ICDC has remained in existence functioning as a forum for discussion of drug control issues and problems, represented by the Drug Enforcement Administration, Food and Drug Administration, National Institute on

Drug Abuse and the White House Drug Abuse Policy Staff. For the remainder of 1975, each agency took turns serving as secret and chairperson. From 1976 to the summer of 1979, the ICDC was chaired by NIDA. From January 1980, the Drug Enforcement Administration chaired the ICDC.

Purpose

The Interagency Committee on Drug Control will serve as an informal forum for discussion of problem areas in drug control that transcend the boundaries of individual agency responsibilities, will help the entire drug control community to keep abreast of the activities of each agency's staffs and advisory committees, and will support the efforts of the heads of member agencies in matters relating to drug control.

The ICDC is not intended to be a substitute for specific agency responsibilities. It is not intended to alter existing statutory obligations or processes, but to facilitate the exchange and coordination of information when feasible.

Operation of ICDC

The ICDC will meet regularly and will include representation from DEA, FDA and NIDA. The chairmanship will be rotated every January among the three agencies, i.e., in 1980 by DEA, in 1981 by FDA, and in 1982 by NIDA, etc. The chairmanship and agency representatives shall be named by the Agency Head. It will be the responsibility of the presiding agency to replace a chairman if the designated chairman resigns or

retires during that agency's operating year for chairing the ICDC. It will also be the responsibility of each agency to replace its retiring or resigning representatives. At the end of the year, when the new agency takes over, the old chairman will be acting chairman until the new chairman is selected.

Three agency representatives will be named by each agency head; three alternate representatives shall be named. Meetings may also be attended by additional staff persons from the respective agencies, who may participate in the discussions. In the case of votes, only the 3 official representatives from each agency (or his or her alternate in the event an official representative is absent) may vote.

The meeting agenda will be provided and minutes kept. Agenda topics will be provided by the agencies represented. Non-government representatives will not be allowed to attend meetings, unless specifically permitted by a majority vote of the ICDC.

Function

The Committee through its individual members will report to the heads of member agencies or their delegated policy surrogates and advise them of significant developments affecting the coordination of drug control activities within the Federal Government. The Committee will in particular examine the following areas:

1. The domestic drug control process, including ways to improve interagency liaison and coordination in order to expedite control decisions.

2. Changes in the law and/or administrative procedures regarding the expeditious control of a drug when the abuse situation is critical.
3. Guidelines for control. Control is understood to mean decontrol or less restrictive control as well as tighter control.
4. The current schedules and criteria for scheduling drugs.
5. Consequences of various control decisions from the economic and legal, as well as the medical and enforcement, points of view.
6. International scheduling recommendations and resulting obligations with respect to drug control.
7. Other tasks and research studies as may properly and by mutual agreement be accepted by the Committee.

The Committee may make recommendations as to measures, including changes in organization, procedure and policy, to improve the coordination of drug control actions..



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

June 3, 2010

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on September 29, 2009, at a hearing entitled "Body Building Products and Hidden Steroids: Enforcement Barriers." We hope that this information is of assistance to the Committee.

Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald Weich".

Ronald Weich
Assistant Attorney General

Enclosure

cc: The Honorable Jeff Sessions
Ranking Member

Responses to Questions for the Record to Joseph Rannazzisi
Deputy Assistant Administrator, Office of Diversion Control
Drug Enforcement Administration
Arising from a Hearing Entitled "Body Building Products and Hidden Steroids:
Enforcement Barriers"
Before the United States Senate Committee on the Judiciary
September 29, 2009

Questions from Senator Orrin Hatch

1.) What exactly do you need from Congress in order to function more efficiently under the law? How may we help you to keep these dangerous products off the market?

ANSWER:

The Controlled Substances Act (CSA) (Title 21 United States Code) does not contain a provision that would allow the Drug Enforcement Administration (DEA) to "emergency schedule" any of these substances causing the immediate removal of these products from the market. Instead, DEA must complete the Administrative Scheduling process before a substance can be placed in schedule III and ultimately be removed from the market. Currently, chemists are able to create new and potentially harmful substances faster than DEA can identify, test and schedule these substances. Therefore, the new substances will be on the market for a period of time potentially harming the general public. Once scheduled, companies simply abandon them for the next new designer steroid. Additionally, for DEA to schedule any new designer steroid substance, it must establish that the substance is both pharmacologically and chemically similar to testosterone. The challenges in meeting these two criteria can be done, but to do so under the current scientific means is a daunting task. The challenges in meeting this two-pronged hurdle are outlined below:

Challenges to Administrative Scheduling of Anabolic Steroids

In order to pursue the scheduling of an anabolic steroid, criteria must be met as provided by the 2004 Anabolic Steroid Control Act. The two-pronged approach requires that the prohormone or designer steroid be:

- (i) Chemically similar to testosterone; and
- (ii) Pharmacologically similar to testosterone, and not an estrogen, progestin, or corticosteroid, and not DHEA,

to be considered for placement in schedule III of the CSA. The collection of pharmacological information presents challenges that greatly influence the scheduling process from identification of the potential anabolic steroid to initiating the scheduling action. General hurdles to the collection of pharmacological effects similar to testosterone are highlighted below.

- identifying synthetic and pharmacological laboratories
- contracting these services
- conducting the synthetic and pharmacological investigations

First Criterion: Chemical similarity to testosterone

Once a new prohormone or designer steroid has been identified, a structural analysis is conducted to determine similarities to testosterone and other anabolic steroids. This structural evaluation compares the chemical structure of the new steroid to testosterone and other anabolic steroids reported in the scientific literature. Based on established structure activity relationships published in the scientific literature, substitution patterns provide detail as to general class designation (androgen, estrogen, progestin, or corticosteroid) and anticipated effect.

Second Criterion: Pharmacologically similar to testosterone

Due to a lack of information in the scientific literature routinely encountered regarding these new prohormones and designer steroids, DEA is required to initiate pharmacological studies to demonstrate a pharmacological effect similar to testosterone to propose placement in schedule III. To initiate pharmacological testing, the steroid must be synthesized. This process is contracted with the stipulation that the steroid is prepared in high purity and amounts sufficient for testing. Since these evaluations may result in a scheduling action, upon completing synthesis, an independent structural analysis is conducted (by DEA) to ensure study integrity and verify DEA is testing the exact substance to be controlled.

To collect information regarding activity, both the chemical synthesis and pharmacological evaluation are contracted, requiring a bid process for both deliverables.

Chemical Synthesis

A laboratory/organization with expertise in chemical synthesis of steroids must be identified and willing to synthesize the steroid. Some of the general challenges to delivery:

1. **Identification of synthesis laboratory.** The synthetic laboratory will have prior experience in the synthesis of steroids. Many labs are not willing to take on the synthesis due to a lack of experience and/or submit impractical proposals, cost, and time estimates. We have encountered situations where we could not identify a synthetic lab to provide the necessary steroid to put into testing.
2. **Issues critical to process and conducting the chemical synthesis.**
 - a. *Number of synthetic steps to steroid.* The synthetic route required to produce the desired steroid is variable and dependent on the chemical structure of the steroid. The number of synthetic steps and the complexity of those steps vary for each steroid, because no two structures are exactly the same.
 - b. *Reputable source.* A chemical synthesis laboratory must be reputable source, *i.e.* cannot be a gray market source supplying substances to illegitimate operations.
 - c. *Purity.* In addition to preparing the steroid, it must be prepared without impurities.
3. **Steroid delivered.** Steroid of high purity with analytical data is provided.
4. **Structural verification.** Independent verification of structure is required prior to pharmacological testing for study integrity.

Pharmacological Evaluation

A laboratory/organization with expertise in conducting the testing methods required to evaluate the steroid's effects relative to testosterone must be identified. *In vitro* and *in vivo* testing may be conducted by the same laboratory or by different. The amount of time is greatly increased by contracting each assay. Some laboratories possess the capability to conduct all assays while others, particularly academic laboratories, are often limited in their capabilities and can be expected to conduct only one assay.

1. **Identification of testing laboratory.**
2. **Bid Process and testing contracted.** Multiple laboratories may be required to provide all relevant information. The laboratory must have the expertise and availability to undertake the studies.
3. **Study Conduct.** Steroid is delivered to the laboratory for testing. Multiple tests are required to completely evaluate the steroid.
 - a. *In vitro* testing (receptor studies)
 - i. Androgen receptor assay
 - ii. Estrogen receptor assay, subtypes (ER α and ER β)
 - iii. Progesterin receptor assay
 - iv. Glucocorticoid receptor assay
 - v. Translocation assay
 - b. *In vivo* testing (animal studies)
 - i. Ventral prostate assay (androgenic)
 - ii. Seminal vesicle assay (androgenic)
 - iii. Levator ani assay (anabolic)
4. **Interpretation of results.** Testosterone-like effects are evaluated based on the data.
5. **Report(s) generated.** Contract laboratory(s) are required to generate a report with testing results. These results may or may not support a scheduling action. May require further testing.

If the steroid meets the criteria for scheduling, a Notice of Proposed Rulemaking is drafted and published. Comments are reviewed and analyzed and if appropriate, a Final Rule is published notifying the public of the scheduling action.

2.) *When is the Food and Drug Administration's (FDA) responsibility and when is it the DEA's responsibility to investigate products containing designer steroids or anabolic steroids? Are most of these products truly dietary supplements?*

ANSWER:

DEA is responsible for enforcing all provisions of the CSA. The CSA currently lists 59 anabolic steroids as schedule III controlled substances. With a very small number of exemptions, anyone who manufactures, dispenses or distributes a controlled substance must be registered with the DEA to conduct such activities. Consequently, DEA has jurisdiction over the regulation and enforcement of such businesses or individuals. In addition, if a product that is marketed as a dietary supplement contains a substance that meets the statutory definition of an anabolic steroid but that substance is not yet listed as an anabolic steroid, DEA has regulatory authority to initiate rulemaking proceedings to administratively schedule the substance. Further, with respect to those substances that meet the definition of an anabolic

steroid but are not yet on the list of anabolic steroids, it is theoretically possible to obtain criminal conviction of a person who manufactures or distributes such substances. Thus, it is possible that a DEA investigation might provide the evidentiary basis for such a criminal prosecution. However, given the current provisions of the CSA relating to anabolic steroids, obtaining such a conviction can, in many cases, be extremely difficult if not impossible. While DEA defers to the FDA for a precise description of its authorities and responsibilities, it is our understanding that the following general considerations apply. The FDA has authority to investigate all aspects of products marketed as dietary supplements. As to whether or not these products are truly dietary supplements, Director Levy from the FDA described these products in the following manner, "A dietary supplement may not contain an article approved as a new drug or an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was first marketed as a dietary supplement or conventional food. If a product marketed as a dietary supplement is excluded from the dietary supplement category because it contains such an article, then a claim that the product is intended to affect the structure or function of the body causes the product to be a drug. Similarly, if a product marketed as a dietary supplement is not a dietary supplement because it contains no dietary ingredients, a claim that the product is intended to affect the structure or function of the body causes it to be a drug. Synthetic steroids are not dietary ingredients." So, many of the products that claim to be "anabolic" or that are marketed to promote muscle growth may contain "designer steroids" and are, in fact, drugs, created to circumvent the CSA and the Food, Drug and Cosmetic Act.

3.) On July 28th of this year, FDA warned consumers not to take certain body building products because they contained steroids or steroid-like substances. What was DEA's role in this investigation and announcement?

ANSWER:

Prior to the FDA's July 2009 warning regarding bodybuilding products marketed as containing steroids or steroid-like substances, DEA had identified three of the eight steroids named in the FDA warning for placement in schedule III of the CSA. A Notice of Proposed Rulemaking (NPRM), was published in the Federal Register in April 2008. In addition to naming these three steroids in the NPRM, information regarding anabolic effect collected from DEA-sponsored testing was presented as justification for placement in schedule III of the CSA. As of August 2007, 22 products had been identified containing one or more of the anabolic steroids named in the rule, boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione. A similar Internet search was conducted to update the final rule, and in August 2008, 61 products were identified as containing one or more of these anabolic steroids. These products were generally found to be marketed with slight variations in their name. The final rule published on December 4, 2009, makes these three compounds schedule III controlled substances (effective date of January 4, 2010).

4.) I understand that there are three steroids in the final stages of the scheduling process. I imagine there are others in earlier stages. How often has DEA used the simplified administrative scheduling authority granted to it by the 2004 Anabolic Steroid Control Act?

ANSWER:

DEA is involved in an ongoing effort to identify and collect scientific information on purported anabolic steroids that are introduced as new bodybuilding products for their placement in schedule III of the CSA as an anabolic steroid. Data may be obtained from the scientific literature or from DEA-sponsored testing. An anabolic effect similar to that of testosterone is used as justification for placement

in schedule III of the CSA. Unfortunately, for the majority of these new steroids, very limited scientific information exists; therefore, DEA is required to support testing to evaluate the potential anabolic activity of these new steroids. As a matter of scientific integrity, DEA will not pursue placement in schedule III without sound scientific data to support the scheduling of these new steroids.

Since the passage of the 2004 Anabolic Steroid Control Act by Congress, DEA has initiated numerous studies to collect information on anabolic activity. The final rulemaking for three steroids identified in an April 2008 NPRM was published on December 4, 2009, with an effective date of January 4, 2010. Additionally, testing was completed in July 2009 on three additional steroids purported to be anabolic and marketed in numerous products. Two of the three were found to be equally, if not more, active than testosterone in animal models. DEA will propose their placement into schedule III of the CSA. One of the steroids was found to be weakly active and DEA concluded that the overall evidence does not support scheduling at this time. Consistent with the current statutory text, if DEA determines that a particular drug or other substance does not meet the criteria for being considered pharmacologically similar to testosterone, DEA will not pursue administrative scheduling of that drug or substance.

5.) Is it currently legal to manufacture and distribute controlled substances without a DEA registration? What are the penalties associated with such a violation?

ANSWER:

With only a few exceptions, all persons or businesses that manufacture and/or distribute a controlled substance must be registered with DEA. Any person who manufactures or distributes any controlled substance in a manner not authorized by the CSA – including those who manufacture and distribute without a DEA registration – violates 21 U.S.C. 841(a)(1). Other violations of the CSA may also apply depending on the facts of the specific case. As provided in 21 U.S.C. 841(b)(1)(E), a person convicted of violating 21 U.S.C. 841(a)(1) involving an anabolic steroid shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18, or \$500,000 if the defendant is an individual or \$2,500,000 if the defendant is other than an individual, or both. The Sentencing Guidelines typically play a significant role in the actual sentence imposed. As part of the sentencing process, aggravating or mitigating circumstances may also impact the actual term of the sentence or fine.

The difficulty that DEA is experiencing is that many new designer steroids are substances that are structurally similar to testosterone, but are not yet scheduled since they are new substances. In some instances these new substances are more potent than similar anabolic steroids that are controlled. As explained above in the answer to question 2, while it is theoretically possible to prove the elements of 21 U.S.C. 841(a)(1) with respect to a drug or other substance that meets the definition of an anabolic steroid but is not currently listed as such, obtaining such a conviction is, as a practical matter, often extremely difficult if not impossible. Consequently, with respect to such not-yet-listed anabolic steroids, those unscrupulous persons who knowingly and intentionally manufacture and distribute such substances typically can circumvent the registration requirement with impunity.

6.) *The impression you convey from your testimony is that those who manufacture steroid precursors are innovating and selling products faster than your administrative procedures can keep up, thus allowing products that should be illegal to remain on the market.*

It is my understanding that some in your agency have been considering proposals to deal with this situation. I would be supportive of measures to amend the 2004 Anabolic Steroid Control Act if it can be shown that the law is too burdensome for the agency to respond quickly to marketed substances which clearly should be illegal. To assist the Committee in its consideration of such measures, it would be helpful to have your views on the following questions:

—Since 2004, how many steroid precursor products which were not listed in the law have come to the agency's attention?

ANSWER:

DEA monitors the introduction of new products, bodybuilding discussion forums, and has routine communications with other federal and non-federal agencies to identify new potential anabolic steroids. DEA maintains a list of steroids of interest which currently identifies 21 steroids. Of these 21 steroids, three have been proposed for scheduling upon sponsoring pharmacological studies to collect information regarding testosterone-like effects (NPRM published in 2008), testing has been completed on five additional steroids, and two of the five will be proposed for placement in schedule III in an administrative scheduling action. The remaining steroids will continue to be monitored, to include the scientific literature for new information pertaining to their activity. Currently, 13 steroids are being maintained on a list of steroids of interest that require additional information. DEA routinely reviews the scientific literature for new investigational reports. Independent reports in the scientific literature for identified new agents is rare, therefore, DEA is required to sponsor testing. Thirteen steroids are under review to ascertain potential anabolic activity that is not available in the scientific literature.

--Will you list each product and tell the status of its administrative scheduling?

ANSWER:

A complete list of products containing these steroids would be nearly impossible as new products regularly enter the marketplace. Products are introduced, discontinued, and reintroduced under new names. For example, products purported to contain 19-nor-4,9(10)-androstadienedione, a steroid proposed for placement in schedule III, has been found in the following products: Tren-X, Tren Xtreme, Xtreme Tren, Halo-Tren, and many more. While some of these products have been discontinued, others are still marketed, even after the FDA Warning on bodybuilding products marketed as containing steroids or steroid-like substances.

Since the passage of 2004 Anabolic Steroid Control Act, the DEA has identified and monitored the introduction of new steroids into the supplement market. DEA has evaluated eight new steroids in cellular and animal studies for pharmacological effect similar to testosterone. Three of these steroids have been proposed for placement in schedule III. DEA recently identified and tested two steroids that will be proposed for placement in schedule III. DEA will continue to collect data on the other three steroids and thirteen additional steroids may undergo testing to evaluate pharmacological activity.

