Dietary supplements and Operation Supplement Safety (OPSS)

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The information presented in this activity represents the opinions of the author and not those of the Uniformed Services University or the Department of Defense.

Andrea Lindsey has no financial interests or relationships to disclose.
Overview

• Definition of a dietary supplement
• Oversight of dietary supplements in the U.S.
• Who uses dietary supplements?
• Issues of concern
• Operation Supplement Safety
• Other resources of dietary supplement information
What is a Dietary Supplement and how is it regulated?
What is a Dietary Supplement?*

• Product intended to supplement the diet and containing one or more dietary ingredients:
  – Macronutrients
  – Vitamins, minerals, amino acids
  – Herbs or other botanicals
  – “Other” dietary substances
• Intended to be taken by mouth
• In the form of a capsule, powder, softgel, gelcap, tablet, liquid, etc.
• Not represented for use as conventional food
• Labeled as a dietary supplement

*Adapted from the U.S. Dietary Supplement Health and Education Act of 1994
Regulation of DS, Foods, and Drugs in the United States

**Food Additives**
Subject to many laws and regulations closely monitored by the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and local agencies

- Mandatory inspections and incident reports

**Dietary Supplements**
Subject to limited pre-market review and no pre-market approval

- No formulation standards
- No product registration
- No approval of claims - Manufacturer responsible for ensuring safety and compliance

- Mandatory reporting of adverse events

**Medical Drugs**
Subject to many laws and regulations that are closely monitored by the FDA, Drug Enforcement Agency (DEA), or other agencies

- Mandatory reporting of adverse events

* No formulation standards. However, manufacturers must follow current good manufacturing practices (cGMPs) - 21 CFR Part 111.
Who uses dietary supplements?

71% of U.S. adult women take dietary supplements.

65% of all U.S. adults reported taking dietary supplements.

74% of U.S. adults 55+ take dietary supplements.

Overall Use of Body Building/Weight Loss Supplements - Military

Taking supplement ≥ once/day (%)

- Body Building
  - 2005
  - 2011

- Weight Loss
  - 2005
  - 2011
Issues of Concern

• Consumers are generally uninformed about dietary supplements.
• Much misinformation surrounds dietary supplements and their regulation.
• Potential for adverse events/reactions (AEs):
  — Thermogenic agents: Increase metabolic rate
  — Stimulants: Strain cardiovascular system and increase blood pressure
  — Combinations of stimulant look-alikes: e.g. synephrine/caffeine/octopamine/phenethylamines
  — Contaminants and adulterants: e.g. steroids, stimulants, prescription drugs, heavy metals
Adverse Events Associated with DS

- Rhabdomyolysis
- Heat injury
- Seizures
- Hepatic injury/failure
- Renal injury/failure
- Syncope
- Arrhythmias
- Tachycardia
- High blood pressure
- Stroke
- Myocardial infarction
- Paresthesias
Supplements that appear safe could be dangerous products in disguise

- Decoding the Dietary Supplement industry video
Emergence of
Operation Supplement Safety
in January 2012

A DoD-wide educational initiative

hprc-online.org/OPSS
OPSS Overview

• Purpose
  - Increase awareness within the DoD community about dietary supplements

• Provide tools to be “smart” supplement users
  – Service members
  – Leaders
  – DoD civilians
  – Family members
  – Healthcare providers
  – Retirees
The Edge You Need For Total Fitness

HPRC’s human performance optimization (HPO) website is for U.S. Warfighters, their families, and those in the field of HPO who support them. The goal is Total Force Fitness: Warfighters optimized to carry out their mission as safely and effectively as possible.

Featured Updates

Natural Medicines Comprehensive Database App

Healthcare provider app to get answers and data on natural medicines at any time.

hprc-online.org/
OPERATION SUPPLEMENT SAFETY (OPSS) is a joint initiative between the Human Performance Resource Center and the DoD to educate service members and retirees, their family members, leaders, healthcare providers, and DoD civilians about dietary supplements and how to choose supplements wisely.

Frequently Asked... Answers to frequently asked questions about supplements

Get the Scoop on Supplements
Report adverse events to dietary supplements here.
Selected Campaign Products

Posters

Logo

Videos
SARMs Postcard

SARMs
SELECTIVE ANDROGEN RECEPTOR MODULATORS
ARE UNAPPROVED DRUGS.

They're also
Illegally marketed and sold as dietary supplements.
Banned in all professional and college sports.
Still in the research phases for AIDS and cancer patients.
Known to adversely affect liver and cholesterol (other side effects are unknown).

Is it worth the risk to your performance and readiness?
OPSS High-Risk Supplement List

Some dietary supplement products contain stimulants, steroids, hormone-like ingredients, controlled substances, or unapproved drugs. The Operation Supplement Safety (OPSS) High-Risk Supplement List helps you identify supplements that might pose a potential risk to your health or career. Not all supplements on the list are illegal or banned, but all pose potential health risks. In addition, the list is not exhaustive, so something that isn’t on the list can still be unsafe.

