

# Dietary supplements market: Tighter rules, better counseling a must

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While millions of patients use dietary supplements, the current regulatory structure does not properly protect the public. Since the Dietary Supplement Health and Education Act (DSHEA) was passed 26 years ago, the dietary supplement industry has been reshaped by a complex global supply chain, the internet and newly discovered ingredients with unknown safety, according to an AMA Council on Science and Public Health report adopted at the November 2020 AMA Special Meeting.

“Patients and physicians expect the dietary supplements they purchase and recommend to be safe, quality products that are accurately labeled with their contents. As the dietary supplement industry continues to grow with little oversight, many more people will use supplements without having a clear understanding of what’s contained in these products—potentially putting their health at risk,” said AMA Immediate-past Board Chair Jesse M. Ehrenfeld, MD, MPH.

“We need the federal government to step up its regulation and enforcement of the dietary supplement industry to remove unsafe products from the market and protect public health,” Dr. Ehrenfeld said.

Since 1994, about 75,000 new dietary supplement products have been introduced. However, the Food and Drug Administration (FDA) has only received adequate safety data for less than 250 new ingredients. To add to that, the FDA does not have a way to determine what ingredients are present in the tens of thousands of products currently on the market.

“With violations in over half of inspected dietary supplement manufacturers, more effective enforcement tools are required to protect the health of patients,” says the council’s report. “All patients will benefit from a regulatory framework that promotes safety and provides appropriate tools and resources for the FDA to maintain appropriate oversight.”

To advance a safe and transparent dietary supplement marketplace, the House of Delegates modified existing policy for the AMA to support:

- Efforts to enhance FDA resources, particularly to the Office of Dietary Supplement Programs, to appropriately oversee the growing dietary supplement sector and adequately increase inspections of dietary supplement manufacturing facilities.
- The FDA having appropriate enforcement tools and policies related to dietary supplements, which may include mandatory recall and related authorities over products that are marketed as dietary supplements but contain drugs or drug analogues, the utilization of risk-based inspections for dietary supplement manufacturing facilities, and the strengthening of adverse event reporting systems.
- Continued research related to the efficacy, safety, and long-term effects of dietary supplement products.

Physicians, meanwhile, should “inquire about patients’ use of dietary supplements and engage in risk-based conversations with them about dietary supplement product use,” the updated policy says.

Delegates also strongly urged Congress to modernize the DSHEA to require that:

- Dietary supplements meet standards established by the United States Pharmacopeia for identity, strength, quality, purity, packaging and labeling.
- The FDA establish a mandatory product listing regime that includes a unique identifier for each product (such as a QR code), the ability to identify and track all products produced by manufacturers who have received warning letters from the FDA, and FDA authorities to decline to add labels to the database if the label lists a prohibited ingredient or new dietary ingredient for which no evidence of safety exists or for products which have reports of undisclosed ingredients.
- Regulations related to new dietary ingredients (NDI) are clarified to foster the timely submission of NDI notifications and compliance regarding NDIs by manufacturers.

With the updated policy, the AMA also:

- Supports adequate funding and resources for Federal Trade Commission (FTC) enforcement of violations of the FTC Act.
- Strongly urges that criteria for the rigor of scientific evidence needed to support a structure/function claim on a dietary supplement be established by the FDA and minimally include requirements for robust human studies supporting the claim.

The AMA also is strongly urging “dietary supplement manufacturers and distributors to clearly label all products with truthful and not misleading information.” The AMA will also support that the product labeling of dietary supplements and herbal remedies to:

- Not include structure or function claims that are not supported by evidence from robust human studies.

- Not contain prohibited disease claims.
- Eliminate “proprietary blends” and list and accurately quantify all ingredients contained in the product.
- Require advisory statements regarding potential supplement-drug and supplement-laboratory interactions and risks associated with overuse and special populations.
- Include accurate and useful disclosure of ingredient measurement.

Lastly, the AMA will “support efforts to increase patient, health care practitioner and retailer awareness of resources to help patients select quality supplements, including educational efforts to build label literacy.”