The thirteen steroids are as follows:

1. 4-Chloro-17 α -methyl-1,4-androstadiene-3 β ,17 β -diol
2. 4-Chloro-17 α -methyl-andro-4-ene-3,17-diol
3. 4-Androstene-3,11,17-trione
4. 6 α -Methyl-androst-4-ene-3,17-dione

5. Androst-4-ene-3,6,17-trione
6. 2 ϵ ,3 ϵ -Epithio-17 α -methyl-5 α -androstan-17 β -ol
7. 3 β -Hydroxy-5-androstene-7,17-dione (i.e., 7-oxo-dehydroepiandrosterone and 7-oxo-DHEA)
8. 17-Hydroxy-6 α -methyl-ethyltiocholan-3,20-diol
9. 13-Ethyl-3-methoxy-gona-2,5(10)-diene-17-one
10. 4-Chloro-11-keto-17 α -methyl-androst-4-ene-17-ol-3,11-dione
11. 17 α -Methyl-androstan-3-hydroxyimine-17-ol (17 α -methyl-ctioallocholan-17 β -ol-3-hydroxyimine)
12. Androstan-3-ol-17-one
13. 17 α -Methyl-androst-1,4-diene-3,17 β -diol

On December 4, 2009, DEA published a final rule placing three steroids (boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione) into schedule III of the CSA (effective date of January 4, 2010).

--Please list the factors, in as much detail as possible; which have contributed to the length of time it has taken to list each product?

ANSWER:

The process describing the administrative scheduling of anabolic steroids as provided by the 2004 anabolic steroid control appears below. Upon controlling the steroid, the corresponding product(s) purported to contain, and those found to contain the steroid but not reported on the label, will be controlled as schedule III products. Schedule III products have the following requirements.

Step-wise detail regarding the administrative scheduling process:

- 1) Multiple sources are utilized to identify the introduction and to monitor new prohormones and designer steroids.
- 2) The chemical structure of the new steroid is compared to testosterone and other known anabolic steroids.
- 3) Scientific literature is thoroughly reviewed for pharmacological information regarding the new steroid.
- 4) Since the majority of new substances found have never undergone scientific evaluation DEA must contract the synthesis of the new steroid.
- 5) The identity and purity of the synthesized steroid is verified by a second source.
- 6) Cell-based studies (*in vitro* analysis) are contracted and conducted.
- 7) Animal studies (*in vivo* analysis) are contracted and conducted.
- 8) Data from testing methodologies is analyzed to assess pharmacological effect similar to testosterone.
- 9) If found to be chemically and pharmacologically similar to testosterone, an administrative scheduling action is initiated.
- 10) Prior to publishing a Notice of Proposed Rulemaking in the *Federal Register*, the rule must be approved by DEA and DOJ. Also, if the rule is identified as significant by the Office of Management and Budget (OMB) under Executive Order 12866, then the rule must be reviewed by OMB prior to publication.
- 11) Public comment period follows publishing of the rule.
- 12) Comment(s) are evaluated and addressed in the final rulemaking.

13) Prior to publishing a final rule in the *Federal Register*, final rulemaking requires DEA and DOJ approval. Also, if the rule is identified as significant under Executive Order 12866, then the rule must be reviewed by OMB prior to publication.

14) Publishing of final rule places substance in schedule III as an anabolic steroid.

7.) I am aware that some in DEA have discussed the possibility of amending the law to allow you to use emergency scheduling authority in order to remove from the market products which are pharmacologically and clinically similar to steroids. If your current authority does not allow such emergency action, it seems a reasonable idea to pursue.

--Why does your current emergency scheduling authority not allow removal of such products from the market?

--What is the status of the proposal on emergency scheduling for steroid similars? When might we expect to see such a proposal from you?

--Will your agency pledge to work with members of the Committee to address any concerns we may have about such a proposal?

ANSWER:

DEA's "emergency scheduling" (or "temporary scheduling") authority to which this question refers is set forth in 21 U.S.C. 811(h). The United States Supreme Court has ruled that this provision of the CSA can only be utilized to control drugs or other substances that meet the criteria for inclusion in schedule I. *Touby v. United States*, 500 U.S. 160, 167 (1991). Because Congress placed all anabolic steroids in schedule III, DEA cannot utilize 21 U.S.C. 811(h) to temporarily schedule a recently emerged anabolic steroid – regardless of the extent of the hazard to the public safety the anabolic steroid may pose. The Department of Justice and the Administration must determine what an appropriate proposal would be to address the emergency scheduling of these substances. DEA is certainly willing to work with members of Congress to address this problem and provide any technical assistance needed in formulating legislation needed to provide DEA with the appropriate authority to emergency schedule these types of products pending any administrative scheduling action.

Questions for Michael Levy, FDA, and Joseph Rannazzisi, DEA, from Senator Orrin Hatch

1.) In a February 21, 2009 FDA Consumer Health Information notice, the FDA stated that since 2004, it has identified several products that claim to be dietary supplements for treating erectile dysfunction and enhancing sexual performance.

Some of these products were found to contain the active ingredient or a substance similar to the active ingredient in Viagra or Levitra. Both Viagra and Levitra were approved by the FDA, went through the premarket drug approval process and, today, may only be sold to consumers with a doctor's prescription.

However, this did not stop unscrupulous companies from marketing these products even though they were in clear violation of the Federal Food, Drug and Cosmetic Act. Similarly, products containing anabolic steroids that are marketed as dietary supplements are adulterated and misbranded. These anabolic steroid products are also in a clear violation of the law. Therefore, requiring the premarket approval of these products will not prevent unscrupulous companies from breaking the law. In my opinion, the better solution is to strengthen the enforcement activities of the FDA and DEA. Mr. Levy and Mr. Rannazzisi do you agree?

ANSWER:

I do not agree for several reasons. First, as a general matter, the fact that certain individuals are willing to engage in blatant violations of a law that is designed to protect the public health and safety does not mean that the law itself should not be modified. To the contrary, such a situation might point to the need to impose additional requirements under the law and/or stricter penalties for those who violate the law. Second, the “designer steroids” encountered on the market today are quite different than the Viagra or Levitra products described above. As I described in my testimony, unscrupulous marketers use existing laws to their advantage. They exploit the requirements under the FDCA to create and sell products that contain drugs similar to testosterone. These are new drugs that, in all likelihood, have never been adequately tested. Some of these new designer steroids are several times more potent than a steroid that is already controlled under the CSA. Products that contain new untested designer steroids have harmed and continue to harm the American public.

There are, however, similarities between the Viagra / Levitra products and the designer steroid products. As you stated above, despite the fact that unscrupulous companies are in “clear violation”, they did not stop marketing these products. Why? In some instances the “companies” that produced and sold the counterfeit Viagra / Levitra products resided outside the United States compounding enforcement efforts. Domestically, however, the answer is quite simple: the risk reward ratio. Under the current legal framework dishonest companies can reap enormous profits from the sale of these products with little or no risk. Even when law enforcement brings to bear all of the existing legal resources, these companies simply stop manufacturing the questionable product, reformulate and market another product. When prosecutions or civil penalties are sought, the outcome is generally minor in comparison to the profits generated from the sale of these dangerous products.

For law enforcement to make a difference it must be able to respond quickly to these newly developed products. When appropriate, DEA must have the ability to immediately restrict the sales of these products or remove them from the marketplace pending any administrative scheduling action. Otherwise these companies will be able to continue operating unabated, always staying one step ahead of any law enforcement action.

2.) In his testimony, Mr. Tygart talks about a product called Superdrol. I have done a little research on this product and am having trouble understanding why it wouldn't be taken off the market through the laws currently on the books? The advertisements I have seen make muscle-building claims and tout it as an anabolic steroid.

ANSWER:

The decision to remove a drug from the marketplace for violation of the FDCA can only be made by the Food and Drug Administration. The DEA does not have any legal authority to remove a dietary supplement from the market for violations of the FDCA.

3.) As I reviewed the testimony of both the DEA and the FDA, both agencies argued that it takes a great deal of time to build a case against a product in order to take it off the market. In other words, the way I interpreted your statements – you are both saying that you cannot just pull a product off the market. But isn't it true that for the vast majority, if not all of these products, they would require an NDI (new dietary

ingredient) notification to FDA? If they are marketing as supplement and haven't filed, FDA can take the product off the market because it is misbranded. If the company has filed an NDI, the FDA may still reject it, as the agency has in over half of all NDI notifications.

ANSWER:

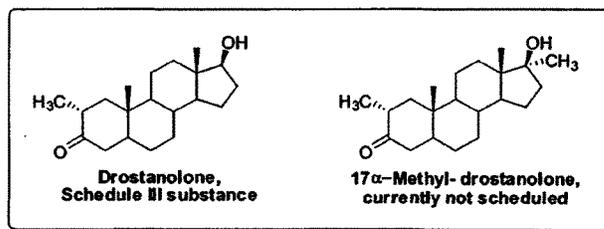
DEA has no authority to remove a product from the market because it contains an NDI. DEA is authorized by the CSA to take action against manufacturers of products that illegally contain controlled substances or that are structurally and pharmacologically similar to testosterone. If a substance, based upon scientific evidence, is found to be structurally and pharmacologically related to testosterone, DEA can utilize its administrative scheduling authority to place the drug in schedule III. However, since these substances are generally introduced into the marketplace with little, if any, scientific data, DEA must sponsor testing to determine pharmacologic similarities.

Questions from Senator Specter

1. Please provide the scheduling status of the anabolic steroid substance contained in the dietary supplement Superdrol and explain why DEA has not scheduled it as a controlled substance on Schedule III.

ANSWER:

The structure of 17 α -methyl-drostanolone (active ingredient in Superdrol) is almost identical to the anabolic steroid drostanolone which is named under the CSA. The two substances differ by the addition of a methyl group to drostanolone to give 17 α -methyl-drostanolone (figure below). This modification demonstrates the ingenuity of the chemist intent on circumventing the laws and these occurrences are routine. There are similar examples in the literature where slight structural modifications to anabolic steroids actually enhance the anabolic effect while others decrease it. Typically at the time of producing this potentially new anabolic agent, the chemist is only speculating as to the effect. In comes the unsuspecting user who becomes the guinea pig, providing data on the safety and efficacy of the new substance.



Due to a lack of scientific information related to 17 α -methyl-drostanolone, DEA initiated and sponsored scientific testing to collect pharmacologic data on this steroid. Studies were completed in July 2009 and the steroid was found to be as much as 4-fold more active than testosterone in animal studies.

With studies recently completed, DEA will initiate the administrative scheduling process for this substance. However, as your question suggests, the product Superdrol provides another illustration of the time-consuming hurdles that DEA faces under current law in attempting to schedule a recently emerged designer steroid – and how the unscrupulous individuals who develop and market these products are able to exploit this situation.

2. Please clarify what if any involvement DEA had with regard to the federal search warrant issued in the Bodybuilding .com investigation.

ANSWER:

For clarity, the federal search warrant discussed by Senator Specter during the hearing was not part of a DEA investigation. Nor was a DEA Special Agent the affiant with respect to the search warrant. Instead, this search warrant affidavit was part of a Food and Drug Administration investigation with an FDA Special Agent as the affiant. DEA defers to the FDA for any additional information regarding its investigation or specifics relative to the circumstances surrounding the issuance of the search warrant.

3. You testified DEA has not yet scheduled any new anabolic steroids since the passage of the Anabolic Steroid Control Act of 2004 but that it is close to completing the process to schedule three new anabolic steroids. Please identify those three products and describe how the scheduling process works for these and other similar type substances.

ANSWER:

DEA published a final rule in the Federal Register on December 4, 2009, placing boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione in schedule III of the CSA (effective date of January 4, 2010). (A list of steps has been included as supplemental information to highlight the administrative scheduling process). Upon identification, DEA searched the scientific literature for pharmacologic data related to anabolic effect. Since no literature was found DEA was required to initiate scientific and pharmacological testing to support an administrative scheduling action.

The general steps to control a new steroid are detailed below:

- 1) Multiple sources are utilized to identify and monitor the introduction of new steroids.
- 2) The chemical structure of the new steroid is compared to testosterone and other known anabolic steroids
- 3) Scientific literature is thoroughly reviewed for pharmacological information regarding the new steroid.
- 4) The steroid must be synthesized. DEA must identify a contractor to synthesize the substance. The new steroid must be synthesized with high purity to ensure only the target steroid is being evaluated.
- 5) The identity and the purity of the synthesized steroid is verified by a second source
- 6) Cell-based studies are contracted and conducted
- 7) Animal studies are contracted and conducted
- 8) Both testing paradigms are essential to assessing pharmacological effect similar to testosterone.
- 9) If chemically and pharmacologically similar to testosterone, an administrative scheduling action is initiated.
- 10) Prior to publishing Notice of Proposed Rulemaking in Federal Register, the rule must be approved by DEA, DOJ, and OMB.
- 11) Comment period follows publishing of the rule.
- 12) Comment(s) are evaluated. Proceed with Final Rulemaking as determined from comment(s).

13) Final Rulemaking requires DEA, DOJ, and OMB approval prior to publishing in Federal Register.

4. *As was done in 2004, should Congress immediately amend Section 102 of the Controlled Substances Act to schedule those three new anabolic steroids referenced in question 3 above?*

ANSWER:

While DEA appreciates Congress's concern over these three substances, they were placed into schedule III of the CSA pursuant to the publication of the final rule which was made on December 4, 2009. Though DEA used its administrative scheduling authority to schedule these three substances, there are many more similar substances on the market. It has been DEA's experience that creative chemists simply modify the chemical structure of a substance and DEA must start the process all over. Even under ideal conditions, this process can typically take at least 18-24 months. More typically, the process takes far longer to complete. DEA willingly accepts its role in the rulemaking process and will continue to work to protect the public health and safety within the authority provided to DEA by Congress. At the same time, it is beyond question that when Congress deems it appropriate to legislatively add a substance to the list of anabolic steroids, there is no faster way to achieve the same result. Nonetheless, DEA believes that a complete solution to the problem requires more than merely chasing after each and every new designer steroid; a successful long-term solution would be more all-encompassing.

Questions for Travis Tygard CEO of the U.S. Anti-Doping Agency (USADA) from Senator Orrin Hatch

1.) How do athletes determine whether or not the product that they have been taking is "spiked?" Do they contact the manufacturer? Do they report to the proper authorities? And how is it proven that the product taken is "spiked?" Are the findings of the lab test provided to the manufacturer of the product? Is the bottle given to an independent body in order to be tested? USADA provides athletes under its prevue, a list of acceptable substances that they may ingest. If an athlete has a question about a particular substance, they can either call the USADA 24 hour hotline or visit the Global Drug Reference Online (Global DRO) to discover if that substance is banned. The Global DRO is reflective of what is found on the World Anti-Doping Agency prohibited list, but the Global DRO is reflective of particular pharmaceutical products to be used by Canadian, United Kingdom, and U.S. athletes. USADA does not encourage an athlete to take any product and especially those that have not been tested by an accredited lab.

In the case of Kicker Vencill, the U.S. swimmer, who received a ban for a positive test that was later attributed to a contaminated multi-vitamin; the athlete did not determine the product was "spiked" until after that positive test.

2.) Given that the industry is predominately small business and doesn't have the revenue the sporting leagues enjoy, has USADA or an allied group of the sporting organizations reached out to industry in a formal capacity to fund initiatives to help distinguish the reputable industry for their athletes so there isn't an issue of contaminated products? USADA has worked with the sports leagues to determine the best course of action to ridding the dietary supplement industry of intentional "bad actors" and securing a safe environment for those athletes who chose to use dietary supplements. USADA is of the understanding that the industry enjoys revenues in the tens of billions of dollars annually and the dietary supplement industry aimed at supplying products to athletes is upwards of \$6 billion per year. USADA feels that collaboration and cooperation between sports leagues, the dietary supplement industry, and USADA can be achieved so that the safest environment exists for healthy marketplace.

3.) I am impressed by your work in this area and the concrete recommendations you made to the Committee. In my experience, it is rare for a witness to provide us with such a level of detail.

There is no question that anabolic steroid use and the use of steroid precursors continue to be a problem, and I do agree it behooves Congress, the Executive Branch, and other interested parties such as USADA, sports leagues, and school officials to collaborate on ways to address the problem. One thing that occurred to me during your testimony, and which I would like to explore now, is the role of personal responsibility on the part of athletes, especially professional athletes who are such important role models for students. This did not seem to be addressed in large part by your testimony.

--Do you believe that a heightened role could be played by your organization, and/or by professional sports leagues, in encouraging a greater measure of personal responsibility on the

part of athletes? USADA cannot comment on the role of professional athletes in educating the public on performance enhancing drugs, but USADA does encourage athletes within its testing pool to become ambassadors of clean and fair sport. USADA spends a good deal of its annual budget on education and marketing to youth about the dangers of untested supplements that are sold either over-the-counter or on the internet. Many of the athletes that participate in the Olympic movement are highlighted in these materials.

--If you believe so, what are your suggestions in this area? USADA feels that its education and marketing materials go a long way to providing a safer environment for youth in the United States, however, with greater resources we feel we can make a larger impact. USADA would enjoy a collaborative campaign with professional sports leagues, industry, and Congress to make this happen. Every classroom in the U.S. could benefit from materials that teach youth the importance of competing fair and clean.

