Supplements and Ergogenic Aids

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Introduction

• Registered Dietitian working with USADA
  ▫ Review TUEs to track supplement usage
  ▫ Educational material
    ▪ 100% Me
    ▪ That’s Dope
    ▪ Athlete Nutrition Manual
  ▫ Nutrition Resource for Employees going into the field to speak to athletes
    ▪ International competitions, OOC Testing, Training camps

USADA
National Anti-Doping Agency

• Independent and external
• Non-governmental agency
• Charged with upholding the Olympic ideal of fair play, and representing the interests of Olympic, Pan American Games, and Paralympic athletes
  – Sample Collection/Testing
  – Results Management
  – Research
  – Education

The conundrum...

• Athletes want a quick, easy fix to put them at the head of the game, or to the finish line faster
• Sports Dietitians are asked to provide advice for safe and reliable sources to get dietary supplements
• Dietitians often first look for efficacy without considering safety
  ▫ May take safety for granted?
  ▫ Assume the supplement is good source of ingredient.
  ▫ Overlook dose size and how it will effect performance and health

There are problems with supplements

• Positive doping tests (Kicker Vencill)
• Among other adverse findings...

• Dietitians have a very difficult job
  ▫ Identifying SAFE and EFFECTIVE supplements for athletes is near impossible
    ▪ What if one of your athletes tests positive?
    ▪ What if one of your athletes has adverse side effects from the supplement (health or performance)

Kicker Vencill Tests Positive

• Jan. 21st, 2003: US National Swimmer
• GNC Mega Men MVI Containing DHEA
• Dehydroepiandrosterone (DHEA) is a dietary ingredient that was marketed in the United States before Oct. 15, ’94.
• DHEA is subjected to extensive metabolism forming a multitude of metabolites
• 19-Norandrosterone (what Vencill actually tested positive for) is also the basic skeleton structure for a family of C18 steroidal compounds called “dehydronorandrosterones”.
• Intentional or unintentional contamination?
Kicker Vencill - The Verdict

Vencill sued the manufacturer, Ultimate Nutrition of Farmington, Conn., after having his own, independent tests done on the supplements.

Court documents revealed that laboratory testing of the multivitamin demonstrated that it was “contaminated by three anabolic agents...in sufficient concentrations to have caused the positive doping results.” (Court of Arbitration for Sport..CAS, pp. 7-9).

The CAS noted that, “Vencill has definitely established that the Ultimate Nutrition Super Complete Capsules that he was taking...were contaminated with steroids.

Vencill received a judgment of $578,000 in May, 2005, but his suspension from swimming was never reduced nor set aside, and he missed a shot at the 2004 Athens Olympics while adjudicating the matter.

Dietary Supplements and Doping

How did we get here?
- Government control of foods and drugs
- Dietary Supplement Health and Education Act (1994)
  - Emphasizes access over safety

Dietary supplements and doping offenses
- Prohibited substances masquerading as dietary supplements
- Contamination of dietary supplements
- Controlling risk

Who’s in charge of regulation?
- Governmental control of foods and drugs
  - Food and Drug Administration (FDA)
  - Dietary ingredient
  - Drug
  - Federal Trade Commission (FTC)
  - Inappropriate labeling claims
  - Inaccurate labeling claims
  - Drug Enforcement Agency (DEA)
  - Steroids are Schedule III Controlled Substances (1991)
  - Additions to Schedule III

Dietary Supplement Health and Education Act (DSHEA)

- DSHEA does not require that a company register its dietary supplement with any agency
- DSHEA specifically restrained the DEA and FDA from using regulatory authority with respect to supplements
- DSHEA “grandfathered in” any dietary ingredient in use before 1994

A dietary ingredient is:
- 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 total dietary intake; or
- a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.
Functional Foods and Beverages and the Similarities and Differences from Supplements

- FDA does not have a classification for “functional” products (Bars, RTD’s, Protein Powders and Gels).
- Current draft guidance has been published from FDA on this product category – It is food or supplement, depending on ingredients.
- Ingredient sourcing is the same as supplements, opening up to the same contamination issues and sources, many from China and India.
- Intentional labeling of supplements as food to keep below banned substance certification radar a growing trend.

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Feb 3rd, ‘09: Dietary Supplement Safety Act

- John McCain (R-AZ) and Byron Dorgan (D-ND)
  - Calls on Congress; Act Swiftly to Protect Consumers from Tainted, Toxic Supplements (S. 3002)
  - AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT…
  - www.opencongress.org/bill/111-s3002/text

- In announcing today’s press conference, Senator McCain’s office identified several groups that support the yet-to-be-introduced legislation. These include USADA, as well as the National Basketball Association, the National Football League, the National Hockey League, the United States Olympic Committee, the American College of Sports Medicine, National College Athletic Association and the PGA Tour.

