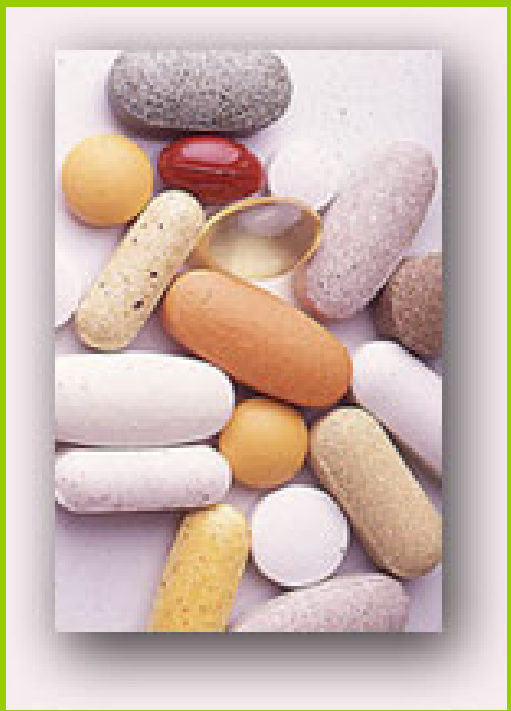
"BARELY LEGAL"

Regulation of Dietary Supplements Update



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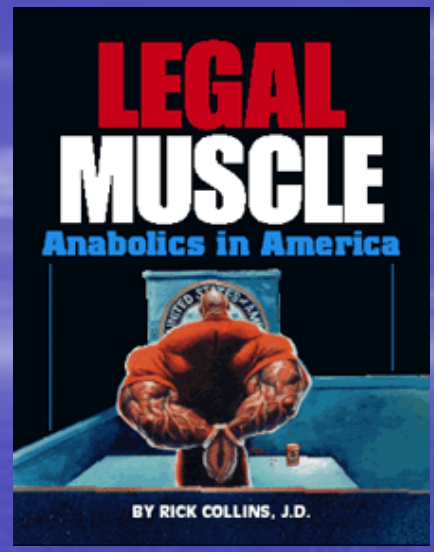

- Authored **Legal Muscle** (2002) to bridge the information gap between illicit steroid users and medical/legal authorities (www.legalmusclebooks.com)
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Being a lawyer…

- We start with

Disclaimers

Disclaimers (the fine print)

Laws and guidances are often open to varying interpretations and sometimes courts must decipher their true meaning. This may well be the case for some of the subjects presented herein, Accordingly, these materials are offered for information, not legal advice.

These materials represent the author's personal views and opinions at the time of authorship, and may be subject to change as new information is presented.

Ali G Seeks the Definition of “Barely Legal”

“Barely Legal” Sports Supplements

- What sports and fitness nutrition ingredients are under scrutiny or banned?
- Why?
- By whom?

Nutritional Supplements and Athletes

- *Ninety percent* (90%) of athletes use some form of dietary supplements, according to 2004 research by the USOC.

Sports Anti-Doping Authorities

- Sports bodies are free to create their own lists of banned ingredients, and athletes are held accountable under *strict liability* to be responsible for everything they put into their bodies.

From the U.S. Anti-Doping Agency:

ATHLETES SHOULD NOTE THAT: THE USE OF DIETARY SUPPLEMENTS IS COMPLETELY AT THE ATHLETE'S OWN RISK, EVEN IF THE SUPPLEMENTS ARE "APPROVED" OR "VERIFIED"

Athletes taking nutritional or dietary supplements may test positive for a prohibited substance which is **not disclosed on the product label**. **Sanctions are imposed** in accordance with applicable rules for all positive test results.

USADA understands that **some trade associations and reputable companies are attempting to test supplements** and even are "verifying" or "certifying" that certain nutritional or dietary supplements are safe for athletes and others to use. Athletes need to be aware that these **verification or certification programs do not guarantee** that those dietary or nutritional supplements are free from prohibited substances which can cause an athlete to test positive.

From NCAA:

What you don't know can hurt your eligibility.

Nutritional/Dietary Supplements

- Are not strictly regulated
- May contain banned substances
- May not list all contents on label
- May be legal but still contain NCAA banned substances

Consult with your institution's sports medicine staff before taking any nutritional/dietary supplement. Ignorance is no excuse!

Canadian Centre for Ethics in Sport

- **Actively discourages athletes** from using any supplement in large part due to the risk of contaminated supplements.
- Advises athletes who do use supplements to **keep a log of the supplements used, to record batch or lot numbers of the supplements, and to always keep some contents** from each container in case a problem arises that requires the product to be investigated.
- While noting that keeping this information may **not provide a valid defense** to an anti-doping violation, they say **it may allow the athlete to seek compensation from the manufacturer**.

CCES: Substance Classification Booklet

Notes:

- All athletes are responsible for ensuring that they comply with the rules and regulations of competition, which include any sport federation restrictions and the WADA Prohibited List. If you are in doubt about any substance or product, avoid its use.
- The CCES provides information services to any individual or organization seeking to know whether or not a particular substance or method is prohibited for use in sport. Please note, however, that the CCES does not “clear” or “endorse” consumer products for consumption by athletes.
- All athletes are responsible for ensuring that they comply with the rules and regulations of Canadian athletes.