The Food and Drug Administration (FDA) is the federal regulatory agency responsible for enforcing legislation about dietary supplements. FDA routinely issues public statements about adulterated, illegal, and dangerous dietary supplements; see their Tainted Products widget displayed to the right on this page.

The information in the OPSS High-Risk Supplement List is not intended to be a substitute for professional advice. You should contact a healthcare provider for specific medical or nutritional advice. Any reliance on the information provided in the OPSS High-Risk Supplement List is solely at your own risk. Please visit other sections of the OPSS website for further education to help you make wise decisions about dietary supplements.

For Healthcare Providers

The OPSS High-Risk Supplement List is also a tool to help healthcare providers identify products that could pose a risk to the health of service members. The OPSS High-Risk Supplement List also identifies some products that have been found to contain undeclared ingredients, which could help healthcare providers identify possible adverse interactions.
OPSS High-Risk Supplement List

THE HUMAN PERFORMANCE RESOURCE CENTER / HPRC-ONLINE.ORG
USU CONSORTIUM FOR HEALTH AND MILITARY PERFORMANCE (CHAMP)

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* User Type: 

* I accept all terms and conditions and opt-in to receive future communications regarding this list (email address can be anonymous and you will not be tracked in any way).

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<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Company</th>
<th>What the label says</th>
<th>Could Contain</th>
<th>Updated</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Andro</td>
<td>IronMagLabs</td>
<td>The Supplement Facts panel lists &quot;1-Androstene 3b, 17-one&quot;</td>
<td>Anabolic Agents</td>
<td>2014-03-13</td>
<td>The product may contain one or more steroids or steroid-like substances. For more information about these substances please see the <a href="#">OPSS FAQ on anabolic substances</a>.</td>
</tr>
<tr>
<td>17-Diol</td>
<td>Sports One Nutrition</td>
<td>The Supplement Facts panel lists &quot;Epithio-17a-methylethiocholanol and Methyl Sympnephrine&quot;</td>
<td>Anabolic Agents</td>
<td>2014-03-14</td>
<td>The product may contain one or more steroids or steroid-like substances. For more information about these substances please see the <a href="#">OPSS FAQ on anabolic substances</a>.</td>
</tr>
<tr>
<td>380 Preworkout</td>
<td>Aviva Nutrition</td>
<td>The Supplement Facts panel lists &quot;Amperall (2-amino-4-methylpentane)&quot;</td>
<td>Stimulants</td>
<td></td>
<td>This product may contain one or more stimulants. For more information please see the <a href="#">OPSS FAQ on Stimulants</a>.</td>
</tr>
<tr>
<td>ABSolute Fuel</td>
<td>BioScience Institute Inc.</td>
<td>The Supplement Facts panel lists &quot;Citrus Aurantium 30% Sympnephrine&quot;</td>
<td>Stimulants</td>
<td>2014-04-03</td>
<td>Testing revealed the presence of oxilofrine (also known as methylsynephrine). For more information please see the <a href="#">OPSS FAQ on synephrine</a> and the <a href="#">OPSS FAQ about stimulants</a>.</td>
</tr>
<tr>
<td>Adipo-X</td>
<td>Axis Labs</td>
<td>The Supplement Facts panel lists &quot;Advantra Z® (Citrus Aurantium 30%)&quot;</td>
<td>Stimulants</td>
<td>2014-04-03</td>
<td>Testing revealed the presence of octopamine, which is a constituent of Citrus aurantium. For more information about Citrus aurantium, please see the <a href="#">OPSS FAQ about stimulants</a>.</td>
</tr>
</tbody>
</table>
High Risk Supplements – OPSS
By Ideavise
Open iTunes to buy and download apps.

Description
Operation Supplement Safety (OPSS) is a joint initiative between the Human Performance Resource Center and the DoD to educate service members and retirees, their family members, leaders, healthcare providers, and DoD civilians about dietary supplements and how to choose supplements wisely.

High Risk Supplements – OPSS Support

Screenshots
Selection of New FAQs

• Are dietary supplements with cannabidiol legal?
• Is Kratom safe to take and will I pop positive on a drug test?
• Can 5-HTP in supplements help with depression, appetite, and other conditions?
• What is DHEA and is it illegal?
• Picamilon: Why is it illegal in dietary supplement products?
Other resources for DS information

• Food and Drug Administration
  fda.gov/Food/DietarySupplements/

• Federal Trade Commission
  consumer.ftc.gov/articles/0261-dietary-supplements

• Office of Dietary Supplements, National Institutes of Health
  ods.od.nih.gov

• Dietary Supplement Label Database, National Institutes of Health
  dsld.nlm.nih.gov/dsld/
Other resources for DS information, cont.

• National Center for Complementary and Integrative Health
  nccih.nih.gov/health/supplements

• United States Anti-Doping Agency
  usada.org/substances/supplement-411/

• WebPOISONCONTROL
  triage.webpoisoncontrol.org/#/exclusions
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