Dietary Supplements: Can the Discerning AT Maneuver the Chaos?

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OUTLINE

• ds defined
• potential benefits
• frame the problem
• regulation
• extensive usage
• incomplete knowledge
• concerning evidence
• consumer protections
• take-home message
DS DEFINED

- A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

- A product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form;

- Is not represented for use as a conventional food or as a sole item of a meal or the diet;

- And is labeled as a dietary supplement.
POTENTIAL BENEFITS

- nutritional challenges
  - food allergies, vegan, Ramadan...
- medical conditions
  - certain disease, anemias, food allergies...
- training complexities
  - caloric issues, time limits, altitude training...
- travel complications
  - food preparation, hygiene, safety, unfamiliarity...

Garthe & Maughan 18, Mathews 17, Thomas et al 16
DSHEA (Public Law 103-417)
- redefined “dietary supplement”
- classified DS as food sub-type
- developed label, promotion, & claim rules
- established “good manufacturing practice”

**Frame the Problem:**
Regulation
“...while the FDA has authority to regulate manufacturers of dietary supplements and to enforce the law, *almost all aspects of efficacy, safety, and quality control still remain at the discretion of the manufacturer.*”  

*Bailey 2020*
SUMMARIZING THE DS EVIDENCE

“Current federal law does not require manufacturers or distributors to provide evidence of purity, safety, or efficacy before products are distributed or sold.” Buell et al, 13
• general population: 49%
• fitness athletes: Solheim et al 17
  • 94% male
  • 100% female
• elite athletes: 69–94% Mathews et al 17

Frame the Problem:
Extensive Usage
FRAME THE PROBLEM: LIMITED KNOWLEDGE

- general public, non-professionals
  - 86% unaware of side effects Tian et al 09
  - 62% unaware of active ingredient Dascombe et al 10
  - 36% unaware of adulteration issues Froiland et al 04
- dubious info sources Loraschi et al 14, Kao et al 12 Braun et al 09, Shaw et al 09 Tian et al 09, Eliason et al 96
healthcare professionals

- only 51%/MDs had reliable info source Pascale et al 16
- 37%/residents unaware of regulation Ashar et al 07
- 65%/residents unfamiliar w/reporting Ashar et al 07

“...the knowledge base of most pharmacists and physicians regarding BDS remains woefully inadequate...” Gurley et al 18
CONCERNING EVIDENCE
OVERVIEW

- contamination/adulteration
- product inconsistencies
- gateway substances
- deceptive marketing
- others
  - interactions
  - product stability
  - bioavailability
  - excess dosages
  - ineffective
  - adverse event reporting
CONCERNING EVIDENCE

CONTAMINATION/ADULTERATION

- **pharmaceuticals**  FDA 19, Mathews 18, Tucker et al 18, Favretto et al 18, Gurley et al 18, Martinez-Sanz et al 17, Skalicka-Wozniak et al 17, Rahnema et al 15, Moreira et al 13, Calvacanti et al 13, Watson et al 10, Watson et al 09, Geyer et al 08, Martello et al 07, Van Poucke et al 07, Baume et al 06, van Thuyne et al 06, Maughan 05, van der Merwe & Grobbelaar 05, Geyer et al 04, Catlin et al 00, Saper et al 08
- **heavy metals & pesticides**  FDA, 19, Gurley et al 18, Genius et al 12, GAO 10, 19, Larson 19, Whitworth 19, Gurley et al 18, Benedict et al 16
- **microbial pathogens: mold, fungus, bacteria...**  US FDA 19, Larsson 19, Whitworth 19, Gurley et al 18, Benedict et al 16
- **others:**  Gurley et al 17, Gabriels et al 15, Pawar et al 15, Cohen et al 14, de Hon & Coumans 07, Striegel et al 05, Abourashed et al 03, Gmeiner & Hofer 02, Green et al 01, Kamber et al 01, Delbeke 01, Ayotte et al 01, Geyer et al 01, Catlin et al 00, Geyer et al 00, Gurley et al 00, Consumer Reports 99, Williamson et al 98, Ko 98, Slifman et al 98, Huang et al 97, Perrotta 96, Markowitz et al 94, Cui et al 94
CONCERNING EVIDENCE
PRODUCT INCONSISTENCIES

- botanicals
  - 15.5% of all hepatotoxicity Avugab 16
  - DS induced liver injury up 3x in 10 years Fontana et al 09
  - kava-kava: 7 deaths & 14 liver transplants White et al 18
- definitions
  - multivitamin?
  - food vs. supplement?
- chemical compounds
  - e.g., calcium?
CONCERNING EVIDENCE
GATEWAY SUBSTANCES

- DS associated with and/or leads to doping
  - Barkoukis et al 15, Backhouse et al 14, Backhouse et al 11, Molinero & Marquez 09, Wiefferink et al 08, Papadopoulos et al 06, Dodge & Jaccard 06, Yussman et al 06, Goldberg et al 00
  - DS associated with Barkoukis et al 15
    - greater doping intentions
    - more positive attitudes toward doping
    - more favorable beliefs toward doping
  - DS users 3.5X more likely to dope Backhouse et al 13
  - DS use good predictor doping intent & actual doping Ntoumanis et al 14
  - DS use significantly predicted doping Lucidi et al 08
CONCERNING EVIDENCE
DECEPTIVE MARKETING

- misrepresentation
- inappropriate research
- non-independent research
- testimonials
- hidden advertising
- others

Avery et al 17, Borchurs et al 16, Striegel et al 05, Ashar et al 08, US IG 08, Chung et al 07, Morris & Avorn 03, US IG 03
CONSUMER PROTECTION

PRODUCT PURITY

• US Pharmacopeia
• National Sanitation Foundation
• ConsumerLab
CONSUMER PROTECTION
PRODUCT PURITY & BANNED SUBSTANCES

- National Sanitation Foundation
- Banned Substances Control Group
- Informed Choice
- Aegis Shield
CONSUMER PROTECTION
PRODUCT SAFETY

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CONSUMER PROTECTION
PRODUCT EFFICACY

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"The current system has led to a “Wild West” scenario where numerous companies blatantly disregard consumer safety, honesty, and integrity. The dietary supplement industry has shown that it cannot police itself."  

White 2020
SUMMARIZING THE DS EVIDENCE

- “food-first” approach (Buell et al 13)
- limited benefits Garthe & Maughan 18, Mathews 17, Thomas et al 16
- buyer beware: purity, safety, & efficacy Austin et al 17, Brown 17 Avigan et al 16, Deldicque & Francaux 16, Steffen et al 07, Roerig et al 03, Blanck et al 07, US FDA 10, Cui et al 15
  - weight gain or loss
  - sexual function
  - botanicals