Dietary substances that are prohibited in certain sports:

- **WADA**: World Anti-Doping Agency and USADA
  - **DHEA** (dehydroepiandrosterone), **ephedrine** [when its concentration in urine is greater than 10 micrograms per milliliter], **octopamine**.
  - The WADA Code explicitly states that **caffeine**, **pseudoephedrine** and **synephrine** are NOT considered Prohibited Substances, but ARE included in the 2007 Monitoring program, along with: bupropion, phenylephrine, phenylpropanolamine, and pipradol.
  - Desoxymethyltestosterone, Methasterone, Boldione and Prostanozol

College Sports

- NCAA: National Collegiate Athletic Association
  - **DHEA** (dehydroepiandrosterone), **ephedra**, **ephedrine**, **Ma Huang**, **synephrine** (also ***citrus aurantium***, ***zhi shi***, ***bitter orange***), **caffeine** (***guarana***) [if the concentration in urine exceeds 15 micrograms per milliliter]

Professional Sports

- NBA:
  - **DHEA** (dehydroepiandrosterone), **ephedra**, **ephedrine** and **pseudoephedrine**
  - Currently found on the dietary supplement market: **Desoxymethyltestosterone**
- NFL:
  - **DHEA** (dehydroepiandrosterone), d**esoxymethyltestosterone, 6-oxo, ephedrine**, **pseudoephedrine** and s**ynephrine**
- MLB:
  - Only **Desoxymethyltestosterone; not DHEA**
  - MLB has also reached an agreement with NSF regarding certification of certain dietary supplements.
- NHL:
  - The NHL has agreed to use the Prohibited Substances List maintained by WADA for “out-of-competition” testing. Changes to the items included on the Prohibited List can only be as negotiated by the NHL and NHLPA.
  - The PESC (Performance Enhancing Substance Committee) is currently compiling a list of supplements that are certified as safe from contamination and disallowed performance enhancing ingredients.

Substances banned by some sports but not by others

- **Octopamine** is banned by WADA
- **Synephrine** is banned by NCAA and NFL
- Certain “prohormone / prosteroid” products found on the dietary supplement market are explicitly banned by WADA and NBA, NFL and MLB
- **Pseudoephedrine** is banned by NBA and NFL
- With the exception of MLB, **ephedrine** is banned across the board!!!

NFL - BANNED COMPANIES!!!

- NFL:

  - Compiled “a list of companies in which players are prohibited from participating in any endorsement agreement because they manufacture products that are on the banned substance list.”

  - Currently, the list includes some sixty-six (66) companies.

Supplements in court…

- Some drug-tested competitive athletes who flunk their doping tests blame supplement contamination.
- If one of these products really is contaminated, it quickly slips into the “barely legal” category.

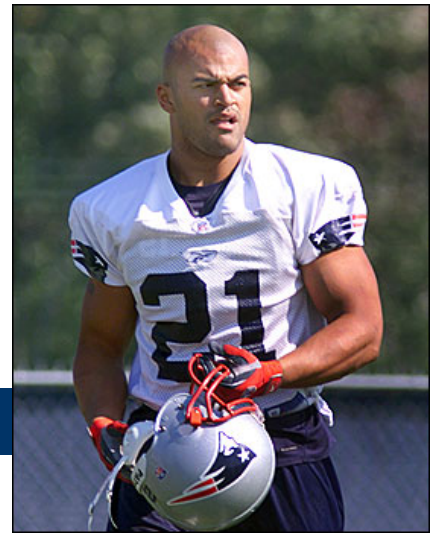
Enter the *lawyers*…

- Highly publicized cases have shown that when athletes fail drug tests, tainted dietary supplements may be blamed and expensive litigation may follow … seeking not only compensation for lost potential income during the ever-lengthening suspensions from athletic bodies and the tarnishing of their names in the press … but punitive damages in the **tens of millions**.

U.S. Tennis Player
Graydon Oliver

- Tested positive for the active ingredient in Librium and a prescription diuretic which could be used as a masking agent.
- The label of the dietary supplement did not list the banned substances.
- ATP panel found that Oliver was aware of the ATP warnings regarding using supplements and that he failed to investigate the product as thoroughly as possible.
- Allegedly the store owner, even after being informed that the user is a pro athlete subject to mandatory testing, told Oliver's mother who purchased the product that the dietary supplement was safe for all sports organizations as it contained no banned ingredients. **Graydon has brought suit alleging $15 million in damages** (economic and non-economic losses). No settlement was disclosed.

NFL Running Back
Mike Cloud



- Tested positive for norandrostenedione and androstenediol, blaming a product called Nitro-Tech™ powder sold by Muscle Tech. No prohormones were listed on the label.
- Muscle Tech countersued, claiming that Cloud's allegations are false and amount to trade libel and product disparagement.
- Muscle Tech asserted that the product has passed purity tests and that the manufacturing partner has "certifications that its processes are pure" and that they follow GMP's. No steroids are stored at the facility, nor do any ingredients of the products manufactured at the facility contain any steroids. They are seeking $25 million from Cloud.
- No resolution or settlement was publicly disclosed.

