James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

May 6, 2022

The Honorable Richard Durbin
United States Senate
711 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
United States Senate
374 Russell Senate Office Building
Washington, DC 20510

Dear Senators Durbin and Braun:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our support for S. 4090, the "Dietary Supplement Listing Act of 2022," which would create a mandatory product listing for all dietary supplements. By requiring dietary supplement manufacturers to provide the U.S. Food and Drug Administration (FDA) with vital information about their products, including product names, a list of all ingredients, an electronic copy of the label, allergen statements, and health and structure/function claims, the Dietary Supplement Listing Act would increase transparency and oversight of dietary supplements, as well as improve safety for consumers.

Patients and physicians expect the dietary supplements they purchase and recommend to be safe, quality products that are accurately labeled with their contents. Many dietary supplements, principally vitamins and minerals, are key components of modern evidence-based medicine for many conditions. In 1994, when Congress passed the Dietary Supplement Health and Education Act (DSHEA) to provide the FDA with authority to regulate dietary supplements, there were only 4,000 dietary supplements marketed in the U.S. There has been an explosive growth in the market, with an estimated 90,000 products in 2017 (U.S. Government Accountability Office. Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness. May 2017). While millions of patients use dietary supplements regularly, the current regulatory structure in place for dietary supplements does not offer adequate protection to the public. Since the passage of DSHEA, 75,000 new supplement products have been introduced, and yet the FDA has received adequate safety data for fewer than 250 new ingredients. The FDA also has no way to determine what ingredients are contained in the tens of thousands of products on the market.

The AMA has long-standing policy supporting stronger oversight of the dietary supplement industry. In 2020, the AMA adopted new policy calling for a mandatory product registry as a simple, least burdensome way for the FDA, patients, and physicians to obtain a complete picture of the marketplace and better protect public health by providing greater transparency, enabling prioritization of limited agency resources, and enhancing efforts to respond to emerging safety concerns. While additional reforms are necessary, we view the mandatory product listing as a critical first step to understanding the size and scope of the industry, so that the FDA has the best chance of enforcing its regulations in an effective way. This is consistent with the regulatory action the agency itself has asked for in its budget requests.

We applaud your leadership in introducing Dietary Supplement Listing Act of 2022 and we look forward to working with you to advance this important legislation in the Senate this year.

Sincerely,

James L. Madara, MD