--For example, should professional athletes who test positive for banned substances be required to turn over the product(s) he or she used for that product to be tested in an analytic lab? USADA certainly benefits from the sharing of information between testing and adjudicating bodies involved with drug collection and analysis. USADA currently works with the NFL on a lab in Utah for research, testing, and analysis. USADA is constantly using its resources to track down tainted substances that could be used for performance enhancement and has worked with and continues to work with several Federal bodies with jurisdiction over the sale and distribution of banned substances and those that may contain performance enhancing drugs. USADA would encourage all sports leagues to share information between each other and with USADA.

--Should the leagues have tighter policies against use of these products, or higher penalties for their use? USADA believes that the only way to run a successful drug testing program is to follow the World Anti-Doping Agency Code, which we believe to be the "gold standard" in drug testing. USADA believe that a tough drug testing code is not only beneficial for the identification of cheaters, but also works as a deterrence.

--Could you place any estimates on the amount of intentional "doping" that may be occurring? What can we do to encourage a change in thinking so that athletes, and young athletes do not seek out products as Jareem did when he thought he had found "a diamond in the rough" – in other words, a legal product which has the effect of illegal ones? It's difficult to give exact numbers of youth who intentionally "dope", but USADA has seen evidence through research done that the issue is not only an athlete issue, but a vanity and self-esteem issue. As mentioned above, USADA has gone a long way to developing an education campaign that focuses on the values of competing clean and healthy, but there will be those youth that are attracted by the marketing done by the manufacturers of products who intentionally give the impression that they are selling legal substances in what should be a reliable marketplace. Jareem purchased a product in a legal manner that contained a substance that was illegal and almost lost his life because of that. The people who have the ability to regulate the system that manipulated Jareem's trust need to help secure the wishes of those that want to exercise their ability to consume safe and legal substances.

SUBMISSIONS FOR THE RECORD

Natural Products Association
Testimony to the
Senate Judiciary Committee
on
"Body Building Products and Hidden Steroids: Enforcement Barriers"

Witness appearing before the
Senate Subcommittee on Crime and Drugs

Daniel Fabricant, Ph.D.,
Interim Executive Director & CEO
Natural Products Association

September 29, 2009

Mr. Chairman and Members of the Committee;

Thank you for the opportunity to be with you today. I am Dr. Daniel Fabricant, interim executive director and CEO of the Natural Products Association (NPA). NPA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 10,000 retailers, manufacturers, suppliers and distributors of health foods, dietary supplements, natural personal care and the millions of Americans who use supplements each year. I am also a former college athlete and a sports nutrition expert, so I have a deep personal understanding of this issue.

First, let me say that we welcome this hearing because we share your concerns about illegal steroids. Selling products containing illegal substances is a crime. Whenever a product containing illegal substances is identified – be they steroids or something else – we are the first to call for throwing the book at the offending party. Anyone caught selling steroids should be prosecuted to the full extent of the law, and the natural products industry has worked for years to pass those laws.

Unfortunately, our industry is being victimized by a guerilla-style criminal drug-peddling operation. And we believe that tougher enforcement and prosecution to the full of the law are the best ways to stop the criminals. The barriers to enforcement are simple: money, manpower and will.

We fully support a strong regulatory and legislative regime to ensure that what's on the label is what's in the bottle -- the criminals who sell steroids illegally don't.

We fought for stronger Drug Enforcement Agency rules, especially the passage of the Anabolic Steroid Control Act of 2004. This law gave DEA additional authority, made it easier to schedule chemicals as anabolic steroids, and increased penalties and fines for criminal activity. We have also worked for Good Manufacturing Practice regulations, Serious Adverse Event Reporting laws, and the New Dietary Ingredient Notification pre-market approval process, and other important provisions of the Federal Food Drug and Cosmetic Act. We also strongly support the Federal Trade Commission enforcement activities against false labeling and deceptive advertising.

We're not surprised that criminals defy these laws -- that's what criminals do. We're not surprised if criminals ignore current legal requirements to notify the government of their intent to sell illegal substances. So again, we urge you to get tough on the criminals.

That is why our industry has fought repeatedly for Congress and the Administration to provide the Drug Enforcement Agency, the Food and Drug Administration, the Federal Trade Commission and other government agencies the resources they need to enforce the law. For many years, quite frankly, those resources were lacking. Within the past 12 months, however, Congress has provided a significant infusion of funding which has led to a noticeable increase in enforcement.

We welcome this increased government enforcement and support efforts to boost resources further -- the criminals who sell steroids illegally don't.

There are additional enforcement measures under current law that are available and could be used. For instance, the FDA sent 28 warning letters to firms that were illegally marketing products containing steroids. Warning letters are a good start, but how many of those were followed by court action, which is well within the authority of the FDA to pursue? Likewise, to our knowledge, the DEA has only proposed the listing of three additional compounds under the Anabolic Steroid Control Act of 2004 -- just three compounds in five years. These limited enforcement activities are not an effective deterrent and make it far too easy for criminals to stay one step ahead of the law.

Finally, it is in our best interest to continue to earn the public's trust, and anything we can do to separate the legal, safe and healthy dietary supplement industry from the seedy, fly-by-night, and unsafe world of illegal steroids is worthwhile.

Indeed, when any athlete suggests an off-the-shelf dietary supplement was the cause for a banned substance being found in their bodies, our industry asks them to name the supplement, name the manufacturer, and name the store where they bought it. We asked the same questions of Donald Fehr, who essentially blamed the entire steroid scandal in Major League Baseball on legal dietary supplements. Clearly, we all have more questions than answers

So Mr. Chairman, we are glad you're having this hearing. We support efforts to stop the sale of illegal steroids. We strongly support resources for government agencies to enforce the law.

We stand ready to work with the Committee, the government, non-governmental organizations, and supporting agencies to help identify and remove criminal activity, which is the root cause of this tragedy, from the system.

Thank you, and I look forward to your questions.

Subcommittee Hearing on Body Building Products and Hidden Steroids: Enforcement Barriers
Statement of Senator Grassley

Mr. Chairman. I remain very concerned about the continuing prevalence of performance-enhancing drugs in sports. The ongoing reports of the use of performance-enhancing drugs/supplements in the professional sporting world, illustrate the presence of a disturbing culture throughout all sports. It is becoming all too common to read not only about professional athletes getting caught using performance-enhancing drugs, but also college and high school athletes turning to these substances to gain a competitive edge. Although much progress was made when Congress passed the Anabolic Steroid Control Act in 2004, we cannot relent in our efforts to keep performance-enhancing drugs out of our society and away from our children.

Congress passed the Anabolic Steroid Control Act to make it easier for the Drug Enforcement Administration (DEA) to control performance-enhancing substances. Before passage of this law, several potentially harmful performance-enhancing substances were being marketed to younger athletes. One of the more famous examples of this occurred when Major League Baseball slugger Mark McGuire credited his use of the now-banned supplement, Andro, for his increased performance. Currently, new products are emerging and being marketed as alternatives to illegal steroids, by underground operations, in an effort to stay ahead of the law.

The dietary supplement, Dehydroepiandrosterone (DHEA), is one example of how a supplement is being promoted as a performance-enhancing substance. According to the World Anti-Doping Agency, DHEA is a pre-cursor hormone to androstenedione and testosterone. These substances became illegal anabolic steroids as a result of the Anabolic Steroid Control Act of 2004. Although the use of DHEA is banned by most professional sports leagues and the NCAA, DHEA is still being marketed online to younger athletes. One bodybuilding website, directed towards teenagers, features a teen bodybuilder of the week to promote performance-enhancing supplements. A 19 year old Junior National Champion bodybuilder is one of the bodybuilders on this website. When asked what supplement gave him the greatest gains for his competition this teenager replied, "DHEA." In another website, DHEA is advertized as follows, "If you're a bodybuilder, and want to increase lean body mass at the expense of body fat, actual studies show this supplement may significantly alter body composition, favoring lean mass accrual." Another example on another website describes DHEA in this way, "DHEA is HOT, and you will see why. As a pre-cursor hormone, it leads to the production of other hormones. When this compound is supplemented, it has shown to have awesome effects." These advertisements are geared to the younger crowd, even though DHEA has no legitimate use for teenagers.

These DHEA advertisements, and others like it, are having some impact on young athletes, especially in my state of Iowa. The Iowa Orthopaedic Journal published a study on nutritional supplement use in 20 Northwest Iowa high schools. In this study, 495 male football players and 407 female volleyball players were asked if they used nutritional supplements. The results of this anonymous survey revealed that 8% of football players and 2% of Volleyball players used supplements. These students identified DHEA as one of the supplements that they used. The students were then asked to give the reason why they used DHEA and the general response was "for performance enhancement."

Although the body naturally produces DHEA, the natural production of the hormone ceases around the age of 35. Many people over this age use DHEA, in low doses, as part of an "anti-aging" regimen. However, when taken in high doses over time, DHEA, like its other relatives in the steroid family, may cause liver damage and cancer. In fact, one study conducted by scientists at Oxford University revealed DHEA use to be strongly associated with breast cancer development. The truth is there are few studies about the long term effects DHEA has on the body. According to Dr. F. Clark Holmes, Director of Sports Medicine at Georgetown University, many proposed studies involving high doses of DHEA are denied approval out of concern that the product may cause irreversible harm to human subjects.

The Anabolic Steroid Control Act gives the DEA the authority to schedule any hormone or drug that is "chemically or pharmacologically related to testosterone." However, the DEA cannot schedule DHEA because it fails to meet the criteria for scheduling. Because DHEA is not an "immediate precursor" to testosterone, but only a precursor to a precursor, it cannot be administratively scheduled. As a result, I have introduced legislation in this Congress and previous Congresses to ban the sale of DHEA to minors. This legislation does not address all the concerns with performance-enhancing drug use, but it will help keep a potentially harmful substance away from our kids.

Other supplements that do fall under the criteria for scheduling are subject to a highly time consuming process. These products remain available online and on the shelves of nutritional stores, even though consumers may not be aware that these products could soon be banned and may be potentially harmful. A simple internet search for "legal steroids" yields many results. One such website even encourages shoppers to buy their products soon before the government bans them.

I am not against the use of dietary supplements. I believe many dietary supplements can be beneficial to the health and well-being for many people. However, we must guard against those who artificially disguise performance-enhancing drugs as safe and legitimate supplements. In the highly competitive world of sports, the pressure to use performance-enhancing drugs can be overwhelming. Even though we, as a society, demand excellence from our favorite teams and athletes, we cannot accept this excellence to be falsely aided by a drug. Furthermore, we cannot allow harmful drugs to destroy the health of so many young and promising athletes. We have to continue to curb the use of performance-enhancing drugs for the health of our country and children.

I look forward to hearing all your views as to how these issues should be addressed.

Testimony of

Richard Kingham
Covington & Burling LLP

before the
Subcommittee on Crime and Drugs
of the
Senate Judiciary Committee

at a
Hearing on Body Building Products and Hidden Steroids: Enforcement Barriers
September 29, 2009

My name is Richard Kingham. I am a partner in the law firm of Covington & Burling LLP. Since joining the firm in 1973, I have concentrated on regulation of foods, drugs, and related products, including controlled substances and dietary supplements. I have taught food and drug law at the University of Virginia School of Law, the Georgetown University Law Center, and universities in the United Kingdom and have served on committees of the Institute of Medicine of the National Academy of Sciences, the National Institutes of Health, and the World Health Organization.

Manufacturers of legitimate dietary supplements share the concerns of Congress and the public with the distribution of body-building products that contain anabolic steroids. The adverse effects of those products are well known, and these substances should not be available for general use. It is important to recognize, however, that the vast majority of dietary supplements are in no way implicated. More than 150 million Americans regularly use legitimate dietary supplements, and those products offer significant health benefits to the people who use them.

There is, moreover, no need to amend existing legislation to deal with anabolic steroids. The Food and Drug Administration and the Drug Enforcement Administration both have ample authority to deal with the problem by making use of existing statutory powers.

Congress has twice amended the Controlled Substances Act to give DEA special power to regulate anabolic steroids. The most recent amendments, enacted in 2004, greatly expanded the list of substances subject to regulation under the statute, including metabolic precursors and salts, esters, and ethers of listed substances. Congress also authorized DEA to add new substances to the relevant schedule without proof of anabolic effect, thus simplifying the burden for administrative scheduling actions. Persons who traffic illegally in scheduled anabolic steroids are liable to severe criminal penalties and other enforcement measures under the Controlled Substances Act.

FDA also has broad powers to prevent distribution of products containing anabolic steroids under existing provisions of the Federal Food, Drug, and Cosmetic Act

(FDCA). Although many of the products currently promoted on the Internet are labeled as “dietary supplements,” they are seldom, if ever, in compliance with the dietary supplement provisions of the law. FDA has multiple enforcement tools at its disposal to deal with those products, including provisions under the FDCA relating both to drugs and dietary supplements. Many products, for example, are advertised with claims that fall within the “new drug” provisions of the FDCA, and are for this reason both misbranded and in violation of statutory provisions that require premarket approval of new drugs. Others contain “new dietary ingredients” for which required premarket notifications have not been made to FDA under the dietary supplement provisions of the FDCA. Those products are legally deemed adulterated and are liable to the full range of enforcement measures under the statute, including seizures, injunctions, and criminal prosecution of responsible persons.

The provisions of the FDCA governing premarket submissions for new drugs and new dietary ingredients do not require FDA to prove that a product is unsafe, but only that the required premarket procedures have not been followed. Thus, the burden of proof on the government is minimal, and experience suggests that courts are willing to interpret the provisions of the FDCA liberally to protect the public against unlawful products. For this reason, a warning from FDA, backed up with a credible threat to take formal enforcement action, is usually sufficient to achieve compliance. FDA has in fact issued a number of warning letters to companies that distribute products containing anabolic steroids, and it has the capacity to issue more warning letters and to take formal enforcement actions as needed to protect consumers against these products.

The FDCA also effectively addresses the problem of “designer drugs” that are formulated to circumvent the scheduling provisions of the Controlled Substances Act. Anabolic steroids that are not listed in the relevant schedule will typically be “new” within the meaning of the provisions of the FDCA that require prior approval of new drug applications or submission of new dietary ingredient notifications.

In addition, recent reports suggest that some of the products currently offered on body-building websites are not actually labeled as containing anabolic steroids, even though such substances are detected in laboratory assays. Those ingredients may in fact be surreptitiously added during the manufacturing process of ordinary, otherwise lawful dietary supplements. Such practices are clearly illegal under the FDCA, which prohibits the addition of deleterious substances, imposes requirements for good manufacturing practice that include detailed controls of the ingredients in dietary supplements, and requires label disclosure of ingredients. Quite simply, what’s in the bottle must be on the label of a dietary supplement. As with the provisions of the law relating to new drugs and new dietary ingredients, these provisions can be enforced using the full range of sanctions under the FDCA, including seizures, injunctions, and criminal prosecutions.

For these reasons, there is no need to amend existing law to deal with the problem presented by anabolic steroids. FDA and DEA have ample authority under current law.

New statutory requirements for legitimate products could greatly increase the expense of bringing new dietary supplement products to consumers and impose unnecessary

administrative burdens on FDA. Body-building products constitute less than 10 percent of the market for dietary supplements in the United States, and the products that are the subject of this hearing are a tiny fraction of that market segment. It would be a mistake to alter the carefully crafted regulatory framework for all dietary supplements simply to deal with a small number of outlier products that can be effectively controlled under existing statutory provisions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

**STATEMENT OF
MICHAEL LEVY, ESQ.
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COMPLIANCE
OFFICE OF COMPLIANCE
CENTER FOR DRUG EVALUATION AND RESEARCH
U.S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON CRIME AND DRUGS
HEARING ON
"BODY BUILDING PRODUCTS AND HIDDEN STEROIDS:
ENFORCEMENT BARRIERS"
SEPTEMBER 29, 2009
RELEASE ONLY UPON DELIVERY**

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Michael Levy, Esq., Director of the Division of New Drugs and Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA or the Agency), which is a part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss FDA's perspective on the issue of steroids in products marketed as dietary supplements.

FDA is very concerned with products containing synthetic steroid ingredients that are marketed as dietary supplements. There is no requirement for the manufacturer of a dietary supplement to provide FDA with evidence of the product's effectiveness, and the manufacturer also need not provide FDA with evidence of product safety prior to marketing, unless the product contains a "new dietary ingredient" that has not been part of the food supply. By labeling steroid products as dietary supplements, unscrupulous firms can easily introduce into the marketplace products that contain ingredients that may pose risks to health. In some cases, the marketing of a steroid product as a dietary supplement is fraudulent because the product is actually an unapproved drug or an adulterated dietary supplement. Marketing a steroid product as a "dietary supplement" conveys to the consumer a false sense of safety and legitimacy for these potentially harmful products.

FDA has taken action to protect the public from illegal steroids in dietary supplements. In July 2009, for example, FDA issued a public health advisory warning consumers to stop using any body-building products that are represented to contain steroids or steroid-like substances. The public health advisory was issued in response to a cluster of serious adverse event reports

submitted to FDA associated with several products containing synthetic steroids and marketed as dietary supplements. Adverse events included serious liver injury, stroke, kidney failure, and pulmonary embolism (artery blockage in the lung). Although the body-building products containing these synthetic steroids were marketed as dietary supplements, they were not dietary supplements. Rather, they were unapproved and misbranded drugs that had not been reviewed by FDA for safety and effectiveness.

In the past five years, FDA has sent 28 Warning Letters to firms that were illegally marketing products containing steroids. These products were either unapproved new drugs or adulterated dietary supplements. Currently, FDA's civil and criminal enforcement offices are gathering and reviewing additional data about other products that are marketed for body building and that claim to contain steroids or steroid-like substances.