U.S. Bobsledder

Pavle Jovanovic

- Used the same product as Mike Cloud.
- Tested positive for 19-norandrostenedione he claims was from a supplement made by Muscle Tech and purchased from GNC.
- Alleged that the manufacturing partner failed to monitor the production of the product or to perform testing on its product that would indicate the presence of those undisclosed ingredients.
- RESOLUTION: U.S. District Judge Dale Kimball dismissed the lawsuits at the request of Jovanovic and the companies. Daniel Fleck, attorney who represented Jovanovic, said the matter has been resolved. Fleck declined to say whether there was a monetary settlement.

World-class Swimmer
Kicker Vencill

- Tested positive for the anabolic steroid nandrolone and received a two-year suspension.
- Blamed it on contaminated multivitamin capsules made by Ultimate Nutrition. He sued, went to trial, and received a near $600,000 jury verdict that was later appealed and the case settled out of court.
- Ultimate Nutrition alleged that the product was “not being used in the way it was intended to be used” and that the product was “modified or altered” after it left the company’s control.

Vencill now says:

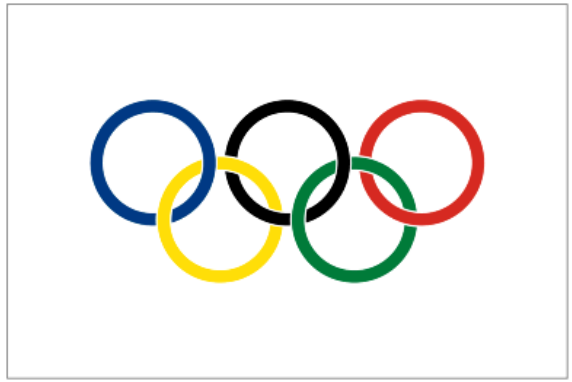
What have you learned about the dietary supplement industry? Do you think that dietary supplements are safe?

-- In my opinion, there are probably some reputable companies out there, and I'm not against supplements. But you have an issue with the industry. I learned personally that some manufacturing practices might be standard for the industry, but in my mind, from a quality aspect for the consumer, they're pretty poor….

Knowing what you know now, would you have done anything differently?

-- Knowing what I know now … [t]he only way I could ever take a multivitamin again is if it was approved by the FDA, and I had a doctor prescribe it to me. It's unfortunate I have to say that, but it's the truth. … So beware, coaches, parents and athletes. Be careful what you're giving your kids.

Cause for Concern…?



- A 2002 IOC Study titled, “Analysis of Non-Hormonal Nutritional Supplements for Anabolic-Androgenic Steroids” done by an IOC accredited drug testing laboratory found 94 of the 634 (14.8%) dietary supplement samples it studied contained substances not listed on the label that would trigger positive drug tests. The dietary supplements were from twelve (12) different countries. **Those from the U.S. tested positive in 45 of the 240 products tested, a failure rate of 18.8%.**
- During the 2002 Salt Lake Winter Games, athletes from the Netherlands submitted 55 supplements to be confidentially analyzed for banned substances. **25% of the supplements tested positive for prohibited substances**.

An Unregulated Market?

- Why are so many people and organizations saying the supplement industry needs more regulation to be safe?

- What effect will their voices have?

The Dietary Supplement Health and Education Act of 1994 (DSHEA)

- Passed with the unanimous consent of Congress;
- Provoked by FDA's anti-supplement tactics;
- Enacted because FDA was viewed as distorting the law that existed before DSHEA to try improperly to deprive the public of safe and popular dietary supplement products.

FDA Rendered Powerless…?

- Anti-supplement critics say: *Yes!*
- Pro-supplement consumers and marketers say: *No way!*
- *Adulterated* supplements:
  - Imminent hazards are removed from the market;
  - But even those that DON'T present an imminent hazard may be banned.

Unsafe supplements

- DSHEA provides that a supplement shall be deemed adulterated if it presents "a significant or unreasonable risk of illness or injury under … conditions of use recommended or suggested in labeling, or … if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use" [under 21 U.S.C. § 342(f)(1)(A)].
- Doesn't require proof that consumers have actually been harmed, or even that a product will harm anyone.

Are Supplements Devoid of Risk?

- No way. Nothing is.
- How do the risks compare?
  - Tobacco (over 440,000 deaths annually)
  - Adverse Reactions to FDA-approved medicines (108,000 deaths annually, 7,000 of which are medication errors)
  - Alcohol (approximately 85,000 deaths annually from excessive or risky drinking)
  - NSAIDS and aspirin (estimated 7,600 deaths and 76,000 hospitalizations annually)

FDA's Failure to Enforce?

- Pro-supplement folks say DSHEA provides all the regulatory authority FDA will ever need.
- They say the concerns of supplement skeptics can be addressed if FDA would only *act!*
- After 10 years without much action, FDA took action in 2004.

