

DIETARY SUPPLEMENTS: THE GOOD, THE BAD AND THE UGLY

KAREN ARMITAGE, MD, FAAP
DIRECTOR OF HEALTH POLICY AND CLINICAL MPH PROGRAMS
COLLEGE OF POPULATION HEALTH

STEPHANIE CHAMBERS, MPH
ADJUNCT FACULTY, SENIOR RESEARCH SCIENTIST
UNM COLLEGE OF POPULATION HEALTH

1

LEARNING OBJECTIVES FOR THIS SESSION

Following this knowledge-based presentation, the pharmacist participants will be able to:

1. Summarize FDA oversight of dietary supplements in the United States (U.S.)
2. State the number of U.S. emergency department visits annually caused by use/misuse of dietary supplements.
3. Summarize new research on the impact of dietary supplements on mortality in the U.S.
4. State the name and describe the seal of U.S. Pharmacopeia (USP) and summarize the unique role of USP in assuring the quality and safety of dietary supplements.
5. Summarize the ethical issues presented by offering dietary supplements in the same retail setting as FDA-regulated over-the-counter and prescription medications.

2

WE'D LIKE TO TAILOR THIS SESSION FOR THIS AUDIENCE...

- Anonymous ZOOM Poll #1

3

FROM THE FDA 101 WEBSITE...

- "The law defines dietary supplements in part as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet."



4

DIETARY SUPPLEMENTS ARE NOT REGULATED LIKE PRESCRIPTION AND OVER-THE-COUNTER DRUGS.

- Federal law:
 - Does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
 - Does not require the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or truthful before it appears on the product.
 - Permits FDA to act only after a product enters the marketplace and presents a significant or unreasonable risk of illness or injury or is otherwise adulterated or misbranded.
- Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the Federal Trade Commission, not the FDA.
- <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements>

5

WE'D LIKE TO ASSESS THIS GROUP RE: DIETARY SUPPLEMENT EXPERIENCE.

Anonymous Zoom POLL # 2

6

BASIC FACTS ABOUT DIETARY SUPPLEMENT USE

More than half of all U.S. adults report taking a dietary supplement in the last 30 days.

— Kantor ED, Behm CD, Du M, White F, Giovannucci EL. Trends in Dietary Supplement Use Among US Adults From 1999–2012. JAMA. 2016;314(14):1464–74.

During 2013-2014, approximately one third of children and adolescents (persons aged ≤19 years) in the United States were reported to use a dietary supplement in the past 30 days

— Gatto DM, Alexander GC, Guadamuz JS, Lindau ST. Prevalence of dietary supplement use in US children and adolescents, 2003–2014. JAMA Pediatr. 2018;172:780–2. 10.1001/jamapediatrics.2018.1008. DOI: 10.1001/jamapediatrics.2018.1008. PMID: 29811111

Among health care providers, 51% of physicians, 59% of nurses and 62% percent of pharmacists report regular use of dietary supplements.

<https://www.crnusa.org/sites/default/files/pdfs-benefits/DACRN-BenefitsBook-whouses.pdf>

7

WHAT HAS BEEN YOUR EXPERIENCE WITH ADVERSE EVENTS RELATED TO DIETARY SUPPLEMENTS?

• Anonymous Zoom
POLL #3

8

THE BAD NEWS ABOUT DIETARY SUPPLEMENTS

• An estimated 23,000 ER visits in the U.S. annually are attributed to adverse events related to dietary supplements.

— N Engl J Med 2015;373:1531–40. DOI: 10.1056/NEJMs1504267

9

WHAT IS YOUR FAVORITE SOURCE FOR RESEARCHING SPECIFIC DIETARY SUPPLEMENTS?

• Anonymous Zoom Poll
#4

10

PHARMACISTS AND PHARMACY TECHNICIANS, AS THE MOST ACCESSIBLE MEMBERS OF THE HEALTH CARE TEAM, MAY BE ASKED ABOUT NEWS HEADLINES LIKE THESE...

Outbreak of Severe Hypoglycemia After Ingestion of a Male Enhancement Supplement — Virginia, August–November 2019

An unlabeled, over-the-counter product sold in Virginia convenience stores as a male enhancement supplement contained sildenafil and glyburide, a potent hypoglycemic agent, leading to life-threatening episodes of hypoglycemia requiring prolonged hospitalization among users.

Arsenic Toxicity Associated with Dietary Mineral Supplements—2017

A patient with severe arsenic poisoning was likely exposed by consuming multiple dietary supplements. Dietary mineral supplements are commonly used and often derived from natural sources that might contain arsenic. There is no requirement that dietary supplements test for contaminants.

11

WHAT IS YOUR OPINION ABOUT EFFECTIVENESS OF DIETARY SUPPLEMENTS?

• Anonymous Zoom Poll
#5

12

DOES TAKING DIETARY SUPPLEMENTS AFFECT MORTALITY IN POPULATION STUDIES?

Dietary supplements do not replace nutrients in food and are associated with higher mortality.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6736694/>

13


CONSIDERING THIS NEW EVIDENCE AND LAX OVERSIGHT BY FDA, WHAT ADVICE CAN YOU GIVE PATIENTS THAT WANT TO BUY AND TAKE DIETARY SUPPLEMENTS?

- RECOMMEND THAT CONSUMERS PURCHASE ONLY DIETARY SUPPLEMENTS THAT HAVE BEEN SCREENED BY AN INDEPENDENT LABORATORY FOR PURITY AND CONCENTRATION.
- THERE IS ONLY ONE NON-PROFIT, INDEPENDENT PHARMACEUTICAL LABORATORY IN U.S. THAT PUBLISHES AND SHARES RESULTS WITH THE PUBLIC FOR FREE.

14

A study comparing actual to expected concentrations of vitamin D₃ in commercially available brands revealed unacceptable deviations, with pill potency ranging from 9% to 146% of the stated concentration; **variability was within acceptable range only for US Pharmacopoeia-verified supplements.**

USP SEAL



• LeBlanc ES, Perrin N, Johnson JD, Jr, Ballatore A, Hillier T. Over-the-counter and compounded vitamin D: is potency what we expect? JAMA Intern Med. 2013;173(7):585-586. [\[PubMed\]](#)

15

WHAT ARE THE BELIEFS OF THIS GROUP REGARDING ETHICS OF THE SALE OF DIETARY SUPPLEMENTS IN PHARMACIES?

- **Anonymous Zoom Poll #6**

16

IS SELLING DIETARY SUPPLEMENTS IN PHARMACIES ALONGSIDE OVER-THE-COUNTER AND PRESCRIPTION MEDICATIONS UNETHICAL?

- In Australia, community pharmacist were polled for the acceptability and feasibility of a new ethical framework to improve pharmacy practice in relation to complementary medicines.
- The classic struggle of income versus ethics played out in this study.

Improving pharmacy practice in relation to complementary medicines: a qualitative study evaluating the acceptability and feasibility of a new ethical framework in Australia. - PubMed (nih.gov)

17



18