Despite these actions, FDA's ability to solve this problem is limited. Because FDA generally does not receive information on these products prior to marketing, FDA generally cannot identify violative products before they enter the marketplace. After products enter the market, we must undertake a painstaking investigative and analytical process to show that they are violative. Currently, the Agency struggles to provide effective civil and criminal deterrents to prevent unscrupulous firms from fraudulently marketing these products, and we are unable to effectively prevent the importation of many violative products. These gaps make it very challenging to interrupt the sale of these dangerous products.

STEROID PRODUCTS MARKETED AS DIETARY SUPPLEMENTS

As background, I would like to describe the substances addressed in this testimony. Chemically, steroids are a family of lipid molecules that include a large variety of substances

such as cholesterol, steroid hormones, bile salts, and many other substances. They occur not only in animals, but also in insects, plants, bacteria, and fungi. Many steroids occur naturally in foods or are used as food ingredients and present no significant regulatory issues. For example, phytosterols occur naturally in some foods, have a beneficial effect on heart health, and can legitimately be used as ingredients in dietary supplements and other foods. However, during this hearing, when I use the term "steroid," I am referring to the subgroup of steroids that have anabolic and/or androgenic effects in humans. This subgroup includes synthetic steroids. Body-building products marketed as dietary supplements are commonly found to contain these types of steroids.

The Dietary Supplement Health and Education Act (DSHEA) defines the term "dietary supplement" as a product that, among other things, is not represented for use as a conventional food or sole item in a meal or diet; is intended to supplement the diet; and contains at least one or more dietary ingredients. A "dietary ingredient" is defined as a vitamin, a mineral, an amino acid, a herb or other botanical, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients (section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Dietary supplements must be intended for ingestion and may be found in many forms such as tablets, capsules, powder, liquids, softgels, or gencaps.

A dietary supplement may not contain an article approved as a new drug or an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was first marketed as a dietary supplement or conventional food. If a product marketed as a dietary supplement is excluded from the

dietary supplement category because it contains such an article, then a claim that the product is intended to affect the structure or function of the body causes the product to be a drug. Similarly, if a product marketed as a dietary supplement is not a dietary supplement because it contains no dietary ingredients, a claim that the product is intended to affect the structure or function of the body causes it to be a drug. Synthetic steroids are not dietary ingredients.

Claims that a steroid ingredient increases muscle mass or strength cause the product containing the steroid to be a drug. Some such products are specifically promoted to athletes to improve sports performance and to aid in recovery from training and competition. Many times they are marketed with claims that they are similar to an anabolic steroid listed in Schedule III under the Controlled Substances Act (CSA). The products can be found on the Internet, in gyms, and in retail stores. They are generally marketed with claims about the ability of the active ingredients to enhance or diminish androgen, estrogen, or progestin-like effects in the body.

Two recent examples of these synthetic steroid products are TREN Xtreme and MASS Xtreme, marketed as dietary supplements by American Cellular Labs, Inc. (ACL). These products were the subject of a recent FDA Warning Letter and search warrant. These two products included the ingredients 19-Norandrosta-4,9-diene-3,17 diene and 17 α -methyl-*etioallocholan-2-ene-17b-ol*, which are the subject of a proposed rule published in the *Federal Register*, proposing to list these ingredients as Schedule III controlled substances. TREN Xtreme was marketed with claims that it was “[s]imilar to Trenbolone” and that it “binds to the androgen receptor 300% better than testosterone.” MASS Xtreme was marketed with claims that it was “[s]imilar to Methyl Testosterone,” “a potent anabolic,” and

had "low androgenic activity." The firm also included misleading safety claims that the products were free from a number of dangerous side effects.

Safety Concerns

Adverse Event Reports. At the time that FDA issued the Warning Letter to ACL, FDA's MedWatch system contained 15 adverse event reports associated with body-building products. On further investigation, FDA determined that 13 of these 15 reports involved products that appeared to contain steroids and were marketed as dietary supplements. The product manufacturers identified in the MedWatch reports included ACL, which was cited in five MedWatch reports. For body-building products that were labeled as containing steroids or steroid-like substances, adverse events involved men (ages 22-55) and included cases of serious liver injury, stroke, kidney failure, and pulmonary embolism. All but one of the reports cited a temporal association with the use of the product(s) days or weeks prior to onset of the adverse event(s). As an example, one report involved a 37-year-old male patient with jaundice, fatigue, weight loss, nausea and vomiting after taking a 3-4 week course of TREN Xtreme, a synthetic progestin-containing product, and MASS Xtreme Size Promoter, a synthetic androgen-containing product. This patient was admitted to the hospital and subsequently diagnosed with renal failure and acute cholestatic liver injury. While it is difficult to establish a direct causal link between these synthetic steroid products and injury, there is at least a temporal association between the use of some of these body-building products and the development of acute liver injury.

FDA believes it is likely that adverse events for these products have been underreported. This may be because adverse events can occur many years after use of a product; because people who use such products may want to conceal their use; because resulting adverse

effects may be considered sensitive or embarrassing; and/or because people may not readily associate adverse events with this type of product.

Public Health Advisory. The July 2009 Public Health Advisory (PHA) was issued in response to the cluster of reports FDA received about serious adverse events associated with several products containing synthetic steroids and marketed as dietary supplements. Due to the potential serious health risks, FDA recommended that consumers immediately stop using body-building products marketed as containing steroids or steroid-like substances and report any adverse events associated with them to FDA. In addition, FDA suggested that consumers consult their health care professionals if they experience symptoms possibly associated with these products, particularly nausea, weakness or fatigue, fever, abdominal pain, chest pain, shortness of breath, yellowing of the skin or whites of the eyes, or brown/discolored urine.

Adverse Effects of Anabolic Steroid Use. Acute liver injury is known to be a possible harmful effect of using anabolic steroid-containing products. Anabolic steroids may also cause other serious long-term health consequences in men, women, and children. These include shrinkage of the testes and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and increased risk of heart attack and stroke. Anabolic steroid use can also induce psychological effects such as aggression, increased feelings of hostility, psychological dependence, and addiction. Upon abrupt termination of long-term anabolic steroid use, users may experience withdrawal symptoms, including severe depression.

FDA Enforcement and Challenges

In general, products that are marketed as dietary supplements but that contain active ingredients in FDA-approved drugs, analogs of approved drugs, and other compounds that do not qualify as dietary ingredients, present an emerging and expanding challenge. Specifically, body-building products that contain synthetic steroids or steroid-like substances, and are marketed as dietary supplements, continue to be a challenging area for FDA. In addition to the Agency's concerns that many of these products have not been clinically studied or demonstrated to be safe, the products are often sold with misleading labeling and are frequently manufactured without quality controls.

Enforcement Authority. At the core of FDA's dietary supplement enforcement efforts is the Agency's commitment to protect the public health by removing unsafe products from the market. The marketing of unsafe or otherwise violative products as dietary supplements places FDA in a position where it must identify the products and the firms that market them after the products have already been introduced into the marketplace. FDA scours online and retail marketplaces in search of illegal supplement products, conducts scientific and legal analyses of the ingredients, discovers the manufacturers' locations, and, when appropriate, takes action. Because of the complexity of this process, it often takes the Agency many months to complete an investigation and take an action against a violative firm.

When violative firms are identified, FDA has a variety of enforcement tools, including both criminal and civil enforcement powers, that it can use to address the problem of steroids in dietary supplements. In the July 2009 action against ACL, FDA both executed a criminal search warrant and issued a Warning Letter regarding the illegal manufacture of various body-building supplements that contain synthetic steroids. This is not the first time FDA has taken action against steroid-containing products marketed as dietary supplements. In 2004,

as part of the HHS crackdown on companies that manufacture, market and distribute products containing androstenedione, or "andro," FDA sent Warning Letters to 23 companies asking them to cease distributing androstenedione-containing products sold as dietary supplements, and warning them that they could face enforcement action if they did not take appropriate action. Androstenedione was subsequently added to the list of Schedule III controlled substances in January 2006. In March 2006, FDA sent Warning Letters to four more manufacturers and distributors of synthetic steroid-containing products illegally marketed as dietary supplements. One of these companies, LG Sciences (formerly Legal Gear), was the subject of an FDA seizure in April 2008 of nearly \$1.3 million worth (23,300 bottles) of illegal synthetic steroid-containing body-building products labeled as dietary supplements.

When criminal sanctions may be warranted, FDA's Office of Criminal Investigations (OCI) will become involved. OCI is the entity within the Agency responsible for the conduct and coordination of criminal investigations and, as such, maintains liaison and cooperative investigative efforts with other federal, state, local, and international law enforcement agencies. OCI is instrumental in implementing FDA criminal investigation policy, training, and coordination. OCI uses all customary and legal criminal investigative techniques, interfaces directly with federal and local prosecutorial offices, and participates in grand jury proceedings and judicial actions as required.

FDA's OCI continues to aggressively investigate distributors and manufacturers of dietary supplements containing synthetic steroids and recognizes the risks that these products pose to consumers. However, these investigations can present legal challenges to law enforcement because many of these dietary supplements contain new steroids that are not specifically

listed as anabolic steroids under the CSA. These new steroids are sometimes called "designer steroids." In such cases, proving that the "designer steroid" meets the definition of an anabolic steroid at 21 U.S.C. 802(41)(A), because it is a substance "chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone)," can be a complicated and time-consuming task. In such cases, only misdemeanor violations of the FD&C Act may apply, unless there is evidence of intent to defraud or mislead, a requirement for establishing a felony violation of the Act. If a dietary supplement contains a steroid that is not a controlled substance under the CSA and the product is accurately labeled, it may be difficult to establish a felony violation of the Act. Nevertheless, OCI is actively engaged with its law enforcement partners, such as the Drug Enforcement Administration (DEA), to target these products more effectively. FDA and DEA are constantly encountering new steroids as firms attempt to stay one step ahead of the law.

Challenge of Distinguishing Legal and Illegal Steroids in Dietary Supplements. Although some steroid-containing products are represented as dietary supplements, the products generally do not meet the definition of a dietary supplement under the Act. To be a lawful dietary ingredient in a dietary supplement, a steroid must fit within one of the categories of "dietary ingredients" defined in section 201(ff)(1) of the FD&C Act – that is, a vitamin, mineral, amino acid, herb or other botanical, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.

Some types of steroids may be dietary ingredients because they are either:

- a dietary substance for use by man because the substance has a history of use as a food or food ingredient;

- a constituent of a 'dietary substance' (e.g., a component of a food such as an animal meat or organs used as food);
- a constituent of a plant or other botanical (e.g., plant-derived ecdysteroids, phytosterols, saponins, etc.); or
- a metabolite of a substance that is a dietary ingredient.

Therefore, these steroids could be extracted and purified and used as dietary ingredients.

However, steroids that are dietary ingredients because they are a constituent of another dietary ingredient are only dietary ingredients if they are in fact extracted and purified from the parent material (e.g., a botanical extract made from a plant). FDA believes that synthetic versions of otherwise eligible steroids are not dietary ingredients unless the synthetic version itself is a dietary substance because it has a history of use as a food or food ingredient. This conclusion results directly from the language of the dietary ingredient definition; that is, a synthetic substance that was never a part of a dietary ingredient cannot be understood to be a "constituent" of that dietary ingredient; rather, it is a synthetic copy of the constituent.

Because we believe that most steroids that are being marketed as dietary supplements are synthetically produced, most are not eligible dietary ingredients. Depending on whether the product contains another active ingredient that falls into one of the dietary ingredient categories (e.g., a vitamin or mineral) and whether it is marketed to affect the structure or function of the body (e.g., with body-building claims), a steroid-containing product may be an adulterated dietary supplement, an unapproved new drug, or both.

FDA faces several challenges when it considers whether a particular steroid-containing dietary supplement violates the Act. When the Agency finds a potential steroid ingredient listed on a label, we must determine what the substance is and whether it is present in any article used as food. This is a time-consuming process that requires staff to search the scientific literature. In cases where we cannot identify the substance (because the ingredient

is named incorrectly or is a novel steroid that we have not previously encountered), or when we are unable to locate information about it in the scientific literature, we must consult FDA's experts—or, sometimes, experts outside the agency—to determine what it is.

If FDA determines that the substance is a steroid, there are several possible enforcement outcomes, depending on the product's ingredients and marketing. First, if the steroid is the only active ingredient and the product is intended to affect the structure or function of the body, the product is an unapproved new drug. Second, if the product contains the steroid, in addition to one or more legitimate dietary ingredients (for example, herbal ingredients), the product would be an adulterated dietary supplement because it contains an unsafe food additive. Third, in rare instances, it may be determined that the steroid meets the definition of a dietary ingredient. In those instances, if the steroid is a new dietary ingredient for which a premarket notification is required, the product would still be an adulterated dietary supplement unless the manufacturer or distributor submitted a new dietary ingredient premarket notification to FDA at least 75 days before marketing.

Analytical Challenges. Analyzing the steroid ingredients requires FDA laboratories to use scientific expertise and sophisticated instruments to identify the presence of synthetic steroids. Each steroid ingredient can have numerous different synonyms, many of which are obscure, alternative chemical names. Some may be nicknames given to the compound by the manufacturer or the body-building community. Furthermore, these products are frequently mislabeled, either intentionally to confuse and mislead consumers or unintentionally because of a misunderstanding of steroid nomenclature. If FDA cannot determine what ingredient is in the product based on the labeling alone, FDA sends the product to the lab for ingredient analysis.

From the laboratory perspective, the steroid analysis is complicated due to the vast array of known steroids (over 7,000), which are all variations of the same basic steroid chemical "skeleton." These variations are caused by the locations and numbers of substituent and double bonds. As a result, while determining the molecular weight may be a useful first step toward identifying a chemical compound, there could be twenty steroids with the same molecular weight, each representing a unique chemical compound. Differences in stereochemistry further complicate the challenges faced by the laboratory. There are so many different steroid compounds that in many instances reference standards, which are needed for the laboratory to conclusively identify the chemical, are not available. In these situations the laboratory's only option is to have the compound custom-made at a cost that is frequently prohibitive.

Importation Challenges. The firms that manufacture and distribute these fraudulently marketed dietary supplements typically do not import them through legal means. It has been our experience that most of the raw steroid ingredient powders and final dosage forms are imported in ways that intentionally evade FDA's review or make such review difficult. For instance, products being imported typically are flagged for FDA review based on, among other things, information provided by the importer and product labeling. However, large commercial-size shipments of raw ingredient and finished product are frequently mislabeled or otherwise improperly identified, including being identified as products not subject to FDA review. In addition, shipments of fraudulently marketed dietary supplements frequently enter the United States through the international mail facilities and courier services. Such shipments can be extraordinarily difficult to effectively address and prevent because of their sheer volume and FDA's inability to perform a comprehensive evaluation of all packages.

Scheduling of Controlled Substances. Although anabolic steroids have been included in Schedule III of the CSA since 1990, the Anabolic Steroid Control Act (ASCA) of 2004 amended the legal definition of anabolic steroid, and expressly listed androstenedione (an anabolic steroid precursor) and a number of other similar steroid substances as anabolic steroids. Specifically, the ASCA amended the CSA to redefine anabolic steroids as “any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone).” There are currently 59 Schedule III anabolic steroids specifically listed in the regulations. In April 2008, DEA published a proposed rule to add three more compounds to the nonexclusive list of Schedule III anabolic steroids.

DEA has the primary role in classifying these anabolic steroids as controlled substances. However, the administrative procedure that DEA must follow to schedule new anabolic steroids is extremely time-consuming. In order to be classified as an anabolic steroid and meet the legal definition of anabolic steroid under the CSA, the drug must be shown to be chemically and pharmacologically related to testosterone. By the time DEA determines the chemistry and pharmacology of the steroid and shows that it meets the definition of “anabolic steroid” under the CSA, the manufacturer may have changed or redesigned the steroid used in the product—in which case DEA must start over and evaluate the chemistry and pharmacology of the new steroid ingredient. Unfortunately, while scheduling new anabolic substances temporarily removes certain ingredients from the market, FDA and DEA may always be a step behind the next novel anabolic steroid compound.

CONCLUSION

Despite FDA's efforts, and those of other agencies, to identify and remove illegal steroid products from the legitimate dietary supplement marketplace, we face significant regulatory challenges. FDA will continue to closely monitor the safety of steroid products marketed as dietary supplements by addressing those products that pose the greatest health risk to the most vulnerable populations. This is an important public health issue that can only be addressed by collaborative efforts with DEA, other federal agencies, regulated industry, health care professionals, and consumers. As a public health agency, we are committed to doing everything we can to protect the American public, not only through regulation and enforcement, but also through education, outreach, and collaboration with entities outside FDA. FDA's Web site (www.fda.gov) contains extensive information for consumers about drug importation, buying drugs online, counterfeit drugs, enforcement activities, and potential public health threats, as well as resources to report problems with FDA-regulated products or Web sites that could be selling fraudulent, adulterated, or harmful products.

Thank you for the opportunity to discuss FDA's activities with regard to steroids marketed as dietary supplements. FDA looks forward to working with Congress on this important public health issue. I would be happy to answer any questions.

Statement for the Record
United States Committee on the Judiciary, Subcommittee on Crime and Drugs
Hearing: "Body Building Products and Hidden Steroids: Enforcement Barriers"
Prepared by Steve Mister, President and CEO,
Council for Responsible Nutrition

The Council for Responsible Nutrition (CRN)¹ shares the Committee's concerns over the serious issue of illegal anabolic steroids being mis-marketed as dietary supplement products. Similarly, CRN would like to clarify the distinction between illegal anabolic steroids and legal dietary supplements, and describe the current enforcement authority available in the Food, Drug and Cosmetic Act (FD&C Act). We would also like to remind the Subcommittee that rogue products containing anabolic steroids are not dietary supplements, regardless of how the bad actors, who manufacture and market these products, might position them—they are illegal, unapproved new drugs. Responsible supplement companies do not condone these practices, and we urge the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) to use its ample authority to crack down on anabolic steroids that put athletes and young people at risk.