Ephedra Dietary Supplements

- In 2004, FDA issued a final rule banning dietary supplements containing ephedra alkaloids.
- Followed deaths of Steve Bechler and Korey Stringer and a tornado of bad press.
- But…was it the end of the story?

EPHEDRA RETURNS!

- On April 13, 2005, a federal court in Salt Lake City [U.S. District Court for the District of Utah, Central Division] issued its decision on a legal challenge to FDA's 2004 Final Rule banning all ephedrine-alkaloid dietary supplements…

The Judge held…

1) The legal analysis used by FDA was incorrect and improper.

   FDA's analysis weighed risks against benefits.

   DSHEA, however, requires a straightforward *risk* assessment.

The Judge held…

2) Requiring supplement companies to demonstrate a *benefit* as a *pre-condition* to marketing violated DSHEA by shifting the burden from FDA to industry.

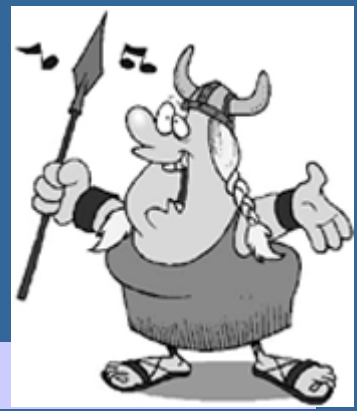
The Judge held…

3) FDA didn't have adequate scientific evidence to find that a daily dose of

10 mg. or less of ephedrine alkaloids

presented a "significant or unreasonable risk of illness or injury" … so the Court effectively held that it's improper to ban all ephedra supplements because FDA lacks data to determine what dosage might be safe.

Was it really over…?

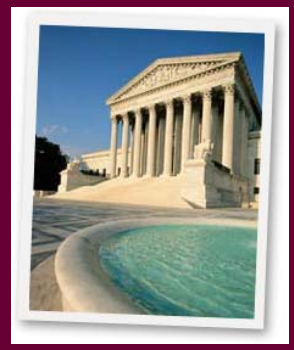


- No…
- On June 13, 2005, FDA filed a notice of appeal, and the 10th Circuit Court of Appeals reversed the District Court's ruling.
- However, FDA did not seek a stay to block renewed ephedra sales while the matter was pending.

Overturned…

- On **August 17, 2006**, the U.S. Circuit Court of Appeals in Denver reversed and remanded the Utah ruling that challenged the FDA ban on products containing ephedra. The Federal Appeals court overturned Judge Campbell's decision, ruling that the FDA was correct in its 2004 analysis of ephedrine products, concluding the FDA had properly examined the facts when it ruled, in 2004, that dietary supplements containing ephedrine alkaloids present an "**unreasonable risk of illness or injury**," and that there is no acceptable dose of the ingredient. Pursuant to this the government has since seized numerous products containing the herbal ingredient.

Final Decision
U.S. Supreme Court?



- Following the Federal Appeals court decision, Nutraceutical filed a petition for Rehearing on September 28, 2006.
- The petition was denied, and Nutraceutical filed a petition for a writ of certiorari to the **United States Supreme Court**.
- On March 16, 2007, the Federal District Court in Utah ruled in favor of the FDA, finding that FDA's rulemaking with regard to dietary supplements containing ephedrine alkaloids was procedurally and substantively proper, granting FDA's cross-motion for summary judgment.
- The U.S. Supreme Court denied Nutraceutical's petition for certiorari on May 14, 2007, refusing to consider their appeal. This is likely the final action in this case, establishing a **precedent** for the applicable legal standards and confirming the FDA's regulatory authority over the issues.

FDA Targets the Next Ephedra?

- Citrus Aurantium, also known as synephrine, is a herbal stimulant similar to ephedra. The extract comes from a fruit and is also known as green orange, sour orange, and bitter orange.
- In the preamble to the final rules banning dietary supplements containing ephedra in February 2004, FDA repeatedly expresses that concerns about the safety of ephedra also extend to similar products, which would include bitter orange.
- On pages 194-5 of the prepublication version of the final rule, FDA says:

"Synephrine is a sympathomimetic agent, and these agents are a class of compounds that also includes ephedrine alkaloids. A number of other potential herbal sources of sympathomimetics probably exist. These ingredients may pose risks that are similar to those of ephedra. If consumers switched to substitute products containing these ingredients, similar health risks might be expected as those with products containing ephedrine alkaloids." **(FDA, 2004).**

The Future of Bitter Orange?

- With mounting concern about potential safety issues being expressed by media, health authorities and government officials, the future of bitter orange and its principal alkaloid synephrine as dietary supplement ingredients is uncertain.
- Synephrine's chemical similarity to ephedra, and the possibility that it may exhibit pharmacologically similar yet milder activity (even without any CNS activity), would appear to be negative strikes against it.
- Like ephedra, whose alkaloids are FDA-approved drug ingredients, bitter orange's synephrine also has the potential disadvantage of being recognized as a drug. The potentially saving grace related to bitter orange is that it is a food and it is GRAS, albeit in serving sizes that are presumably significantly smaller than the synephrine levels in many supplements.