Industry Pushback Well Organized & Funded

- Industry position... already adequately regulated, only a few bad eggs and athletes who blame supplements the real problem, not the industry.
- Hatch & Harkin... "Industry Champions"
- National Products Association (NPA)....
- The Council For Responsible Nutrition (CRN)
- American Herbal Products Association (AHPA)

Contamination

- Supplements may be adulterated by substances not shown on the label
- A number of published studies show that up to 20% of selected supplements are contaminated
- Some studies demonstrated that there are significant difference between lots of the same dietary supplement

Coalition for Anabolic Steroid Precursor and Ephedra Regulation (CASPER)

- 2004 Steroid Controlled Substance Act modified to add more substances by name including a number of compounds that were contaminants
- Procedure to add substances to Schedule III was modified...
Dietary Supplements

- Inaccurate or confusing labeling
  - Companies intentionally use outmoded nomenclature apparently to confuse consumers and regulators
  - Etioallocholanolone = androsterone
  - 10,13-dimethyl-3-hydroxy-gona-17-one = androsterone

- Contents may not be what is stated on the label
  - Missing active ingredients
  - Alternative active ingredients

- Label suggests that contents are from a botanical (e.g., geranium oil) when the contents are actually a concentrate that potentially contains a Prohibited Substance

Designer Steroid Supplements

Take Home Messages:
1. Be sure your supplier is compliant.
2. Why do you get your supplement information from?
3. Don’t fall for the quick fix – Pills don’t add 20 lbs of lean body mass. You can’t analogously have more fat and lose weight without eating.

Unsafe and Contaminated Supplements

- “American Roulette”
  - More than 140 contaminated products identified by FDA
  - Ingredients have not been tested for safety

- Majority of consumers believe that dietary supplements must be approved by a government agency
- Two thirds of consumers believe that the Federal government requires labels to include warnings about side effects and dangers
- One third of 300 internal medicine residents believed dietary supplements required FDA approval

- Some contain drugs or drug analogs that could result in heart attacks, fulminant hepatic failure, or other serious adverse reactions

(New England Journal of Medicine 2009; 361: 1523-5)

Managing Risk

- Informed consumers
- Good Manufacturing Practices (GMP)
  - FDA published GMPs for supplement industry in 2007
  - Guidance for companies
- Assessment of facilities and raw materials against GMP
- Testing of random batches of product
  - Third Party Testing: NSF, Informed Choice

Prohibited List Resources

- Global DRO
  - www.GlobalDRO.com
- Drug Reference Line- get your phones out!
  - 719-785-2020
GlobalDRO Search Results

Therapeutic Use Exemptions

- Many medications are on WADA’s Prohibited List; athletes may apply for a Therapeutic Use Exemption.
- Process is detailed on the USADA Website www.USADA.org
- Hardest parts of the process:
  - Getting enough medical documentation to support the application
  - Determining who has the jurisdiction to grant the TUE.

USADA’s Position on Dietary Supplements

- Strict Liability
  - Athletes who use dietary supplements do so at their own risk and are 100% responsible for what is in their system.
    - Health risks
    - Risk of inadvertent positive test
  - Label provides no guarantee of ingredients contained in the bottle
  - Risk of Contamination

What I hear from Athletes…

“Okay. I get it…take at your own risk…But what can I take?”

Meaningful Steps in Risk Reduction

Understand the Risk

<table>
<thead>
<tr>
<th>Food</th>
<th>SUPPLEMENTS</th>
<th>Drugs</th>
</tr>
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<tbody>
<tr>
<td>Health</td>
<td>Health Anti-Doping</td>
<td>Health Anti-Doping</td>
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<tr>
<td>&lt;Conventional +Regulations</td>
<td>&lt;Complicated products +Where it is sourced? +Product to product? +Company to company?</td>
<td>&lt;Simple products +Regulations +Ample resources (PDR, Merisofar)</td>
</tr>
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What can you do to help your athletes?

1. Know what your athletes are taking
2. Look for products that have been AUDITED to Good Manufacturing Practices- this is tough.
3. Look for products tested by a third-party (without conflicts of interest) that tests for banned substances AND conducts label verification.
4. Consult USADA’s Supplement Website (launch in November) for Supplement Alerts.
5. Notify USADA of your concerns about particular products- we can add them to our alerts.
6. Letter campaigns- write to supplement manufacturers and ASK them to have their products certified.

When looking at a supplement...

- Categorically set aside muscle building, weight loss and erectile dysfunction “supplements”.
- Watch out for ingredients ending in -ol - diol or –stene.
- View “guarantees” with skepticism- find out what’s behind the guarantee.
- Beware Proprietary Blends
- Seek info on the Company.
- Ask the FDA for adverse events (or visit USADA supplement site for adverse events 2007-2009)
- Scrutinize press, advertisements, and “research studies”

Summary

- While there is little evidence that dietary supplements are necessary for a healthy lifestyle, many people have chosen to use them
- There are many vitamins, minerals, amino acids, and proteins that can be safely taken
- When herbal, botanicals, and particularly extracts and concentrates are added to the contents, there is the potential for increased risk of contamination and mislabeling

What does USADA do?

Beyond “testing” - Education

- Two areas
  - Olympic
    - Elite-level athletes: Functional rules and regulations
  - Outreach
    - Pipeline athletes, community and school-based programs: Ethics, decision making, character development

Curriculums

- 100% Me – Ages 10-14
- That’s Dope – Ages 15-19

100% Me Website for Youth

Ethical decision-making, body type and body image, nutrition, informed consumption around dietary/performance supplements, consequences of taking anabolic and other dangerous performance-enhancing substances.
That’s Dope
Website for Teens

www.USADA.org/ICOMPETECLEAN

Other Resources

• Be Aware & Guide Compliance
• Know what to look for & when to intervene
• Cooperation
• You SET THE TONE!
Conclusion

- Approach the use of supplement with caution
- Get info to reduce your risk
- Stay in the know on supplement trends and also anti-doping trends
  - Visit USADA website for new sanctions on athletes
- Supplement Safety now
- Supplement education website – SOON!

Thank You

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  - Dr. Larry Bowers, Chief Science Officer, USADA
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