Under the Controlled Substances Act, Congress has given DEA special power to regulate anabolic steroids. An unscrupulous manufacturer may misrepresent a product as a dietary supplement, but this does not circumvent DEA's legal authority to pursue these illicit substances. Under the Dietary Supplement Health and Education Act (DSHEA), it is illegal for supplements to contain drugs or undeclared substances, and FDA has the regulatory authority under existing law to take action against companies manufacturing and marketing unapproved drugs masquerading as dietary supplements. FDA can remove these products from the marketplace if they pose an imminent threat to public health or if there is a significant or unreasonable risk of injury or illness associated with use of the products.

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 70+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics.

Further, under DSHEA, all new dietary ingredients (NDIs) must go through the NDI notification process before they enter the market—if they do not, then the products are considered adulterated. Anabolic steroids, and steroid precursors in particular, would be subject to this notification requirement especially if not already listed under the Controlled Substance Act, and FDA can take enforcement action against companies that fail to notify the Agency.

It also cannot be ignored that there are societal forces that push some competitive athletes to adopt a 'win at all costs' mentality, resulting in their seeking out of questionable products that they hope will give them an advantage over their competition. This leads to a demand that serves as a catalyst for the subsequent illegal and deleterious supply. We support FDA's efforts to crack down on individual companies that are manufacturing illegal, unapproved drugs and urge athletes to be aware of the rules of their athletic governing bodies and to choose their supplements wisely.

Below is an overview of dietary supplement regulation and the enforcement authority available to FDA to remove illegal products from the market.

Dietary Supplement Regulation

Dietary supplements, as defined in Section 201(ff) of the FD&C Act, codified at 21 U.S.C. §321(ff), are vitamins, minerals, herbs and other botanicals, amino acids and other dietary substances used to supplement the diet. These products include multi-vitamins, individual vitamins and minerals, specialty supplements like glucosamine, chondroitin and omega-3 fatty acids, plant-based products like Echinacea, saw palmetto, green tea and garlic, and a variety of weight-loss and sports nutrition products. Dietary supplements are regulated by the Food and Drug Administration (FDA), the Federal Trade Commission (FTC) and state agencies that have authority over dietary supplement products similar to the federal government through their own state food and drug laws. FDA is charged with reviewing new ingredients and product labeling as well as all aspects of manufacturing and packaging (including inspecting facilities where supplements are manufactured, packaged or stored for sale). The FTC has authority over product

advertising and brings legal actions for advertising that is false, misleading or fails to have adequate substantiation to support those claims.

How dietary supplements are regulated: Dietary supplements are regulated by FDA through a combination of premarket notification, good manufacturing practices for production, post-market surveillance and robust enforcement authority.

Premarket Authority: The FD&C Act, as amended by DSHEA, provides FDA with authority over the ingredients, the manufacturing, the claims and the labeling of dietary supplements.

1. *New Ingredients.* All ingredients that were currently on the market (either in food or in a dietary supplement) when DSHEA was enacted were presumed to possess a history of safe use and were "grandfathered" under the statute. However, if a manufacturer introduces a new dietary ingredient after that time, it is required to provide FDA with a New Dietary Ingredient (NDI) notification at least 75 days before the ingredient is introduced. This notification must contain evidence that when the dietary ingredient is used according to label instructions, the dietary supplement will reasonably be expected to be safe. *See* FD&C Act § 413(a) [21 U.S.C. §350b(a)]. If FDA objects to the notification, a company may choose to market a product in the face of FDA's objection, once the FDA is on notice. What is clear, however, is that a new dietary ingredient for which the manufacturer has failed to file an NDI notification is adulterated under the Act. *Id.* If the product is adulterated, FDA has a variety of legal sanctions it may seek to compel compliance (*see* section on Enforcement Authority below).
2. *Notification/Approval of Product Claims.* In addition, DSHEA also provides for certain types of permissible claims for dietary supplements. Dietary supplements may make nutrient content claims (e.g., "A good source of calcium") and structure/function claims (e.g., "Calcium helps to build strong bones"), provided that FDA must be notified of these claims within 30 days after first marketing the supplement with such claims. Manufacturers must have substantiation that any such claims are truthful and not misleading, FD&C Act §403(r)(6)(B) [21 U.S.C. §343(r)(6)(B)], and the product must

carry disclaimers that, "This statement has not been evaluated by the Food & Drug Administration," and, "This product is not intended to diagnose, treat, cure or prevent any disease." *Id.* at FD&C Act §403(r)(6)(C) [21 U.S.C. §434(r)(6)(C)]. Dietary supplements may also make health claims regarding the relationship between an ingredient and the reduction of risk of certain diseases (e.g., "Getting adequate calcium may reduce the risk of osteoporosis"). These, however, require submission of the exact wording of the proposed claim to FDA along with evidence supporting the claim and FDA approval before they can be used.

3. *Labeling.* Dietary supplements are required to have a standard Supplement Facts box on their labeling that describes the suggested use, serving size, amount per serving, percentage of the daily value and list of ingredients. If the label does not provide this information, along with the quality and quantity of ingredients, then the product is misbranded and subject to penalties. 21 C.F.R. §101.36.

Current Good Manufacturing Practices. Dietary supplement manufacturers are required to abide by Good Manufacturing Practices (GMPs) specific to dietary supplements for the manufacturing and holding of these products. 21 C.F.R. part 111. These require identity testing of all incoming ingredients, qualification of suppliers from whom manufacturers purchase materials, cleaning validation of all manufacturing equipment, validation of all manufacturing processes, and testing of finished products to assure conformance to labeled amounts of ingredients. These final regulations were issued in 2007 and all but the smallest of manufacturers must comply with these requirements (manufacturers with fewer than 20 employees have until 2010 to fully comply). In addition, the existing bioterrorism law requires registration of all dietary supplement manufacturing and processing facilities, and all parties in the production and distribution of dietary ingredients must keep records – "one up and one down" – of their supply chain that permits the agency to trace the pedigree of ingredients back to their original source.

Post-market surveillance. Dietary supplement manufacturers are required to report to FDA serious adverse events associated with their products within 15 days of receiving notice of such incidents and maintain records of all adverse event reports they receive for six years. *See* FD&C

Act §761 [21 U.S.C. §379aa-1]. A serious adverse event is one that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability, incapacity or a congenital anomaly or birth defect. By providing this information to FDA, the law permits FDA to identify early signals of a possible problem and respond to post-market issues of concern that may result from issues of ingredient safety, manufacturing problems, contamination (of either raw ingredients or finished products), tampering, and bio-terrorism.

Enforcement Authority: FDA may seize and destroy a product if it is “adulterated,” meaning it is unsafe (FD&C Act §402 [21 U.S.C. §342]), or “misbranded,” meaning that the labeling is false or misleading (FD&C Act §403 [21 U.S.C. §343]). Because the Food, Drug & Cosmetic Act is, at its heart, a criminal statute, it provides criminal sanctions, including fines and imprisonment. See FD&C Act §301 and §303 [21 U.S.C. §331 and §333]. Further, DSHEA has provided FDA with additional enforcement authority specific to dietary supplements, including the authority to immediately remove a dietary supplement from the market if it considers the product to present an “imminent hazard to public health or safety,” FD&C Act §402(f)(1)(C) [21 U.S.C. §342(f)(1)(C)] or if the dietary supplement presents a “significant or unreasonable risk of illness or injury,” FD&C Act §402(f)(1)(A) [21 U.S.C. §342(f)(1)(A)].

Dietary Supplements and Anabolic Steroids

Anabolic steroids and prescription drugs have no place in dietary supplements. Most anabolic steroids are considered prescription drugs and are listed on the Drug Enforcement Agency (DEA) controlled substance schedules and, as such, have always been outside the scope of permissible dietary ingredients that could be used in a dietary supplement. In 2004, Congress enacted the Anabolic Steroid Control Act of 2004 [P.L. 108-358] with the support of the dietary supplement industry that placed androstenedione (known as “andro”) along with its analogs on the controlled substance schedules, thereby prohibiting their inclusion in a dietary supplement as well. As a result, it is patently against the law to add a prescription drug or an anabolic steroid to a product and label it as a “dietary supplement.” Under the Food Drug & Cosmetic Act, such a product is both an “unapproved new drug” under the drug provisions of the Act and an

"adulterated" and "misbranded" dietary supplement under the food/dietary supplement provisions of the Act.

The Food, Drug & Cosmetic Act also expressly prohibits the distribution or possession with intent to distribute a human growth hormone except for the treatment of a disease under the order of a licensed physician. *See* FD&C Act § 303(e) and (f) [21 U.S.C. §333(e) and (f)]. These provisions separately prohibit the distribution of human growth hormone to anyone under 18 years of age with enhanced jail time for these offenses. *Id.*

In addition, the new, synthetic analogs of anabolic steroids that seem to appear from time to time would also be considered "new dietary ingredients" since none of these entities were in the marketplace prior to the passage of DSHEA in 1994. The purveyors of these products have not filed with FDA a NDI notification as required by DSHEA (nor would they even be likely to demonstrate a reasonable assurance of safety for these products), so the products are "adulterated" simply by their failure to file the NDI notification, which makes them, on their face, illegal and subject to seizure. The persons responsible are subject to criminal penalties, including fines and imprisonment. FDA's authority and criminal enforcement powers are separate and distinct from the DEA's authority over illicit drugs and anabolic steroids. So while the Controlled Substance Act requires DEA to "keep up" with the ever evolving list of new metabolites and analogs of these anabolic steroids, FDA has authority to declare them to be "adulterated," seize the products and impose criminal sanctions on the marketers and manufacturers.

The key to addressing the problem of anabolic steroids that are passed off as dietary supplements is not a change in the statute, but rather robust enforcement of these existing laws along with adequate resources and funding of the FDA to permit the agency to do its job. The requirements of DSHEA, from inspection of manufacturing facilities for compliance with the dietary supplement GMPs, to product testing and seizures, all require an agency that is fully-staffed and committed to utilizing the authority it has been given.

Some have suggested that preapproval of dietary supplements (much like the preapproval process that exists for drugs) would solve the problem of anabolic steroids. That assertion is misplaced because the current problems do not arise from dietary supplements that are clearly labeled as containing an anabolic steroid; rather the marketers of these products simply add the illicit ingredients during production to otherwise lawful products and do not even disclose their presence. Even under a premarket approval scenario, illicit traffickers of anabolic steroids would simply get approval for a legitimate ingredient and then add anabolic steroids during manufacturing to achieve the desired results. The inclusion of anabolic steroids in products labeled as dietary supplements already violates existing laws, so products can be seized and their distributors prosecuted.

More than 150 million Americans use dietary supplements as part of a healthy lifestyle. While even one tainted product is too many, the vast majority of dietary supplements are safe and beneficial products. Congress must continue to provide additional appropriations to FDA to fund its enforcement activities, and FDA must continue to enforce the laws and utilize the tools it has at its disposal. The most effective way to ensure that criminals do not continue to sell or market illegal anabolic steroids as legal dietary supplements is to ensure that FDA has the funds, resources and manpower to implement and enforce the provisions provided by DSHEA.



Department of Justice

STATEMENT OF

**JOSEPH T. RANNAZZISI
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BEFORE THE

**SUBCOMMITTEE ON CRIME AND DRUGS
JUDICIARY COMMITTEE
UNITED STATES SENATE**

ENTITLED

**"BODY BUILDING PRODUCTS AND HIDDEN STEROIDS:
ENFORCEMENT BARRIERS"**

PRESENTED

SEPTEMBER 29, 2009

**Written Statement of
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration**

“Body Building Products and Hidden Steroids: Enforcement Barriers”

September 29, 2009

**Subcommittee on Crime and Drugs
Judiciary Committee
United States Senate**

Introduction

Chairman Specter, Ranking Member Graham, and distinguished Members of the Subcommittee, on behalf of Acting Administrator Michele Leonhart and the more than 9,400 men and women of the Drug Enforcement Administration, I want to thank you for the opportunity to appear before you today and testify in this hearing, “Body Building Products and Hidden Steroids: Enforcement Barriers.

Background

To understand the use of steroid products for body building and performance enhancement, we must start by discussing testosterone. Testosterone is a hormone that is produced in the body and primarily responsible for the development and maintenance of male sexual characteristics (androgenic effects) and the promotion of muscle growth (anabolic effects). Testosterone was first synthesized in the 1930s and was subsequently utilized by bodybuilders, weight lifters, and amateur and professional athletes to perfect body appearance, increase physical performance, and gain muscle size and mass. In short, testosterone is used for performance enhancement, that is, to get bigger, stronger and faster. In addition to professional and amateur sports figures, we are now seeing law enforcement and public safety officials using these substances as well.

Testosterone has very limited effectiveness as an oral medication since it is rapidly broken down in the liver. It is generally given by inter-muscular injection, however, creams or gels have also been used as a delivery system to take advantage of absorption through the skin, avoiding the liver and subsequent breakdown of the drug.

Over time, scientists developed and synthesized compounds or derivatives that were structurally similar to testosterone (“designer steroids”) and prohormones or precursors, inactive or minimally active compounds that, when ingested, metabolize into an active anabolic steroid.

An example would be androstenedione ("andro"), a moderately active steroid that, when ingested, metabolizes into testosterone. Androstenedione was sold over the Internet and in health food and nutrition stores as a dietary supplement until 2004, when FDA sent warning letters to 23 companies asking them to cease distribution of the product or risk enforcement action. The FDA took this action because it believed that the use of supplements containing androstenedione would increase the risk of serious health problems. Many, if not all of the testosterone "boosters", testosterone derivative compounds, and steroid prohormones/precursors on the market today are sold as dietary supplements.

In 1990, Congress passed the *Anabolic Steroids Control Act of 1990*, which placed 27 anabolic steroids into schedule III of the Controlled Substances Act. By virtue of placement in schedule III, the law increased penalties for steroid trafficking and imposed strict production and record keeping requirements on pharmaceutical firms. In 2004, Congress passed the *Anabolic Steroid Control Act of 2004*, which placed an additional 36 steroids and over-the-counter prohormone dietary supplements into schedule III of the Controlled Substances Act, including androstenedione and its derivatives.

Dietary Supplements and Designer Steroids

Dietary supplements are regulated by HHS's Food and Drug Administration (FDA) under amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) added by the Dietary Supplement Health and Education Act (DSHEA) which was enacted in 1994. (For convenience, this testimony will refer to those FDCA provisions as "DSHEA".) Under DSHEA, the manufacturer is responsible for ensuring that their products are safe and properly labeled prior to marketing. If a product containing a steroid or steroid precursor meets the definition of a dietary supplement, FDA must show that the product is adulterated (e.g., because it presents a significant or unreasonable risk of illness or injury) before the supplement can be removed from the market. However, if the product meets the definition of a drug, FDA need not show that the product is unsafe or otherwise adulterated to take enforcement action against it. The Drug Enforcement Administration does not have statutory authority to enforce provisions of DSHEA and has very limited authority to enforce other provisions within the FDCA.¹

Although DEA does not have statutory authority to enforce DSHEA, DEA does have statutory authority to investigate incidents involving the illegal manufacture and distribution of anabolic adrenergic steroids in the dietary supplement market. DEA also is involved to the extent that it can administratively schedule a substance that is chemically and pharmacologically related to testosterone and that is used in dietary supplements. Additionally, DEA has the authority and responsibility to investigate companies that are marketing products as dietary supplements that are adulterated with controlled substances.

Administrative Scheduling

¹See 21 U.S.C. 333. DEA has authority under the FDCA to investigate the illegal distribution of human growth hormone, a non-controlled legend drug.

With the passage of the *Anabolic Steroid Control Act of 2004*, Congress refined the definition in the original 1990 law (21 U.S.C. 802(41)(A)) to allow DEA to administratively classify additional steroids as schedule III anabolic steroids. The statute defines an anabolic steroid as a substance that is both chemically and pharmacologically related to testosterone; is not an estrogen, progestin or corticosteroid; and is not dihydroepiandrosterone (DHEA). Using this provision, DEA identifies substances marketed as anabolic products in the dietary supplement market and then conducts a chemical and pharmacologic analysis of the substance to determine if it is related to testosterone, conducts a comprehensive review of existing peer reviewed scientific literature and if necessary, conducts additional pharmacologic testing to ultimately determine if the substance meets the criteria for a schedule III anabolic steroid. The scheduling process requires an interagency review, the publication of a Notice of Proposed Rulemaking, a review of public comments, and the publication of a Final Rule in the Federal Register that provides notice to the public and industry that the substance will be designated as a schedule III anabolic steroid. This process is conducted in accordance with the Administrative Procedures Act and takes many months to complete. There is no method, under the current statute, to expedite the scheduling process.

DEA has uncovered several products that we are currently evaluating for scheduling. These products were being sold and marketed as anabolic substances in the dietary supplement market and were found to be chemically and pharmacologically similar to testosterone. DEA is in the final stages of the scheduling process for three (3) of these substances, identified as boldione, desoxymethyltestosterone, and 19-nor-4,9(10)- androstadienedione. As of August 2008, DEA was aware of 58 dietary supplements purportedly containing one or more of these three steroids. The initial Notice of Proposed Rulemaking concerning the scheduling of these substances was published in April of 2008. We anticipate publishing the Final Rule within the next several months. If finalized as proposed, these products would be the first three substances scheduled under the 2004 *Anabolic Steroid Control Act*. As you can see, the overall time period to perform an anabolic steroid scheduling action may take as long as two years to complete.