The BIGGER picture

- **The decision may have key implications *beyond* ephedrine alkaloids and bitter orange.**
- **Critics have renewed their cries to *repeal or reform* DSHEA, saying that the ruling is evidence that DSHEA prevents FDA from pulling dangerous products from store shelves.**
- **The watchdog group Public Citizen claims DSHEA has been a “disaster” and should be repealed.**

…Some in Congress Think So

- On March 9th, 2006, the House Committee on Government Reform held a hearing on "*The Regulation of Dietary Supplements: A Review of Consumer Safeguards*." During the hearing, **Congressman Henry Waxman of California stated his view that "FDA lacks the legal authority and political backing to protect the public."** He voiced concerns about issues such as labeling, contamination, Adverse Event Reports (AER's) and lack of a pre-market review of the efficacy and safety of dietary supplements.

Amending DSHEA

- At the March 9th hearing, Congress also received testimony from representatives of four major organizations that perform testing on dietary supplements: NSF International, U.S. Pharmacopoeia (USP), Consumerlab.com and Consumers Union. Their testimony included discussion of their testing methods and the problems they perceive with quality control and safety of dietary supplements.
- The **general consensus was that Congress should amend the Dietary Supplement Health and Education Act (DSHEA) to include mandatory pre-market testing** of all dietary supplements, or at a minimum, certain categories of dietary supplements.

New Legislation… Update

- Senate Bill 1082:

Controversial or Misunderstood

Subtitle B of Title II of S. 1082, establishes the Reagan-Udall Foundation for the Food and Drug Administration. The simple purpose of the non-profit Foundation is to lead collaborations among the FDA, academic research institutions and industry designed to bolster research and development productivity, provide new tools for improving safety in regulated product evaluation, and in the long-term make the development of those products more predictable and manageable.

Congressional Clarification

- SEN. KENNEDY: Let me make absolutely clear that the Reagan-Udall Foundation will in no way override, overturn or conflict with the Dietary Supplement Health and Education Act. Nothing in this bill would have that effect.
- SEN. ENZI: Yes, we took great pains to make certain there would be no conflict with DSHEA. Regarding foods, and dietary supplements are generally regulated as foods, the general directive of the Foundation is to identify holes in the evaluation of food safety and identify ways to address those deficiencies through collaborative research with industry.
- SEN. HARKIN: So, to make this absolutely clear, what you are saying is that the bill we are debating would in no way interfere with consumers' access to dietary supplements?
- SEN. HATCH: To add to that point, it seems that the language could, in fact, help dietary supplement consumers, because it would allow collaboration between government and industry to conduct research on issues that might be helpful to supplement consumers?
- SEN. KENNEDY: Yes, that is the case.

Supplement Adverse Event Reporting

- Most within industry have believed that a system of reporting adverse events would help promote confidence in dietary supplements and in DSHEA.
- S.3546 - the Dietary and Supplement and Nonprescription Drug Consumer Act was passed by Congress in December. The House adjourned a few minutes after it passed the Bill by a 2-1 majority. It still awaits the President's signature. The legislation was supported by industry.
- The bill affects not only dietary supplements but OTC products.
- Must report **serious adverse events** associated with product use to FDA.

Serious Adverse Event (SAE) Reports

- A manufacturer will be required to submit a serious adverse event (SAE) report, defined as an adverse event that results in death, a life-threatening experience, in-patient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect.
- An adverse event is defined as an event that occurs after overdose, abuse, drug withdrawal and failure of expected pharmacological actions of the drug.
- The report must be filed with the FDA no later than 15 business days after the report is received by the manufacturer, using the MedWatch form.
- Requirement pre-empts any local or state laws.

New SAE Reporting Law

- Bill takes effect one year after passage [DECEMBER 22, 2007].
- Manufacturers of dietary supplements and OTC products must begin to prepare and design internal means of compliance.
- A supplement retailer whose name appears on the label may authorize the manufacturer to report SAEs for them. All labeling must show a domestic address OR telephone number through which a person may report an SAE, otherwise the product will be deemed misbranded.
- For dietary supplements, that labeling provision goes into effect, but there will be a guidance issued to explain the data elements that would be included in an SAE.

Meanwhile… Reporting (AERs)

- FDA can be contacted to report general complaints or concerns about food products, including dietary supplements.
- If you think you have suffered a serious harmful effect or illness from a dietary supplement, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or using the website http://www.fda.gov/medwatch/report/hcp.htm.
- The MedWatch program allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices and dietary supplements. The identity of the patient is kept confidential.

“Prohormones”

- Another category of products has been a major focal point for criticism of DSHEA.
- Started with androstenedione (“andro”), introduced in the mid 1990’s.
- Promoted as a natural way to help increase strength and muscle mass in athletes and to combat the effects of the aging process in older men, much of which is attributed to declining testosterone levels.
- Andro is a naturally derived precursor to testosterone.
- Converts directly to testosterone in the metabolic pathway.

The Andro Scandal

- Andro achieved national notoriety in 1998 when a bottle was spotted in the locker of St. Louis Cardinals slugger Mark McGwire.
- In the years that followed, Andro was followed by other steroid precursor pills – commonly called "prohormones" by industry and consumers – marketed to increase lean body mass.

