HERBALS AND DIETARY SUPPLEMENTS

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OBJECTIVES

- Define dietary supplement
- Discuss the Dietary Supplement Health and Education Act of 1994 (DSHEA)
- Discuss the implications of the DSHEA
- Discuss ways we can ensure safe/safer use of dietary supplements

"FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of the Federal Food, Drug, and Cosmetic Act as amended by DSHEA and FDA regulations.

FDA has the authority to take action against any adulterated or misbranded dietary supplement product after it reaches the market." [2]

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 (DSHEA)

- Classified herbals and other medicinal products as "dietary supplements." [2]
  → MAJOR CONFUSION between two classes of products
- Supplements to diet (calcium, magnesium, etc.) have nutritional value and are generally safe
- Herbals are used for medicinal purposes, do not supplement the diet, and may cause AEs if taken at incorrect doses
- DSHEA prevented the FDA from regulating herbal supplements as medicines (no clinical trials) leading to
  - Poor regulation
  - Poor quality

WHY HERBALS?

- Popularity among "natural medicines" has continued to grow over the past decade
  - Natural = safe
  - Big Pharma = toxic
- Reality → Active ingredients in herbals act very similarly to synthesized medications → Same potential for harm
- According to a report from 2019, the natural medicines market was valued at $140 billon USD and projected to reach over $216 billion USD by 2026 [1]
- Most of the marketing for these products is inaccurate

18–34 y	35–54 y	55+ y
Overall Wellness (42%)	Overall Wellness (47%)	Overall Wellness (49%)
Energy (37%)	Energy (33%)	Fill Nutrient Gaps (33%)
Hair, Skin, Nails (28%)	Fill Nutrient Gaps (32%)	Bone Health (31%)
Immune Health (25%)	Immune Health (31%)	Heart Health (29%)
Fill Nutrient Gaps (22%)	Hair, Skin, Nails (23%)	Healthy Aging (28%)
Weight Management (21%)	Digestive Health (21%)	Joint Health (23%)

QUALITY CONTROL

- In 2014, 255 facilities were inspected by the FDA and common infractions included: [1,3]
  - No validation testing to identify the active ingredient
  - No tests of identity, purity, strength, and/or composition

- The FDA reviewed 598 sites from October 1, 2018 to September 30, 2019 and found that 51% failed inspections. [1,3]
  - Lack of recipes/written protocols (25%), lack of quality control operations (25%), unsanitary conditions/rodent infestations (25%), no batch records (15%).

NEW YORK TAKES ACTION

- New York State attorney general's office accused 4 major retailers of selling fraudulent herbal supplements and demanded they be removed from their shelves (2015). [4]
  - Conducted tests on top selling supplements from GNC, Target, Walgreens, and Walmart → 4/5 products did not contain ANY of the herbs indicated on the label.
  - Pills often contained cheap fillers like powdered rice, asparagus, and houseplants.

ADULTERATION

- "The act of making something impure or altering its original form by adding materials or elements that aren't usually part of it's makeup."
- Weight loss products contain sibutramine [5]
  - FDA took off the market due to association with CV events and strokes
- Athletic enhancing supplements [5]
  - May contain amphetamine analogues
- Sexual health supplements [6,7]
  - May contain sildenafil or other PDE-5 inhibitors
  - 75% of sexual enhancement supplements seized in the Netherlands contained PDE-5 analogues [6]

SAFETY

- Until recently, supplement manufacturers were not required to report AEs to the FDA
  - Most of our data comes from EDs and Poison Control Centers
    - FDA estimates that 50,000 AEs annually from dietary supplements
      - Most common AEs: hepatic and renal damage [8]
  - A prospective study of drug-induced hepatic disease found that approximately 20% of cases of acute liver failure in the US were associated with the consumption of dietary supplements. [9]

EFFICACY

- Claims for the efficacy of plant extracts are based on a long history of use.
- Most systematic reviews and meta-analyses of herbal trials are uninterpretable due to defects in design and publication/interpretation bias.
- Many trials supported by the NIH have found no benefit beyond placebo effect for many popular herbals/supplements such as echinacea, ginkgo biloba, ginseng, black cohosh, saw palmetto, and glucosamine. [10]

CASE EXAMPLE

WHAT CAN WE DO?

- Recommend dietary supplements that have been approved by the US Pharmacopeial Convention (USP)
- USP is an independent, non-profit organization that analyzes food ingredients, medicines, and dietary supplements to improve quality and safety of those products.
  - Identity: Is the product what it claims to be?
  - Potency: Is it present in the right amounts?
  - Purity: Is it free from impurities, contaminants?
  - Performance: Can the active ingredient be absorbed in the body as intended?

Photo:

WHAT CAN WE DO?

- Recommend dietary supplements that have been approved by ConsumerLab.com
- Claims to have the “highest testing standards of any third party group certifying the quality of dietary supplements.”
- Tests for the following:
  - Identity
  - Strength
  - Purity
  - Disintegration

WHAT CAN WE DO?

- Recommend dietary supplements that have been evaluated by *Natural Medicines* (formerly *The Natural Medicines Comprehensive Database*).
  - Subscription website published by independent pharmacists who also publish Prescriber's Letter
  - Give ratings on Safety and Effectiveness

QUESTIONS?

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