DEA is reviewing three other substances identified as methylrostanolone, prostanazol, and adrenostreone. All three are found in the dietary supplement market and two of these products are believed to be more potent than testosterone. So, in the time that it takes DEA to administratively schedule an anabolic steroid used in a dietary supplement product, several new products can enter the market to take the place of those products that have completed the lengthy administrative process. Chemists continue to create new derivative products by substituting and altering the testosterone molecule and then market them as "dietary supplements". Often, these new formulations have never been clinically tested and any adverse reactions in humans are simply unknown. In some instances these products have been linked to serious liver damage or other health issues.

Dietary Supplements Containing Controlled Substances

Recently, DEA has identified products in the dietary supplement market that contain small amounts of schedule III anabolic steroids. The presence of these anabolic steroids was not listed on the label of specific products and the consumer was not aware that the substance that he or she had purchased from the local nutrition shop contained a controlled anabolic steroid. Analyses of some dietary supplements by DEA labs as well as independent analytical labs have identified controlled anabolic steroids in products purchased directly from the local nutrition shop. The companies manufacturing, bottling and marketing these products do not hold controlled substance registrations and the manufacture and distribution of these products violate various provisions of the Controlled Substances Act. It is not unusual for some dietary supplements products to contain controlled anabolic steroids in one batch and not the next. These are often referred to as "hot" batches in the industry. The intent is to stir public interest in a product that is marketed by word of mouth or on blogs across the Internet. These products may contain subpotent or superpotent levels of controlled anabolic steroids. In these instances consumers are completely unaware of the actual contents of the products they are purchasing.

An analysis of more than 600 dietary supplements revealed that approximately 15% contained anabolic steroids.² Two-hundred and forty of these supplements were from the United States with 18.8% containing undeclared anabolic steroids.

Adverse Effects of Anabolic Steroids

The use of anabolic steroids or dietary supplements that contain anabolic steroids or designer steroids, in high doses that boost, alter or derive from testosterone may trigger numerous adverse health effects in the human body including liver toxicity, baldness, uncontrolled rage, and heart attacks. Long-term, large dose usage of anabolic-androgenic steroids (AAS) has been shown to result in dependence associated with acute withdrawal syndrome to include depressed mood, fatigue, anorexia, and insomnia. The abuse of AAS also causes abusers to become dependant on multiple drugs.³ For example: use of sedatives as a sleep aid, narcotic use to decrease pain, use of anti-depressants for mood swings, and amphetamine use to increase endurance and burn fat.

The use/abuse of steroids by adolescences also is a cause of concern. In 1993, Yesalis et al reported that 80% of 12-17 year olds who had used steroids at least once in their lives had committed acts of violence or crimes against property within the past year, a rate more than twice that of those not having taken anabolic steroids. An Internet survey of 500 AAS users

²Geyer, H; Parr, M.,K.; Mareck, U.; Reinhart, U.; Schrader, Y.; Schanzer, W. International Journal of Sports Medicine 2004, pp. 124-129: *Analysis of Non-Hormonal Nutritional Supplements for Anabolic-Androgenic Steroids-Results of an International Study.*

³Skarberg, K.; Nyberg, F.; Engstrom, I. Eur Addict Res 2009, 15 (2), 99-106, *Multisubstance Use as a Feature of Addition to Anabolic-Androgenic steroids.*

revealed that 26% of the respondents started use during their teenage years with 95% reporting poly-drug use.⁴

Conclusion

DEA is committed to protecting the health and welfare of the American people. DEA continues to investigate and uncover dietary supplement products that contain either controlled anabolic steroids or designer steroids that are structurally similar to testosterone. Once found, DEA then initiates a scientific review and analysis followed by any appropriate administrative scheduling process. However, unscrupulous chemists take advantage of this lengthy administrative scheduling process. They continue to create and market products that contain chemicals which have never been adequately tested on humans and by the time government agencies become aware of adverse effects it is often too late as the damage has already been done.

Chairman Specter, Ranking Member Graham, and members of the Subcommittee, I thank you for the opportunity to discuss this vital issue and welcome any questions you may have.

⁴Parkinson and Evans, *Med Sci Sport* 2006, 644-651, *Anabolic Androgenic Steroids: A survey of 500 Users*.

Senate Committee on the Judiciary, Subcommittee on Crime and Drugs
Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"
September 29, 2009
Testimony of Travis T. Tygart
Chief Executive Officer
United States Anti-Doping Agency

Mr. Chairman, members of the Committee, good afternoon. My name is Travis T. Tygart and I am the Chief Executive Officer of the United States Anti-Doping Agency (USADA). I want to thank this Committee for its interest in protecting America's consumers from the proliferation of over-the-counter products containing dangerous steroids, stimulants and other drugs. On behalf of the millions of participants who demand fair, clean and safe sport that USADA represents, I appreciate the opportunity to appear before you today to discuss our perspective on this important health issue.

USADA has been recognized by Congress as the independent, national anti-doping agency for Olympic, Paralympic and Pan American sport in the United States. Our mission is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sport through the elimination of doping. As part of the effort to fulfill that mission, USADA has made a concentrated effort to better understand the availability and use of steroids, stimulants and other dangerous performance-enhancing drugs in the United States.

USADA's interest in over-the-counter products containing steroids and other drugs originated with two issues related to America's elite Olympic athletes. First, USADA was concerned that the ease with which products containing these could be purchased in America's supplement retail store fronts and over the internet was making doping too easy for that small percentage of athletes who wanted to cheat the system through the use of steroids. Second, USADA became equally concerned that some elite athletes were testing positive for banned drugs because they were taking products that were either accidentally contaminated or purposefully spiked by manufacturers with designer steroids, stimulants and other drugs. Importantly, the more we have learned about the prevalence of these dangerous drugs in allegedly "healthy" products, the clearer it has become that this problem extends well beyond elite level athletes and is impacting an ever-increasing number of American consumers.

Our interest in this issue over the last nine years has led us to recognize that there has been a dangerous convergence of two troubling trends. The first trend involved the unfortunate decision by certain elite level athletes to purposefully seek out designer steroids. The proliferation of designer steroids began with an effort by rogue chemists to create steroid compounds that would allow an athlete to dope without being detected through routine anti-doping screening procedures.

Designer steroids made their leap into the nation's headlines and the consciousness of American sports fans in 2003 when the investigation into the Bay Area Laboratory Co-Operative (BALCO) doping conspiracy was revealed. As many of you will recall, the designer steroid at the center of that conspiracy was the "Clear" which later was identified as tetrahydrogestrinone or THG. It was that previously unknown or designer steroid that the BALCO athletes were taking in order to avoid detection. These athletes were taking a potent and untested steroid that had never been clinically tested on human beings. They made a tragic choice to turn themselves into human science experiments in order to try and cheat the system. While the consequences to the careers of these athletes were severe, the health consequences of their choice to use designer steroids may not be fully known for many years.

Significantly, THG was not the only designer steroid involved in the BALCO conspiracy. Another designer steroid known as "Madol" (aka DMT or Desoxymethyltestosterone), was also identified during the investigation into BALCO. As a result of that investigation, USADA and anti-doping agencies throughout the world have been testing for Madol since 2004. Accordingly, there is no longer an incentive for elite athletes to use this substance because it is now a known compound that will be detected in routine testing. But the story of this second designer steroid does not end there.

Instead, the story of Madol confirms the second trend which is the alarming migration of designer steroids from the underground to mainstream merchandising. Designer steroids may have started with small batches prepared in clandestine laboratories for elite athletes, but today they are big business in America. According to a recent New York Times article, in 2007 American consumers spent over \$24 billion on supplements, and an estimated \$2.8 billion of those consumer dollars were spent on products claiming to build muscles or enhance athletic

performance.¹ As one indication of the scope of this business, Bodybuilding.com is an industry award winner and leading on-line seller of performance-enhancing and muscle building supplements, which in early 2008 sold a controlling interest in its business to media conglomerate Liberty Media for approximately \$100 million.²

A number of the products manufactured to try and cash in on America's appetite for fitness and athletic improvement were products featuring Madol, which had risen from an obscure substance in hand-labeled bottles shoved in a corner of a BALCO storage unit, to the signature ingredient in mass produced products marketed through slick, high-dollar ad campaigns and readily available in nutrition stores and over the internet.³

Following a lengthy FDA investigation into products featuring such ingredients the FDA took action last week against Bodybuilding.com and in July of this year against Max Muscle Sports Nutrition Store and American Cellular Laboratories for marketing and distributing products as supplements that actually contained potentially harmful designer steroids including Madol, the same drug discovered in the BALCO investigation four years earlier. The FDA in July also issued a public warning to consumers regarding these and other dangerous products, that while masquerading as healthy supplements, may actually contain dangerous designer steroids. Specifically the FDA warned consumers to "stop using body building products that are represented as containing steroids or steroid-like substances." The FDA release also warned consumers that the FDA had received reports of serious adverse health events associated with such products, including "cases of serious liver injury, stroke, kidney failure and pulmonary embolism (artery blockage in the lung)."⁴

¹ See Attachment 1, NY Times article "Supplements For Athletes Draw Alert From F.D.A.," by Natasha Singer and Michael S. Schmidt.

² See Attachment 2, announcement of Bodybuilding.com winning two Nutritional Business Journal business achievement awards. See also, paragraph 21, Application and Affidavit for Search Warrant (hereinafter "Bodybuilding.com Search Warrant") dated September 24, 2009, publicly available at: https://ecf.idd.uscourts.gov/cgi-bin/HistDocOrv.pl?875643538248804-L_795_0-1.

³ See paragraph 60 of the Bodybuilding.com Search Warrant citing March 2008 edition of *Muscular Development* magazine article written by exposed steroid manufacturer and supplement industry icon Patrick Arnold acknowledging the migration of designer steroids from small, clandestine operations to "neat bottles with supplement labels and sold to thousands of folks of all ages . . ."

⁴ See Attachment 3, FDA news release and other documents.

Unfortunately, Madol is just one example of a designer steroid that unscrupulous companies are inserting into products and then marketing those products as legitimate dietary “supplements” to an unsuspecting public. While the permissive regulatory scheme governing the introduction of supplements makes it difficult to precisely analyze the issue, best estimates suggest that there are hundreds of products currently available that contain one or more of over 20 designer steroids. Moreover, the ease with which new supplement products can be introduced to the market means that this proliferation of products containing designer steroids is likely to continue unchecked under the current regulatory scheme. While the FDA’s action against Max Muscle Sports Nutrition Store, American Cellular Laboratories and Bodybuilding.com are important steps in the effort to protect consumers from these dangerous products, the FDA is operating in a regulatory environment that is simply too burdensome to allow for effective post-market regulation of these products. While American Cellular Laboratories voluntarily removed its Madol products from the shelves following the search, numerous other Madol supplements continued thereafter to be sold in this country.⁵ It is also beyond dispute that new products featuring similar compounds had already been introduced by other supplement companies seeking to become part of this designer steroid gold rush.

Accordingly, in the last six years we have gone from a paradigm where the average user of a designer steroid was an elite level athlete looking to avoid detection, to a new reality where mainstream American consumers are spending significant dollars on products that while promising to be healthy alternatives to steroids, actually contain dangerous designer steroids. One of the most troubling side effects of this migration is that unlike the athletes who made a decision to compromise their health by taking such products, the average designer steroid consumer of 2009 is not an elite athlete but a broader population of people who want to be healthy and fit including young athletes, junior high and high school athletes, weekend athletes, those that want good general health and law enforcement, fire department and military personnel. We believe this group is likely taking these products under an understandable misperception that they are improving their health.

⁵ See also Attachment 4, iProNutrition.com sent an email the afternoon of the FDA’s raid on Bodybuilding.com to potential customers advertising that Mass Tabs, a product containing the designer steroid Superdrol (aka methasterone or 17-methyltestosterone), that was the subject of the Bodybuilding.com raid, was still for sale at a discount price.

Imagine for a minute the high school or college athlete who wants to improve his or her performance in sports. He or she has been raised the right way by his or her parents to try his or her best, work hard and play by the rules. He or she spurns the health club steroid dealer and instead walks into a local health food store or logs on the internet and peruses the countless products offering healthy ways to improve performance. He or she sees the glossy labels promising muscle gains and the bright bold claims of "LEGAL" and "ALL NATURAL." He or she thinks, as we all believe, that because these products are available so readily over-the-counter or on-line and can be purchased relatively cheaply without an ID that they must be safe and effective. He or she may even believe that the manufacturers of such products are required to prove that their products are safe and effective before offering them for sale. He or she selects a bottle, pays the \$50 or \$75 and starts using the product faithfully. He or she is excited by the progress, because the product works.

It is what this consumer does not know that is the reason we are all here today. What he or she does not know is that all it takes to cash in on the storefront steroid craze is a credit card to import raw products from China or India where most of the raw ingredients come from, the ability to pour powders into a bottle or a pill and a printer to create shiny, glossy labels. What he or she does not know is that we could agree in this room right now to create a new steroid product, have it on the shelves within a matter of weeks, and if we make the right unsubstantiated marketing claims, sell a million dollars or ten million dollars of product before the FDA is able to maneuver through the current regulatory scheme to take action. Most importantly, what he or she does not know is that the reason the product works is because it contains an actual designer steroid and he or she has now become a steroid user; thereby, unknowingly subjecting himself or herself to all the potential harmful health effects of these drugs.

Unfortunately, we do not have to imagine such an athlete, because one is here with us today. His name is Jareem Gunter. I have not known Jareem long but it does not take long to realize Jareem and kids like him are the future of this country. Unfortunately, unscrupulous supplement companies and the current regulatory system compromised Jareem Gunter's pursuit of the American dream.

Jareem listened to his parents when they told him to work hard, do his best and stay away from drugs. Jareem was fortunate to have some God-given athletic ability and to work hard to earn financial assistance to play baseball while enrolled in a small Division II school, Lincoln University in St Louis, Missouri. While in school, he was having a good pre-season and he was holding on to his dream of possibly being drafted by a professional team in the upcoming or a future draft. Jareem, wanting to leave nothing to chance in his pursuit of the American dream, decided to look for a legal nutritional supplement to help his workout. He checked the school's prohibited drug list and did his due diligence. What he found was a product called "Superdrol." In its advertising materials at that time Superdrol invoked the name of Congress to suggest that because Congress had not added it to the Controlled Substances Act in 2004 it is "100% legal to sell" and thus must also be safe and effective.

Jareem purchased the product and added it to his workout regime and continued taking it according to the instructions on the bottle. Approximately three weeks into his use of Superdrol, Jareem started feeling ill. He tried to tough it out but eventually the pain drove him to the emergency room. If he had gone a day later he might not be alive today. He woke up in a hospital bed with the doctor explaining to him that he had suffered acute liver failure, a textbook side effect of taking steroids orally. Jareem spent the next several weeks in the hospital and his weight plummeted from approximately 210 to 150 pounds. There was no guarantee that his health would ever return. Jareem's pursuit of the American dream was compromised by what he reasonably believed to be a "safe" and "legal" product. His financial aid is gone, his ability to afford college has been compromised and has been left with a life adversely affected.

I want to thank Jareem for being here today and letting me share his story. Today Jareem's weight is back up, but he is forced to be constantly vigilant looking for the return of the symptoms caused by the damage Superdrol did to his liver. He was not able to return and finish college, but he now works with children at a mentoring center, City of Dreams, trying to help other kids stay away from drugs and find a path off of the streets. He is here because he does not

want to see another young person's dreams compromised by a dangerous drug masquerading as a legal supplement.⁶

Jareem's only mistake was in believing that products sold over-the-counter and on-line in America can be assumed to be safe. No one told him that there was no way to know what might be in that bottle that he purchased and that there is no system in place to make manufacturers accountable for proving the safety of their products. Jareem had no way of knowing that a regulatory scheme designed over fifteen years ago for a few companies selling a limited number of simple vitamins and established mineral supplements has been hijacked by unscrupulous profiteers. He had no way of knowing that these companies are exploiting the lack of pre-market regulation to sell magic powders and pills in a bottle while using the reputation of the health food and vitamin industry to cloak themselves with the appearance of safety and respectability. Finally, he had no way of knowing that these companies had found the perfect system, because when he attempted to hold the manufacturer fully responsible for his injury accountable through the court system, the company simply declared bankruptcy and disappeared.

The sale of steroids disguised as dietary supplements is one part of the more general problem of dietary supplements that contain substances that are not disclosed on the product label. This problem has been documented in published studies, e.g: 2004 IOC-Funded study (18.8% of the 245 supplements purchased in the USA were positive for steroids);⁷ 2007 HFL study (of the 54 supplements that were analyzed for stimulants, 6 were positive (11.1%); of the 52 supplements analyzed for steroids, 13 were positive (25%)).⁸

While not every high-profile athlete who claims a contaminated supplement is to blame for a positive doping test is necessarily telling the truth, given the overall probability of supplement contamination, the risk of taking a mislabeled supplement is a real threat to the careers of American athletes and the health of all consumers. We see cases in the United States where high-profile athletes test positive and are made ineligible for competition because they

⁶ Shockingly, the same designer steroid ingredient in "Superdrol," methasterone, is still widely available in the U.S. today. We ordered a bottle through Amazon.com two days ago.