Prohormone Problems

- Perceived health risks;
- Defied traditional sports values: pills that might give the player who swallowed them a chemically-induced advantage over the player who didn't;
- Some steroid precursors shared metabolites with banned anabolic steroids, raising the specter of false positives [norsteroid prohormones, for example];
- Traditional drug screens might fail to detect some of the newer "designer" steroid configurations;
- Poor quality control at manufacturing: possibility that some dietary supplement products might inadvertently contain steroid precursors by "cross-contamination," resulting in false positives for anabolic steroids.

The Push Toward Regulation

- The obvious first step toward a solution was to ban steroid precursors in sports;
- However, the products remained on the public market as popular over-the-counter dietary supplements;
- Continued availability undermined the message of the sports authorities;
- Array of new compounds forced a process of constant vigilance and revision of drug screens;
- Outraged anti-doping authorities demanded federal legislation to remove “legal steroid products” from the market. Coalitions were formed, lobbyists were engaged, and several bills were introduced on Capitol Hill;

A Decade Earlier…

- Congress added steroids to the federal Controlled Substances Act [21 U.S.C. § 802(41)(A)] in 1990.
- Simple unlawful possession became punishable by up to one year in prison.
- Unlawful distribution and possession with intent to distribute became punishable by up to *5 years* in prison.
- Unlawful distribution and possession with intent to distribute to an individual under 21 years of age became punishable by up to *10 years* in prison for a first offense and up to *30 years* for a second.

The New "Anabolic Steroid Control Act of 2004"

- Adds many new steroids and formerly over-the-counter "prohormone" dietary supplements to the Controlled Substances Act;
- *Does* include androstenedione, androstenediol, and many others, such as THG;
- Does *not* include DHEA*;
- Took effect on January 20, 2005;
- You can be arrested for possessing prohormones.

"*Anabolic Steroid*" as Legally Re-Defined as of January 20, 2005

- Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and DHEA) *regardless* of its ability to promote muscle growth and on an expanded list of 49 compounds.

The END of the Prohormone Story…?

- Nope!
- 109th Congress: In March of 2005, Sen. Grassley and Rep. Sweeney, introduced legislation in the House and the Senate to add DHEA to the list of controlled substances. With the help of Sen. Hatch, industry lobbied against the legislation and both bills died in Committee.

Relentless…DHEA under fire AGAIN!

- 110th Congress: On March 5, 2007, Senator Grassley again proposed legislation that seeks to "include *dehydroepiandrosterone* (DHEA) as an anabolic steroid." S.762 is identical to the previous legislation and has been referred to the Committee on the Judiciary, pending approval by the Senate.
- H.R.1249 is the related bill proposed by Rep. Peter Roskam in the House of Representatives, which is identical to S.762. Once again the dietary supplement industry may need to call on Sen. Hatch for his support in defeating this legislation.

Sen. Grassley says…

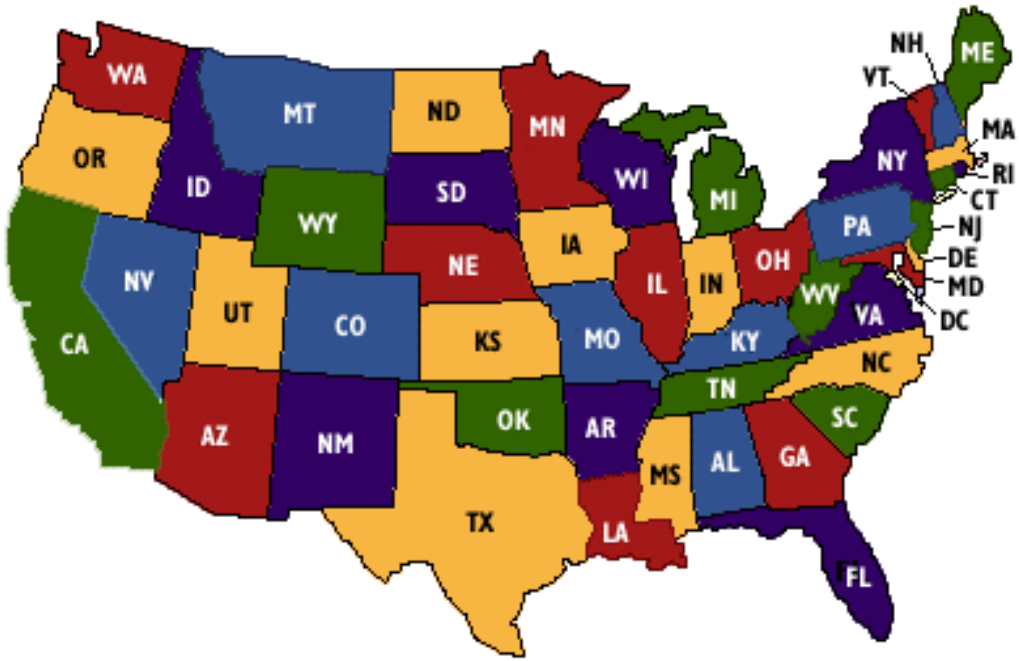
- **On March 5, 2007:** Statement before the Senate

  "DHEA, is a steroid hormone that when ingested in the body, is converted into other more powerful steroid hormones including Andro and Testosterone."

