May 5, 2022

The Honorable Richard Durbin 711 Hart Senate Office Building Washington, DC 20510 The Honorable Mike Braun 374 RussellSenate Office Building Washington, DC 20510

Dear Senators Durbin and Braun,

On behalf of the United States Pharmacopeia (USP), I am writing in support of S. 4090, the "Dietary Supplement Listing Act of 2022." This bipartisan legislation is step in the right direction for providing the Food and Drug Administration (FDA) and the public with much needed transparency into the dietary supplement industry.

USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust where it matters most: in the world's medicines, dietary supplements, and foods through rigorous science and public quality standards. USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. The USP Convention elected the 12 members of the USP Board of Trustees, which oversees our work. USP provides dietary supplement quality standards in a dedicated publication, the *Dietary Supplements Compendium* (*DSC*), available as an online platform. The *DSC 2022* includes more than 600 standards for botanical and non-botanical dietary ingredients and dietary supplements supported by 23 General Chapters.

In the last 25 years, the dietary supplement industry grew from \$4 billion with roughly 4,000 products to over \$50 billion with more than 50,000 products – possibly tens of thousands more since the FDA has no firm figure for the number of dietary supplments currently on the market. The number of adulterated products marketed by bad actors has also increased in this time and unfortunately, we do not know the scale of the problem. As the size of the industry continues to grow and consumer approaches to health and wellness evolve, so too have e-commerce websites and mobile applications with the sole purpose to sell dietary supplements, making it harder to keep track of all products on the market and address quality and safety concerns.

USP supports the modernization of dietary supplement regulation to require the establishment of a FDA-administered mandatory product listing (MPL) regime for dietary supplement products that at a minimum, requires dietary supplement manufacturers to provide a listing of products that are or will be sold, the ingredients contained in each product, and a copy of each product label.



¹ USP standards are developed by Expert Bodies comprised of more than 750 scientific experts. These experts collaborate to develop USP standards through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology.

² USP's governing bodies in addition to the <u>Council of the Convention</u> include its <u>Board of Trustees</u> and Council of Experts.

³ The 2020-2025 USP Board of Trustees, https://www.usp.org/about/board-of-trustees.

To protect consumers from unsafe products, public health, health care, patient, and consumer advocacy organizations have long called for reform to the regulation of dietary supplments and many have specifically called for MPL. 4,5,6,7,8,9 The concept of MPL listing for dietary supplements is also supported by 95% of American adults. 10,11 This legislation, which calls for implementation of MPL, is a critical step to increasing transparency and oversight of the growing industry. The MPL could provide much needed transparency to FDA and the public on the type and number of dietary supplement products, as well as products marketed as dietary supplements that do not meet the definition of a dietary supplement, that are available on the U.S. market and could help facilitate FDA actions against non-compliant products and the manufacturers and/or distributors of such products. It could provide FDA and industry the ability to respond more quickly to emerging safety concerns, support FDA efforts to prioritize resources and expertise, support consumer access to quality products, and increase the transparency and awareness of the ingredients in dietary supplements.

USP thanks you for introducing this important legislation. We are committed to working with you on the advancement of this bill. Should you need additional information or wish to further discuss ways in which we can work together, please do not hesitate to reach out to Joseph M. Hill, Director, U.S. Government Affairs at Joe.Hill@USP.org or 202-239-4137.

Sincerely,

Anthony Lakavage, J.D.

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¹¹ Long J. FDA, consumer groups in favor of mandatory listing of dietary supplement products. 2020; https://www.naturalproductsinsider.com/regulatory/fda-consumer-groups-favor-mandatory-listing-dietary-supplement-products. Accessed February 22, 2022



⁴ Richardson E, Akkas F, Cadwallader AB. Dietary supplement oversight in the US: outlining the case for reform and current proposals. *AMA Journal of Ethics*. 2022;24(5)

⁵ Amy B. Cadwallader PhD and AMA Council on Science and Public Health. Which Features of Dietary Supplement Industry, Product Trends, and Regulation Deserve Physicians' Attention? *AMA Journal of Ethics*. 2022;24(5)

⁶ Council on Science and Public Health. *Dietary Supplements: Update on Regulation, Industry, and Product Trends*. American Medical Association;2020. 3-Nov-2020.

⁷ Pew Charitable Trusts. Congress Should Prioritize Dietary Supplement Reform as Part of Its Efforts to Strengthen Public Health: FDA needs a mandatory product listing requirement and clear recall authority to improve oversight. 2021; https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2021/04/congress-should-prioritize-dietary-supplement-reform-as-part-of-efforts-to-strengthen-public-health. Accessed February 22, 2022.

⁸ Consumer Healthcare Products Association. Statement by John Troup, PhD, CHPA Vice President of Scientific Affairs and Dietary Supplements on Los Angeles Times Column Regarding Dietary Supplement Regulations. 2020; https://www.chpa.org/news/2020/12/statement-john-troup-phd-chpa-vice-president-scientific-affairs-and-dietary. Accessed February 22, 2022.

⁹ Center for Science in the Public Interest. Letter in Opposition to CBD Bill, H.R. 841. 2021;

https://www.cspinet.org/sites/default/files/HR%20841%20Opposition%20Letter.pdf. Accessed February 22, 2022.

10 Pew Charitable Trusts. Americans support requiring supplement makers to tell FDA about their products. 2018;

https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2021/04/congress-should-prioritize-dietary-supplement-reform-as-part-of-efforts-to-strengthen-public-health. Accessed February 22, 2022.