⁷ "Analysis of non-hormonal nutritional supplements for anabolic-androgenic steroids - results of an international study," *Int J Sports Med.* 2004 Feb;25(2):124-9, by Geyer, H., et al., publically available at: <http://www.ncbi.nlm.nih.gov/sites/entrez>.

⁸ "Investigation into Supplement Contamination Levels in the US Market," HFL 2007, by Judkins, C., et al., publically available at: <http://www.usatoday.com/sports/hfl-supplement-research-report.pdf>.

took a dietary supplement that contained an undisclosed prohibited substance. For example, in 2003, Kicker Vencill, a swimmer who had qualified for the U.S. Pan American Games Team, was declared ineligible after he tested positive for an undisclosed steroid that was contained in a “multi-vitamin” product that he was taking. Last year, Jessica Hardy, a medal favorite in several Olympic swimming events, was removed from the 2008 U.S. Olympic Team after testing positive for an anabolic agent that a hearing panel later found was an undisclosed ingredient in a “multi-nutrient supplement drink.” Similarly, there have recently been several press reports of NFL players who, after taking Starcaps, a “natural dietary supplement” advertised for weight loss, tested positive for the potent and controlled diuretic, bumetanide, which was not disclosed on the product label. In an ironic twist, we are also aware of a situation where a prominent dietary supplement manufacturer sold a product advertised as “Pure Pharmaceutical Grade DHEA” (DHEA is prohibited in sport) which, upon laboratory analysis, was revealed to contain no DHEA.

Beyond undisclosed substances that are prohibited in sport, studies have also shown that nutritional supplements contain unsafe and undisclosed levels of lead and other substances that are a general public health concern. A 2004 study published in the Journal of the American Medical Association found that 14 out of 70 herbal medicine products contained heavy metals, lead, mercury, and/or arsenic. If taken as recommended by the manufacturers, each of the 14 could result in heavy metal intakes above published regulatory guidelines.⁹ Similarly shocking, a study conducted by Consumerlab.com found defects in over 30% of the supplements tested. Three out of four children’s multivitamins were too high in Vitamin A. One of the men’s multivitamins tested was contaminated with lead and another had too much folic acid. One general multivitamin had no more than 50% of its labeled folic acid. Another was missing 30% of its labeled calcium. A senior’s vitamin, a prenatal vitamin and a woman’s multivitamin each had only 44.1%, 44.3% and 66.1%, respectively, of their labeled vitamin A.¹⁰ Until these problems are addressed even the most informed and cautious consumer cannot have full confidence in their choice when selecting supplements for their health.

⁹ “Heavy Metal Content of Ayurvedic Herbal Medicine Products,” JAMA 2004 Dec 15;292(23):2868-73, by Saper, R., et al., publically available at: <http://jama.ama-assn.org/cgi/reprint/292/23/2868>.

¹⁰ Consumerlab.com, “Does your Multivitamin Provide the Right Ingredients?” publically available at: http://www.consumerlab.com/reviews/Multivitamin_Multimineral_Supplements/multivitamins/.

I want to again thank the Committee for holding this hearing, because now is the time to commit to achieving a solution. Jareem Gunter is here with us today, because right now a thousand or ten thousand young people like him perusing the aisles of health stores or reading message boards on the internet looking for a product that will help them get to the next level of success. And for every young person out there stumbling into these products, there is a middle-aged consumer looking to get back into shape, or an elderly consumer looking to prolong their healthy lifestyle. What these consumers do not know is that every purchase of one of these unscrupulous products is a gamble with their health and possibly their life. Unfortunately, we also know that there are hundreds of companies chasing those consumer dollars and hoping that their product will be the next big winner in the storefront steroid lottery.

The current regulatory scheme is not adequate to address the problem. Both pre-market notification and post-market enforcement changes in the regulation of dietary supplements are required. In the pre-market area, the FDA needs to know which companies are making dietary supplements, what products they are making and what the ingredients in those products are. Further, products containing potential designer steroids should not go on the market without advance notice to the FDA. For example, specific legislative improvements could include:

- All dietary supplement companies should be required to register as “dietary supplement companies” so that the FDA can identify them.
- Dietary supplement companies should provide the FDA with a comprehensive list of all dietary supplements they manufacture with a copy of the master formulas and product labels.
- Dietary supplement companies should provide a 75 day pre-market notice to the FDA not only for New Dietary Ingredients, but for all products containing steroids (including, hormones, pro-hormones and hormone analogues) and must establish that the product is safe under its intended use.
- Dietary supplement companies should be required to maintain a substantiation file that is available on request to the FDA.
- Distributors and retailers of dietary supplements should obtain evidence of compliance from the manufacturers and licensors that all pre-market requirements have been complied with or bear responsibility for the products they sell as if they were the manufacturer.

Even with these pre-market changes it will still remain very easy for legitimate dietary supplements to be put on the market.

Post-market legislative changes must also be made so that it is easier for the FDA and DEA to quickly take designer steroids and other unsafe products off the market. Also, advertising claims that compare a product to steroids should be prohibited. For example, specific legislative improvements could include:

- Supplement companies should be required to report all adverse events not just “serious adverse events” requiring hospitalization, surgery or death.
- The FDA should be given the power to unilaterally prohibit sales and initiate immediate recall of any product that has not followed all pre-market requirements or when the FDA determines that there is a reasonable probability that the product poses a safety risk or contains an ingredient that will ultimately be scheduled as a controlled substance.
- The DEA should be given emergency scheduling power for steroids and the criteria for scheduling steroids under Schedule III of the Controlled Substances Act should be modified to better address the current reality of designer steroids.
- As was done in 2004, Congress should immediately amend Section 102 of the Controlled Substances Act to schedule the 20 or more designer steroids that have been identified but not yet scheduled as controlled substances.
- Dietary supplement companies should be prohibited from advertising that any product performs like a steroid, is named similarly to a steroid, affects the structure of the body or touting the fact that a product may soon be declared illegal.

To make sure that the burden of insuring these products are safe is placed on the companies that stand to profit from selling the products and not the American taxpayer, violation of any of these requirements in connection with a product should make a dietary supplement company liable for a civil penalty up to two times its gross profit from the sale of the product.

Legitimate dietary supplement companies should have nothing to fear from these proposals, however, the companies that are reaping huge profits from the sale of designer steroids and other unsafe products should expect to see their current business model seriously curtailed.

USADA's interest in this issue may have started with America's elite level athletes, but it has become obvious to us that this is a fundamental health issue that extends throughout America's culture. USADA is committed to being part of the solution and looks forward to working with all groups that have a sincere interest in preventing these dangerous products from reaching the shelves of America's storefronts and allowing all consumers to have access to safe and effective products that they can have confidence in.

I would like to thank this Committee for its time and its interest in this important public health issue and for inviting me to share USADA's experience and perspectives. Thank you.

ATTACHMENT 1

Supplements For Athletes Draw Alert From F.D.A. - New York Times

Page 1 of 2

The New York Times

July 29, 2009

Supplements For Athletes Draw Alert From F.D.A.

By NATASHA SINGER AND MICHAEL S. SCHMIDT

Federal regulators warned consumers on Tuesday not to use body-building products that are sold as nutritional supplements but may contain steroids or steroidlike substances, citing reports of acute liver injury and kidney failure.

The Food and Drug Administration said it issued the warning because of increased reports of medical problems in men who had used such products.

But except for naming eight specific supplements sold by a single company, the Food and Drug Administration did not provide much clear guidance to consumers on what other products to avoid. The F.D.A. acknowledged that it did not know how many products its warning affects.

Generally, the F.D.A. said, buyers should beware of body-building products that claim to enhance or diminish the effects of hormones like testosterone, estrogen or progestin. In particular, the agency said consumers should not buy products labeled with code words like "anabolic" and "tren," or phrases like "blocks estrogen," and "minimizes gyno." The references to estrogen and "gyno" are meant to indicate the products do not have a feminizing effect on the body, like swelling breasts or shrinking testicles, which can be unwanted side effects of steroid use in men.

The F.D.A. cited eight popular products from American Cellular Labs, including Mass Xtreme and Tren Xtreme, that the agency found to contain hidden and potentially hazardous steroids. The agency sent a letter on Monday warning the company to make the products comply with federal regulations. Last week, federal agents in San Francisco executed search warrants for the company and for a San Francisco outlet of Max Muscle, a chain of sports nutrition stores, some of which sold the products cited by the F.D.A.

"We think that there may be a number of firms that are marketing similar products, if not products that are exactly the same," Michael Levy, director of the Division of New Drugs and Labeling at the agency's Center for Drug Evaluation and Research, said in a conference call with reporters on Tuesday. The agency, he said, is considering taking action against those firms as well.

The warning is part of a larger investigation into body-building products that contain hidden steroids, according to court documents in the American Cellular Labs case. A spokesman for Joseph P. Russoniello, the United States attorney for the Northern District of California, said he could not comment on open investigations.

But Travis Tygart, the chief of the United States Anti-Doping Agency, which oversees the drug testing of Olympic athletes, estimated that there could be 50 or more other brands on the market that contain the same steroids as those in the American Cellular products. The F.D.A. warning follows the agency's crackdown on more than 70 brands of weight-loss supplements that the agency found to illegally contain hidden and potentially dangerous active pharmaceutical ingredients.

But the federal regulations governing dietary supplements are inadequate to protect consumer health, according to some experts who have studied the safety of such products.

Unlike drug makers, which must demonstrate that a drug is safe and effective before the agency approves it for sale to the public, dietary supplements are a largely self-regulating industry. Manufacturers of such products are themselves responsible for the safety and effectiveness and marketing claims of their products, and for voluntarily recalling them if problems arise. The F.D.A. has authority to act only after it has received reports of serious health problems associated with products already on sale and it is able to prove a serious health hazard. If a company refuses to voluntarily recall problem products, the agency can then file an injunction and seize the products.

Such a reactive strategy puts consumers at risk, critics said.

<http://query.nytimes.com/gst/fullpage.html?rcs=9B02E7DD1730F93AA15754C0A96F9C8B63&sec=&spon...> 8/21/2009

"I applaud what the F.D.A. is doing, but the law handcuffs their hands behind their backs when they are dealing with the tsunami of products that get on the shelves," said Mr. Tygart, the antidoping official. "This shows a glaring light on the ineffective regulatory scheme that allows these products to get to the market."

He added: "The reality is that these products are still out, and consumers who don't hear or read about the warning will continue to use them because it's so hard to recall them."

Over the last two years, the F.D.A. has received 15 reports of serious health problems -- including stroke, liver problems and pulmonary embolism -- associated with body-building products from various makers, the agency said. One of the five reports connected to American Cellular products concerned a 38-year-old man who had severe liver and kidney problems that needed to be treated with dialysis after he used the company's products, according to warrants issued in the case.

Steroids are organic compounds, like hormones or cholesterol, that naturally occur in the body. Some compounds called anabolic androgenic steroids, which affect both the metabolism and the endocrine system, are approved as drugs to treat medical problems like testosterone deficiencies.

But the F.D.A.'s action pertains to unapproved forms of synthetic steroids -- popularly known as designer steroids because they are intended to evade detection by sports authorities who test athletes for performance-enhancing drugs.

Under the law, dietary supplements are defined as products that contain natural foodstuffs like minerals or herbs and do not claim to prevent, mitigate or cure specific illnesses. But it is illegal for dietary supplements to contain ingredients like synthetic steroids, said Mr. Levy of the F.D.A.

The F.D.A. considers body-building products that contain synthetic steroids -- like modified forms of testosterone or progesterin -- to be illegal, unapproved drugs that may put consumers at risk because they have not been evaluated for safety or efficacy, he said.

The overwhelming majority of dietary supplements are made by reputable manufacturers that ensure the products are safe, said Andrew Shao, the vice president for science and regulation at the Council for Responsible Nutrition, an industry trade group representing manufacturers and distributors.

Americans spent nearly \$24 billion on dietary supplements in 2007, according to Nutrition Business Journal, a market research firm.

Of that total, Mr. Shao estimated that tablets or capsules that claim to build muscles or enhance athletic performance represented perhaps \$2.8 billion in sales. He advised consumers not to buy body-building products with hyped-up claims.

But a law firm that represents sports nutrition companies said the F.D.A.'s action left consumers and manufacturers in the dark as to what specific products the agency considered to be problematic. Moreover, the agency seems to be taking action against some steroid ingredients that the Drug Enforcement Administration, which has jurisdiction over controlled substances, has not yet declared to be illegal unless prescribed by a physician, said Michael J. DiMaggio, a lawyer in Mineola, N.Y.

"The F.D.A. kind of kicked the door in and said 'we believe they are illegal now,'" Mr. DiMaggio said. "This is going to come as a shock to many companies and big distributors."

ATTACHMENT 2

Bodybuilding.com - Bodybuilding.com In The News - Bodybuilding.com Nabs Two NBJ... Page 1 of 3



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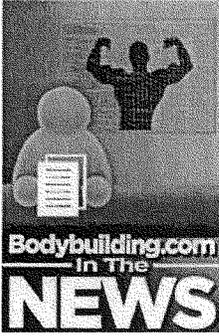
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Bodybuilding.com Nabs Two NBJ Business Achievement Awards



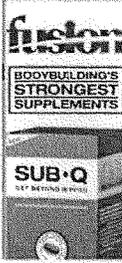
Boise, ID – July 28, 2009 - Bodybuilding.com, the Internet's most-visited bodybuilding and fitness site and largest online retailer of nutritional supplements, is the proud recipient of two Nutrition Business Journal (NBJ) Business Achievement Awards: for "Growth in Large Companies" (recognizing their outstanding 43% revenue growth in 2008), and "Deal of the Year" (for their acquisition by conglomerate giant Liberty Media).

NBJ is a monthly executive journal focusing primarily on the nutrition industry. NBJ also addresses how the industry impacts the larger food, pharmaceutical, and health care industries. They focus on such topics as business activities, market size & growth, trends, and opportunities in the nutrition industry.



Strategic Information for Decision Makers In the Nutrition Industry

In order to win a Business Achievement Award, companies must first be nominated by their peers, with final winners being decided upon by an



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Bodybuilding.com In The News's Stats for Bodybuilding.com Nabs Two NBJ Business Achievement Awards

http://blog.bodybuilding.com/in_the_news/2009/07/29/bodybuildingcom-nabs-two-nutritio... 9/23/2009

Created: 07/29/2009
Last Modified: 07/29/2009
Total Comments: 0

internal committee of NBJ staff and editorial advisory board members.

Bodybuilding.com President Jeremy DeLuca had the honor of accepting these prestigious awards at the 2009 NBJ Summit at St. Regis Rcsort in Dana Point, CA.

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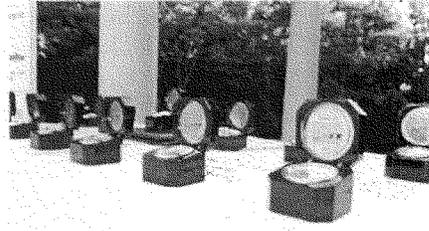
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"To be recognized by such an important group in the health and fitness industry is quite the honor. As exciting as our growth has been, the best part is knowing we are able to help more and more people every day reach the healthy lifestyle they are striving for," said DeLuca.



Bodybuilding.com offers more than 10,000 health and fitness supplements & accessories to help people achieve their health, fitness and appearance goals, as well as over 25,000 pages of FREE bodybuilding & fitness information—including more than 12,000 articles (written by 525+ writers), video & audio segments, and new content added daily.

For more information: <http://www.bodybuilding.com>
Contact: Crystal Matthews
Phone: 208.472.9311
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By: Crystal Matthews

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ATTACHMENT 3**News & Events****FDA NEWS RELEASE**

For Immediate Release: July 28, 2009

Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Warns Consumers Not to Use Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
Agency issues Warning Letter to American Cellular Laboratories for marketing and distributing potentially harmful steroid-containing products

en Español

The U.S. Food and Drug Administration today issued a Public Health Advisory (PHA) warning consumers to stop using body building products that are represented as containing steroids or steroid-like substances. Many of these products are marketed as dietary supplements.

The agency also issued a Warning Letter to American Cellular Laboratories Inc. for marketing and distributing body building products containing synthetic steroid substances. Although these products are marketed as dietary supplements, they are not dietary supplements, but instead are unapproved and misbranded drugs.

The PHA notifies consumers and health care professionals that the FDA has received reports of serious adverse events associated with the use of body building products that claim to contain steroids or steroid-like substances. Those adverse events include cases of serious liver injury, stroke, kidney failure and pulmonary embolism (artery blockage in the lung). The PHA also advises consumers to stop taking body building products from any manufacturer that claim to contain steroid-like substances or to enhance or diminish androgen-, estrogen-, or progestin-like effects in the body.

The FDA has received five adverse event reports, including serious liver injury, in men taking products marketed as dietary supplements by American Cellular Laboratories including TREN-Xtreme and MASS Xtreme. Acute liver injury is generally known to be a possible side effect of using products that contain anabolic steroids. Some of the cases resulted in hospitalization, but there were no reports of death or acute liver failure.

"Products marketed for body building and claiming to contain steroids or steroid-like substances are illegal and potentially quite dangerous," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "The FDA is taking enforcement action today to protect the public."

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm174060.htm>

9/28/2009

The products listed in the Warning Letter to American Cellular Laboratories Inc., include "TREN Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme," and are sold on the Internet and in some stores. These products, which claim to contain steroid-like ingredients but in fact contain synthetic steroid substances, are unapproved new drugs because they are not generally recognized as safe and effective. In addition, the products are misbranded because the label is misleading and does not provide adequate directions for use.