  "DHEA like all other steroids, may cause a number of long-term physical and psychological effects. Women could experience facial hair growth, scalp hair loss, deepening of the voice, and increased girth. Men could experience increased blood pressure or breast enlargement. Unfortunately, side effects associated with hormones don't always appear right away. While these effects may be mild at low doses, according to many experts high levels of DHEA might promote liver damage and cancer of the breast or prostate over time. The truth is we know very little about DHEA's long term effects. "
- **Truth:** DHEA has been an enormously popular supplement for middle-aged and elderly Americans. Mature consumers will likely refute the adverse health effects claimed by Sen. Grassley and even be offended by his initiative to criminalize their conduct and jail them for possession.

State Laws to come…

- The states have already begun amending their laws to the new federal steroid law.
- *www.steroidlaw.com*



FDA’s Initiatives

- After a ten year period of passivity, FDA has rediscovered supplements;
- Has begun using DSHEA to regulate industry;
- Has coordinated with FTC to more vigorously regulate dietary supplement claims and advertisements.

1) New Dietary Ingredients

- Quote from the former head of FDA:

  “One of the initiatives under our new umbrella strategy is intended to result in clarification of when a dietary ingredient is a "new dietary ingredient" for which notification is required and what safety information should be sent to FDA before marketing of the product.” – L. Crawford

Dietary Ingredients

- **21 U.S.C. 350b(c)** - The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined both of the terms "dietary ingredient" and "new dietary ingredient" as components of dietary supplements. In order for an ingredient of a dietary supplement to be a "dietary ingredient," it must be one or any combination of the following substances:
  - a vitamin,
  - a mineral,
  - an herb or other botanical,
  - an amino acid,
  - a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
  - a concentrate, metabolite, constituent or extract.

New Dietary Ingredients (NDIs)

- A new dietary ingredient is a dietary ingredient that was not marketed in the United States before October 15, 1994.
- A new dietary ingredient is deemed adulterated and subject to FDA enforcement sanctions unless it meets one of two exemption criteria: either (1) the 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” provided by the manufacturer or distributor to FDA at least 75 days before introducing the product into interstate commerce.
- There is yet no guidance as to what evidence is required to establish a reasonable expectation of safety.

FDA to Tighten Regulation of NDIs

- FDA held a Public Meeting in November, 2004 regarding the Pre-Market Notification Program for NDIs.
- Co-authored "Comments on FDA's Pre-market Notification for New Dietary Ingredients," available through a link on the "Sports Nutrition" page of the CMG Web site at www.cmgesq.com.
- FDA's Web site offers guidance on the pre-market notification process for NDI's at http://www.cfsan.fda.gov/~dms/dslg-7.html. But…

2) Good Manufacturing Practices

- DSHEA has *always* included authorization for the Government to issue regulations prescribing good manufacturing practices specifically for supplements, rather than the generic ones applicable to all foods. Accordingly, the FDA issued a *proposed* rule about good manufacturing practices back in 1997. But then it let ten long years go by – despite repeated demands from Congress and industry – before issuing its *final* rule on the subject.

GMP's are Announced!

- The final rule has just been announced – all 1,300 pages of it! What does it mean for consumers? Supplement products will be required to meet new government standards to show they're free of contamination and contain exactly what the label says. Companies will have to test purity, strength and composition.
- The rule, with limited exceptions, applies to all domestic and foreign companies that manufacture, package, or hold dietary supplements intended for sale in U.S. commerce, including those involved with the activities of testing, quality control, packaging, labeling, and distributing. The largest companies will need to comply by next June; the smallest businesses (>20 full-time employees) by June 2010.

3) Substantiation of Claims

- "The third major initiative under our overall implementation strategy for DSHEA will center around protecting consumers against dietary supplement manufacturers who make false or misleading claims, including unsubstantiated claims for their products. We will also continue to monitor and evaluate dietary supplement labeling, including labeling claims and accompanying literature such as flyers, brochures, and catalogs; and will take enforcement action against products whose labeling fails to reveal material facts such as interactions with prescription drugs. Based on our review of all this information, FDA expects … to articulate a substantiation standard of 'competent and reliable scientific evidence' … consistent with the FTC standard for advertising." – L. Crawford

Guidance Documents

- Section 403(r)(6) of the Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading.
- FDA has released a guidance document, intended to describe the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate such a claim.
- Substantiation for Supplement Claims Draft Guidance (Nov. 2004)
  http://www.cfsan.fda.gov/~dms/dsclmgui.html
- Dietary Supplement Labeling Guide (April 2005)
  http://www.cfsan.fda.gov/~dms/dslg-toc.html

Draft Guidance: Complementary and Alternative Medicine

COMPLIMENTARY AND ALTERNATIVE MEDICINE PRODUCTS AND THEIR REGULATION BY FDA

http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0480-gld0001.pdf

- **Q: Does this Draft Guidance change how FDA regulates dietary supplements?**
- A: No – The Draft Guidance provides FDA's proposed definition of CAM products (Complimentary and Alternative Medicine Products) and explains how these products, depending on how they are labeled and marketed and for what specific intended uses, will fall into existing FDA regulatory categories such as "drugs," "biologics," "devices" or "foods" (which include "dietary supplements").
- **Q: Can dietary supplement products still be marketed with structure/function claims?**
- A: Yes – The Draft Guidance has no impact on legal structure/function claims for foods or dietary supplements, and does not change how products making such claims will be regulated.

