Dietary supplements: Underregulated, unknown and maybe unsafe

MAY 11, 2022

Staff News Writer

Unlike prescription drugs and over-the-counter medications, dietary supplements are not approved by the Food and Drug Administration (FDA) for safety and efficacy. And while that puts limits on how oral vitamins, minerals and herbals can be marketed, almost all still claim to have some salubrious effects, hence that curious disclaimer on their packaging: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases.”

The May issue of?*AMA Journal of Ethics*® (@JournalofEthics) investigates why consumers and physicians should not only beware of dietary supplements’ risks, but also carefully evaluate their assumptions and beliefs about the roles these underregulated products play in forming expectations and planning care.

Just days before this themed issue was published, bipartisan legislation was introduced in the U.S. Senate to improve safety and ensure transparency in the dietary supplement industry—a move commended by the AMA.

It would require manufacturers of dietary supplements to submit vital information about their products to the FDA, including their names and ingredients. The agency already has the authority to regulate dietary supplements, but it is simply unaware of many of the 50,000–80,000 on the market.

“The dietary supplement marketplace is an uncertain place for consumers—so little transparency, so much confusion,” AMA President Gerald E. Harmon, MD, said in a statement. He said the AMA appreciated the “bipartisan effort” of Illinois Democrat Sen. Richard Durbin and Indiana Republican Sen. Mike Braun to “introduce some clarity to this situation. The Dietary Supplement Listing Act would create a much-needed electronic database so consumers can access vital product information. We urge Congress to be on the side of consumers and pass this legislation.”

Articles in the May issue of *AMA Journal of Ethics* include:

1 **“How Should Clinicians Respond to Patient Interest in Dietary Supplements to Treat Serious Chronic Illness?”**
Consumption of over-the-counter vitamins, minerals and herbals is widespread, but clinicians lack critical information about their use.

2 **“What Should Clinicians Know About Dietary Supplement Quality?”**
Increase in dietary supplement use in the United States suggests a great need for clinicians to be aware of the range of their quality parameters.

3 **“Is My Patient Taking an Unsafe Dietary Supplement?”**
Dietary supplements can have side effects; interact with medications, food or other supplements; or be unsafe.

4 **“What Should Dietary Supplement Oversight Look Like in the U.S.?”**
Statutory limitations prevent the FDA from effectively regulating dietary supplements and have generated numerous calls for reform.

Listen and learn

The journal’s May “Ethics Talk” podcast features Amy B. Cadwallader, PhD, director of regulatory and public policy development for the U.S. Pharmacopoeia, Joshua J. Klein, a JD candidate at DePaul University College of Law, in Chicago, and Scott J. Schweikart, JD, MBE, senior research associate for the AMS Council on Ethical and Judicial Affairs, discuss product safety and the limited legal means available to rein in social media influencers’ advertisements about dietary supplements.

The May issue also features 10 author-interview podcasts. Listen to previous episodes of the “Ethics Talk” podcast or subscribe in iTunes or other services.

Earn CME

These?*AMA?Journal of Ethics* CME modules are each designated by the AMA for a maximum of 1? *AMA PRA Category 1 Credit*™:

- "Should Clinicians Ever Recommend Supplements to Patients Trying to Lose Weight?"
- "How Should Clinicians Respond to Patient Interest in Dietary Supplements to Treat Serious Chronic Illness?"
- "How Does Cognitive Bias Affect Conversations With Patients About Dietary Supplements?"
- "Do You Know How to Assess Risks Posed by Over-the-Counter Vitamin A Supplements?"
- "What Should Clinicians Know About Dietary Supplement Quality?"
- "Does Regulating Dietary Supplements as Food in a World of Social Media Influencers Promote Public Safety?"
- "What Should Dietary Supplement Oversight Look Like in the U.S.?"
- "Which Features of Dietary Supplement Industry, Product Trends and Regulation Deserve Physicians' Attention?"
- "Reimagining Roles of Dietary Supplements in Psychiatric Care."
- "Seven Points for Athletes to Consider Before Using a Dietary Supplement."

Additionally, the CME module "Ethics Talk: Should You Trust Influencers' Posts About Dietary Supplements?" is designated by the AMA for a maximum of 0.5?*AMA PRA Category 1 Credit*.

The offerings are part of the AMA Ed Hub™, an online learning platform that brings together high-quality CME, maintenance of certification, and educational content from trusted sources, all in one place—with activities relevant to you, automated credit tracking and reporting for some states and specialty boards.

Learn more about AMA CME accreditation.

A look ahead

Upcoming issues of the?journal?will focus on health care in conflict zones and arts-based research in health care.?Sign up?to receive email alerts when new issues are published.

Editor's note: *This article originally ran with a headline and several instances in the body describing dietary supplements as "unregulated," which was inaccurate. We regret the errors.*