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May 21, 2022

The Honorable Patty Murray,
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr,
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
833 Hart Senate Office Building
Washington, DC 20510

Dear Senators Murray and Burr:

Thank you for your continued efforts to promote the regulation of dietary supplements through comprehensive mandatory listing legislation. The Pew Charitable Trusts is an independent, nonpartisan research and policy organization with a longstanding focus on the quality and safety of medical products, including research and policy analysis on issues related to the regulation of dietary supplements.

We appreciate your leadership and your continuing efforts to move this legislation forward and we welcome the opportunity to provide further input on this important topic.

Since the enactment of the Dietary Supplement Health and Education Act (DSHEA) 27 years ago, the dietary supplements market has grown exponentially from a $4 billion industry with 4,000 products to a $40 billion one with an estimated 80,000 products. Most Americans have taken a supplement. However, not all supplements are safe. From 2014 to 2018, 23,000 adverse events reports and 300 deaths related to supplements were reported to the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS). Current regulation has not been able to keep up with this exploding market to keep patients safe.

Legislation like the Dietary Supplement Listing Act of 2022 (S. 4090) authored by Senators Richard Durbin and Mike Braun would significantly strengthen FDA oversight of this market by establishing a mandatory product listing requirement for all dietary supplements. This low-cost and low-burden tool would increase transparency and protect patients by giving the agency richer and more up-to-date information about an opaque market that directly affects the health and well-being of many Americans. When threats occur, FDA would have the ability to react quickly. Additionally, the agency could prioritize and better distribute limited resources and expertise to more effectively regulate these products.

This bill carefully balances patient safety and innovation, giving FDA necessary tools to protect patients while simultaneously giving patients the information they need to make informed decisions. Pew has previously laid out key principles to dietary supplement reform including labeling that at a minimum includes: product names, ingredients, including the composition of

proprietary blends, a copy of the label, directions for use, any relevant warnings or precautions, allergen statements, dosage amount, serving size, and any product claims. We are pleased to see most of these principles captured in the bill. We particularly applaud the inclusion of both the proprietary blend information and health, structure, and function claims to the listing requirements. However, we do hope that next iteration of the bill will include the requirement that the developer also submit a copy of the product label to ensure that FDA has easy access to this information in the same comprehensive data package that manufacturers will already be submitting.

Mandatory product listing has garnered support from all sides. According to a 2018 Pew study, 95 percent of US adults back a mandatory product listing requirement. This support is true across party lines. Additionally, the Durbin-Braun bill has bipartisan support on the Hill and is supported by various industry partners such as the American Medical Association (AMA) and the Council for Responsible Nutrition (CRN). FDA has also communicated its support in its recommendations to Congress through multiple budget requests. With this broad stakeholder support in place, now is the time for Congress to pass the Dietary Supplement Listing Act.

Thank you for your continued leadership on this critical public health issue. Pew remains a long-standing champion of dietary supplement regulatory reform, and we stand ready to work with you and your colleagues in your efforts to improve dietary supplement oversight. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Kyle Kinner at kkinner@pewtrusts.org; (202) 540-6597.

Sincerely,

Elizabeth Richardson, MSc.
Project Director, Health Care Products