Complementary and Alternative Medicine (cont'd)

- **Q: If a dietary supplement manufacturer or its representatives make oral or written claims for a dietary supplement that the product will help prevent or treat a disease, how will the product be regulated according to the Draft Guidance?**
- A: As an illegal drug -- Disease prevention or treatment claims, such as curing or preventing cancer, diabetes, arthritis or other disease, would cause FDA to regulate the dietary supplement as an illegal drug, with the exception that if there is an FDA-approved health claim, disease prevention claims might be legal. Disease treatment claims for dietary supplements were illegal before the issuance of the Draft Guidance and continue to be illegal. Claims to decrease risk or prevent disease should not be made in the context of the sale of dietary supplements without first confirming that such claims are legal as a result of an FDA-approved health claim.

4) Enforcement

- FDA and FTC continue to work together to regulate the dietary supplement industry. There is an increased sharing of information and overlapping of jurisdiction with regard to marketing and advertising of dietary supplements.

FTC Plans to Continue Policing Supplement Marketers

- In its 2007 Budget Justification Summary, the Federal Trade Commission warned that in the coming year it will continue to scrutinize dietary supplement marketing practices. The FTC highlighted health products, including dietary supplements, as a key area on which it will be keeping an eye.
- *"The deceptive marketing of products that may affect consumer health and safety will continue to be an FTC priority. The FTC will focus on health care products, including dietary supplements. Consumer demand for such products is increasing, and fraudulent or deceptive claims about these products can pose risks to consumers' well-being. Going forward, the FTC will continue its aggressive program by focusing its law enforcement on violations that create the greatest risks to consumer health."*
- *-2007 Budget justification summary: http://www.ftc.gov/ftc/oed/fmo/budgetsummary08.pdf*

Testimonials in Advertising

- One area where supplement marketers can expect greater scrutiny from the FTC is in the use of testimonials. Recently, FTC published "Guides Concerning the Use of Endorsements and Testimonials in Advertising" and requested public comment. According to FTC, the Guides "are designed to assist businesses and others in conforming their endorsement and testimonial advertising practices to the requirements of the FTC Act."

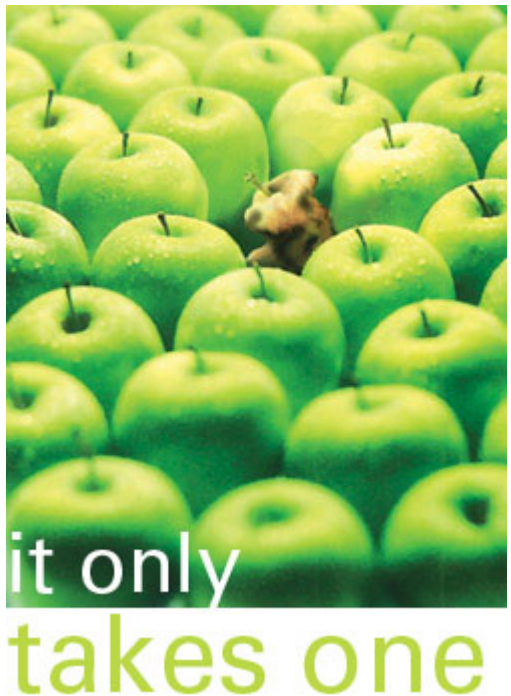
- **The focus is clearly on the use of testimonials in supplement advertising, as there are two past studies, one conducted in 2003 and the other in 2004, which have led to increased FTC intervention today. These two studies have led to the proposed FTC "Guides Concerning the Use of Endorsements and Testimonials in Advertising".**

FTC Targets Bogus Anti-Aging Claims for HGH Pills and Sprays

- ***Settlement Provides Up To $20 Million In Consumer Redress***
- Two Florida businesses agreed to a federal court order requiring them to pay up to $20 million in consumer redress – the largest monetary judgment ever obtained in an FTC health fraud case – to settle charges that they deceptively claimed that their pills and sprays would increase consumers' human growth hormone (HGH) levels and provide anti-aging benefits, including weight loss and increased cognitive function.
- FTC has also issued warning letters to more than 90 Internet marketers making similar claims.

FDA versus Industry

- The perception continues among the sports and fitness supplement industry that FDA is *anti-supplement*.
- Bad apples in the industry spoil FDA's perception of industry.
- These perceptions impact the actions, philosophies, and attitudes of *both* sides.



And so, there will always be “Barely Legal” Supplements!

For more information on supplement legal issues:

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