Consumers taking body building supplements that claim to contain steroids or steroid-like substances should stop taking them immediately. Consumers should also consult a health care professional if they suspect they are experiencing problems associated with the products. Health care professionals and consumers are encouraged to report adverse events that may be related to the use of these types of products to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

To view the Public Health Advisory:
<http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm173935.htm>

To view the July 27, 2009 Warning Letter to American Cellular Laboratories Inc., and the FDA consumer article on body building products marketed as containing steroids or steroid-like substances:
<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173965.htm>

#

RSS Feed for FDA News Releases [what is RSS?]

Drugs

Public Health Advisory: The FDA recommends that consumers should not use body building products marketed as containing steroids or steroid-like substances

7/28/2009

7/28/2009

The FDA is notifying the public about new safety information concerning products marketed for body building and increasing muscle mass. The FDA has sent a Warning Letter to a manufacturer of body building supplements that claim to contain steroid-like ingredients, but in fact contain synthetic steroids. The products named in the Warning Letter are marketed by American Cellular Laboratories, Inc., and include "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme."

The FDA has received reports of serious adverse events associated with the use of these products and other similar products. Products like these are frequently marketed as alternatives to anabolic steroids for increasing muscle mass and strength and are sold both online and in retail stores. They are often promoted to athletes to improve sports performance and to aid in recovery from training and sporting events. Although products containing synthetic steroids are frequently marketed as dietary supplements, they are NOT dietary supplements, but instead are unapproved new drugs that have not been reviewed by the FDA for safety and effectiveness.

Adverse event reports received by the FDA for body building products that are labeled to contain steroids or steroid alternatives involve men (ages 22-55) and include cases of serious liver injury, stroke, kidney failure and pulmonary embolism (blockage of an artery in the lung).

Due to the potentially serious health risks associated with using these types of products, the FDA recommends that consumers immediately stop using all body building products that claim to contain steroids or steroid-like substances.

Consumers should consult their health care professional if they are experiencing symptoms possibly associated with these products, particularly nausea, weakness or fatigue, fever, abdominal pain, chest pain, shortness of breath, jaundice (yellowing of the skin or whites of the eyes) or brown/discolored urine. The FDA also recommends that consumers talk with their health care professional about

<http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm173935.htm>

7/30/2009

any body building supplements they are taking or planning to take, particularly if they are uncertain about a product's ingredients.

Health care professionals are advised to ask their patients about any over-the-counter products they may be using, including products marketed as dietary supplements. Additionally, health care professionals should be alert to patients presenting with the warning signs that may be associated with the use of steroids or steroid-like substances, including liver injury, kidney failure, stroke, and hormone-associated adverse effects, such as blood clots, including pulmonary embolism and deep vein thrombosis.

Health care professionals and consumers are encouraged to report any adverse events related to the use of these products to FDA's MedWatch Adverse Event Reporting program, either online, by regular mail or by fax, using the contact information at the bottom of this page.

For more details about these products see FDA's Consumer Information piece (Consumer Update) Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like Substances.

Related Information

- FDA Warns Consumers Not to Use Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
Press Release
- Americall-labs.com VMG Global Inc 7/27/09
Warning Letter
- Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
Consumer Article
- The FDA recommends that consumers should not use body building products marketed as containing steroids or steroid-like substances
Podcast
- Body Building Products Marketed as Containing Steroids or Steroid-Like Substances

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<http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm173935.htm>

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Public Health Advisory: The FDA recommends that consumers should not use body build... Page 3 of 3

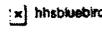
Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20852-9787

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7/30/2009

Inspections, Compliance, Enforcement, and Criminal Investigations

Americall-labs.com VMG Global Inc 7/27/09

 Department of Health and Human Services

Public Health Service
Food and Drug
Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone:
510/337-6700

July 27, 2009

WARNING LETTER

**via FedEx
via Certified Mail
Receipt Requested**

Maurice Sandoval
American Cellular Labs
117 Arcadia Drive
Pacifica, CA 94044

Dear Mr. Sandoval:

This is to advise you that your firm's marketing and distribution of the products "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" violates the Federal Food, Drug, and Cosmetic Act (the Act), as described below.

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

7/30/2009

Misbranded and Unapproved New Drugs

The product label and your Internet website, www.americell-labs.com, state that your products contain the following ingredients:

- **TREN-Xtreme:** 19-Norandrosta-4,9-diene-3,17 diene, which you state is "[s]imilar to Trenbolone"
- **MASS Xtreme:** 17 α -methyl-etioallocholan-2-ene-17b-01, which you state is "[s]imilar to Methyl Testosterone"
- **ESTRO Xtreme:** 4-hydroxyandrostenedione (4-OHA)
- **AH-89-Xtreme:** 5 α -androstano[3,2-c]pyrazole-3-one-17B-01-THP-ether, which you state is "[s]imilar to Stanozolol"
- **HMG Xtreme:** 2 α ,3 α -epithio-17 α -methyl-17 β -hydroxy-5 α -etioallocholane
- **MMA-3 Xtreme:** Androsta-1,4-dien-3,17-dione, which you state is "similar to Boldenone (Equipose)"
- **VNS-9 Xtreme:** 17 α -methyl-4-chloro-androsta-1,4-diene-3B, 17B-diol, which you state is "[s]imilar to Turinabol"
- **TT-40-Xtreme:** 1-androsterone, which you state is "very similar to 1-testosterone" and "[c]onverts to 1-Testosterone"

Further, your website includes claims about the effects of these products, such as the following:

TREN-Xtreme

- "MUSCLE ACTIVATOR"
- "DRY LEAN MASS"
- "TREN-Xtreme™ binds to the androgen receptor 300% better than testosterone. This high androgen receptor affinity means TREN-Xtreme™ delivers quality gains in muscle mass and strength."
- "These benefits mean TREN-Xtreme™ delivers hardness to go with the lean mass gains."
- "For maximum results combine TREN-Xtreme™ with proper nutrition and intense training to build high quality muscle mass, solid strength gains and maximum hardness. Get the hard body you want with TREN-Xtreme™!"
- "PRODUCT HIGHLIGHTS ...• Quality Mass Gains • Solid Strength Gains • Excellent Hardness ...• Men Wanting Dry Lean Gains & Hardness"

MASS Xtreme

- "SIZE PROMOTOR"
- "MASS POWER STRENGTH"

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

7/30/2009

- "MASS-Xtreme™ is perfect if you are focused on adding muscle mass, power and strength to your physique."
- "MASS-Xtreme™ is a potent anabolic and has low androgenic activity. In fact, tests show an anabolic activity that is two to five times that of methyltestosterone with an androgenic activity that is 0.4 to 0.6 that of methyltestosterone. The chemical structure of MASS-Xtreme™ makes it androgen receptor specific while also actively stimulating IGF-1 and myostatin mRNA expression. So you get a lot of mass building effects without a lot of unwanted androgenic effects."
- "What you do get are significant and noticeable gains in muscle mass and strength."
- "Before you know it you'll notice the gains in the gym and the mirror. Use the original mass building supplement, MASS-Xtreme™!"
- "PRODUCT HIGHLIGHTS ... • Selective Androgen Agonist • Excellent Mass Gains' Increased Strength ... • Promotes Anabolism ... • Men Wanting More Muscle Mass, Power & Strength"

Estro Xtreme

- "POWERFUL ESTROGEN BLOCKER"
- "... ESTRO-Xtreme™, the ultimate in Estrogen management and control. Estrogen can cause fat gain, gyno, water retention and bloating, all of which lead to a smooth nonmuscular appearance. Controlling estrogen is the key to developing and maintaining a lean, hard, muscular physique."
- "ESTRO-Xtreme™ prevents the production of estrogen by irreversibly binding and inactivating the aromatase enzyme, preventing the conversion of androgens to estrogens."
- "ESTRO-Xtreme™ decreases estrogen production as well, which means reduced body fat gains, less water retention, bloating"
- "4-OHA also decreases the receptor counts for both estrogen and progesterone. ESTRO-Xtreme™ blocks the conversion of androgens to estrogens and it minimizes the effect of existing estrogens by decreasing the number of receptors for estrogen and progesterone. You get two estrogen blocking effects in one fantastic product!"
- "PRODUCT HIGHLIGHTS ... • Blocks Estrogen • Minimizes Estrogen Receptors • Minimizes Progesterone Receptors ... • Men Wanting to Manage and/or Lower Estrogen"

AH-89 Xtreme

- "MUSCLE MODIFIER"
- "LEAN HARD STRONG"

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

7/30/2009

- "... AH-89-Xtreme™ is best when used for achieving a leaner and harder appearance."
- "This means mass gains will be minimal, while hardening effects will be more prominent."
- "Only mildly anabolic, AH-89-Xtreme™ has greater androgenic effects."
- "Use AH-89-Xtreme™ to take your body to new levels of lean hard muscle!"
- "PRODUCT HIGHLIGHTS ...• Muscle Hardener ...• Men Wanting to be Leaner and Harder"

HMGXtreme

- "PRO-ANABOLIC/ANTI-ESTROGEN"
- "DRY LEAN HARD"
- "The compound in HMG-Xtreme™ binds to muscle androgen receptors causing increased protein synthesis rate while also binding muscle stem cells causing them to become activated. Together these two anabolic actions increase potential muscle repair and growth."
- "Besides the anabolic effect, HMG-Xtreme™ is a tissue specific estrogen blocker. This means that HMG-Xtreme™ only binds to 17β-estradiol receptors in certain tissues such as mammary (breast). This can significantly reduce and/or even reverse gynecomastia caused by temporary elevations in estrogen. HMG-Xtreme™ specifically blocks estrogen in mammary (breast) tissue resulting in reduced size, even shrinking the tissue to pre-gynecomastia levels."
- "Superior muscle gains and estrogen management in one product!"
- "PRODUCT HIGHLIGHTS ...• Dry Lean Hard Gains • Tissue Specific Estrogen Blocker • Promotes Anabolism • Increases Protein Synthesis ...• Men Wanting Muscle Gains & Estrogen Management"

MMA-3 Xtreme

- "GROWTH PROMOTER"
- "BIG SIZE GAINS"
- "One of the main effects of MMA-3-Xtreme™ is an increased appetite, which may be the main reason for the excellent mass gains seen with its use."
- "Build the muscle size you've been looking for with MMA-3-Xtreme™."
- "PRODUCT HIGHLIGHTS ...• Excellent Mass Gains ...• Men Wanting More Muscle Mass"

VNS-9-Xtreme

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

7/30/2009

- "STRENGTH GENERATOR"
- "STRENGTH, MASS GAINER"
- "Similar in structure to oral Turinabol, VNS-9-Xtreme™ is ideal if your goal is to obtain solid muscle mass and strength gains. VNS-9-Xtreme™ works directly upon the anabolic receptors so there is no conversion needed."
- "The compound in VNS-9-Xtreme™ has a high anabolic effect and a low androgenic effect."
- "PRODUCT HIGHLIGHTS ... • Excellent Mass Gains • Solid Strength Gains Direct Receptor Activity ... • Men Wanting Solid Muscle & Strength"

TT-40-Xtreme

- "MUSCLE INITIATOR"
- "SIZE POWER STRENGTH"
- "If you are seeking to gain muscle mass along with strength then look no further than TT-40-Xtreme™."
- "You can expect mild estrogen related effects along with excellent anabolic benefits. The muscle gains from TT-40-Xtreme™ are going to be slightly more watery than some non-estrogen forming compounds, while strength gains should be superior."
- Combined with proper nutrition and intense training, TT-40-Xtreme™ will provide the anabolic/androgenic stimulus for muscle mass gains and strength increases. Lift heavier, increase your strength, and add more muscle to your physique with TT-40Xtreme™!"
- "PRODUCT HIGHLIGHTS ... • Moderately Anabolic· Mildly Androgenic • Strength Gains • Men Wanting More Size & Strength Gains"

Your products are represented as dietary supplements on their labels, on your website, and in other labeling and advertising; however, the products do not meet the definition of a dietary supplement in section 201(ff) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. § 321 (ff)). To be a dietary supplement, a product must, among other things, "bear or contains one or more ... dietary ingredients" as defined in section 201(ff)(1) of the Act (21 U.S.C. § 321(ff)(1)). Section 201(ff)(1) defines "dietary ingredient" as a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories. The substances listed as dietary ingredients on the labels of "TREN-Xtreme," "MASS-Xtreme," "ESTROXtreme," "AH-89 Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT40 Xtreme" are the synthetic steroids 19-Norandrosta-4,9-diene-3,17 dione; 17a-methyletioallocholan-2-ene-17b-ol; 4-hydroxyandrostenedione (4-OHA); 5a-androstano[3,2-c]pyrazole-3-one-17B-ol-THP-ether; 2a,3a-epithio-17a-methyl-17B-hydroxy-5a-etioallocholane; Androsta-1,4-dien-3,17-dione; 17a-methyl-4-chloro-androsta-I,4-diene3B,17B-diol; and 1-

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

7/30/2009

androsterone, respectively. None of these steroids is a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake; further, none of them is a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient. Thus, because your products listed above do not bear or contain a dietary ingredient as defined in section 201(ff)(1) of the Act, the products do not qualify as dietary supplements under section 201(ff) of the Act.

Under section 201(g)(1)(C) of the Act (21 U.S.C. § 321(g)(1)(C)), products (other than foods) that are intended to affect the structure or function of the body are defined as drugs. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution. 21 C.F.R. § 201.128. Your products are intended to affect the structure or function of the body by, among other things, building muscle, increasing strength, and affecting the levels of estrogens and androgens in the body. Accordingly, "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" are drugs.

Moreover, these products are "new drugs," as defined by 201(p) of the Act (21 U.S.C. § 321 (p)), because they are not generally recognized as safe and effective for their labeled uses. The introduction or delivery for introduction, or causing the introduction or delivery for introduction, of any new drug lacking an FDA-approved new drug application (NDA) is a violation of sections 301(d) and 505(a) of the Act (21 U.S.C. §§ 331(d) and 355(a)). Your sale of the new drugs "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" without approved NDAs violates these provisions of the Act.

Furthermore, your products are "prescription drugs" as defined at section 503(b)(1)(A) of the Act (21 U.S.C. § 353(b)(1)(A)), in that because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them. Indeed, all anabolic steroid drugs which have been approved for marketing by the FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

According to section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)), a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. Prescription drugs can only be used safely at the direction, and

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under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 353(b)(2).

In light of the fact that they are unapproved prescription drugs, the labeling of "TREN-Xtreme," "MASS-Xtreme," "ESTRO-Xtreme," "AH-89 Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40 Xtreme" fails to bear adequate directions for the products' intended uses; therefore, the products are misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)). Because they lack required approved applications, these drugs are not exempt from this requirement under 21 C.F.R. § 201.115. Therefore, the introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of these misbranded products violates section 301 (a) of the Act (21 U.S.C. § 331(a)).

Additionally, your website contains claims that "TREN-Xtreme," "MASS Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" minimize or are free from certain side effects, such as "No Estrogen Conversion," "decreases estrogen production," "without a lot of unwanted androgenic effects," "No Hair Loss," and "No Acne." At the same time, the products all contain "WARNINGS" similar to the following:

WARNING: Consult a Physician before using this product if you have, or have a family history of, prostate enlargement/cancer, heart disease, high cholesterol, kidney, liver, or hormone problems or if you are using any other dietary supplement, prescription or OTC drug. Exceeding recommended serving may cause adverse health effects. Possible side effects include acne, hair loss, facial hair growth (women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a Physician immediately if you experience adverse events.

The claims on your website concerning the side effects of these products assert that the products minimize or do not have the potential to cause certain side effects, whereas the "Warning" statements provide otherwise. These statements render the labeling of your products false and misleading. "TREN-Xtreme," "MASS Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" are therefore misbranded under section 502(a) of the Act (21 U.S.C. § 352(a)). The introduction or delivery for introduction into interstate commerce of these misbranded products violates section 301(a) of the Act (21 U.S.C. § 331(a)).

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Anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

The Act authorizes injunctions against manufacturers and distributors of illegal products, and the seizure of such products, under sections 302 and 304 (21 U.S.C. §§ 332 and 334). In addition, there is criminal liability for all violations of the prohibited acts described in section 301 of the Act (21 U.S.C. § 331). You should take prompt action to correct the violations cited in this letter and to prevent their recurrence. Failure to do so may result in enforcement action without further notice. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the cited violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please advise this office what actions you will take to address product that you have already distributed. Additionally, if another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070, Attention: Carl Lee, Compliance Officer. You may reach Carl Lee by phone at (510) 337-6737, or email at carl.lee@fda.hhs.gov.

Sincerely,

/S/

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm173874.htm>

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ATTACHMENT 4

--- On Thu, 9/24/09, ipronutrition.com <customerservice@ipronutrition.com> wrote:

From: ipronutrition.com <customerservice@ipronutrition.com>
Subject: IDS Mass Tabs Still Available
To: XXXXXXXXXXXXX
Date: Thursday, September 24, 2009, 5:54 PM

Hi,

Just a quick note to let you know that iProNutrition.com is still offering IDS Mass Tabs. And they are still available at the discounted rate of \$39.99 per bottle... a 30% savings off the list rate.

You might want to hurry, though. This hard-to-find product is quickly selling out online.

Login to your account at: <http://www.iProNutrition.com> for more savings and special deals on all major sports nutrition supplements.

Regards,
Customer Service Team
iProNutrition.com
p: 315.391.0969
e: customerservice@ipronutrition.com

This email address was given to us by you or by one of our customers. If you feel that you have received this email in error, please send an email to customerservice@ipronutrition.com

This e-mail is sent in accordance with the US CAN-SPAM Law in effect 01/01/2004. Removal requests can be sent to this address and will be honored and respected.

