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Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Woodcock:

Since enactment of the Dietary Supplement Health and Education Act (DSHEA) over 25 years ago, the dietary supplement industry has grown from around \$6 billion in annual sales to more than \$46 billion in 2020.¹ This number will likely continue to increase, especially given the growing consumer demand for supplements during the current coronavirus pandemic.² The FDA's Office of Dietary Supplement Programs (ODSP) is in charge of overseeing the safety of dietary supplements; however, it faces multiple challenges that limit its effectiveness.

One of these challenges is the lack of transparency in the supplement market. FDA lacks the authority to require supplement manufacturers to provide basic information—such as product names, ingredients, and labels—to the agency before marketing their products to consumers. Without this requirement—known as a mandatory product listing—the agency has no formal mechanism to know what products are on the market or what ingredients they contain. This hampers the agency's ability to target its limited resources in a risk-based manner, leaving consumers vulnerable to potentially harmful products.

Instead of a central database, the FDA relies on intermittent and passive strategies to identify potentially harmful products in the supplement marketplace, such as conducting internet searches, monitoring the agency's CAERS database (the Center for Food Safety and Applied Nutrition Adverse Event Reporting System), and following up on proactive notifications from industry. This is a largely ineffective and inefficient way to oversee a marketplace that contains an estimated 80,000 products.

A mandatory product listing requirement could also serve as an important transparency tool for consumers. Over half of all Americans consume supplements,³ and they should have important safety information about them. Although the CAERS database serves the purpose of tracking safety information related to supplement products, the database is not user-friendly and has significant gaps in the information it tracks.⁴

¹ https://www.reportlinker.com/p05900383/Global-Dietary-Supplements-Industry.html?utm_source=GNW

² <https://www.naturalproductsinsider.com/business-resources/how-covid-19-has-sparked-new-normal-health-and-wellness-industry>

³ <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/12/americans-support-requiring-supplement-makers-to-tell-fda-about-their-products>

⁴ <https://www.consumerreports.org/dietary-supplements/fda-hid-names-of-dietary-supplements-linked-to-hundreds-of-reports-of-harm/>

More broadly, the agency has limited authorities either to keep harmful supplements from entering the marketplace or remove them once they have entered. This means that, even when the agency identifies potentially harmful products, it may take years of regulatory action to remove them from store shelves. For example, a recent investigation by WIRED revealed how Quincy Bioscience introduced its supplement, Prevagen, into the marketplace even though FDA rejected the company's New Dietary Ingredient Notification for apoaequorin—the main ingredient in Prevagen—due to lack of safety information. Prevagen has since been linked with thousands of adverse events—including deaths—but the company continues to sell it to consumers as a memory boosting supplement. And although the FDA has issued warning letters to the company over the last several years, it has not mandated a product recall.⁵

This is due in part to the fact that, under current law, the burden is on the agency—rather than the manufacturer—to prove that a dietary supplement is unsafe before it can take action to restrict the product's use or remove it from the market. This can be a highly resource intensive and time-consuming process. For example, it took seven years of litigation and a Supreme Court decision to finally ban the use of DMAA (an amphetamine derivative) in supplement products, despite significant evidence that the ingredient is unsafe and can harm consumers.⁶

Underpinning all these challenges is the significant underfunding of the FDA's ODSP. While the current ODSP budget is just over \$10 million, the office—which serves as a central hub for the agency's efforts related to supplement guidelines, regulations, safety assessments, and compliance strategy—is responsible for overseeing a \$40 billion industry.⁷

Consumers should have confidence that the supplement products they purchase are safe, properly labeled, and that the claims made on the label have a scientific basis. A Pew survey of American adults found that most people overestimate the level of FDA oversight of supplements—falsely believing that the FDA reviews or tests supplement safety before products go on the market. After respondents were informed that the FDA is not authorized to review all supplements before they are marketed, 70% did not think FDA is able to keep consumers safe.

Recommendations for Dietary Supplement Reform

Former FDA Commissioner Dr. Scott Gottlieb pledged in 2019 to improve the agency's oversight of supplements by leveraging existing resources and authorities. These new policies would ensure product safety while promoting innovation and efficiency in the marketplace. Since then, FDA has been on a trajectory to reform dietary supplement oversight. The agency also asked for a mandatory product listing requirement in its FY2021 budget request. These were encouraging steps, and the agency should continue to build upon those actions and follow through on its pledge to improve supplement oversight. With your incoming leadership, there is an opportunity to reevaluate the DSHEA framework and develop a comprehensive package of reforms that can help the agency to better oversee this large and rapidly growing market.

As a part of these efforts, we urge you to pursue the following reforms:

⁵ <https://www.wired.com/story/prevagen-made-millions-fda-questioned-safety/>

⁶ <https://www.naturalproductsinsider.com/regulatory/supreme-court-settles-fate-dmaa>

⁷ <https://www.naturalproductsinsider.com/regulatory/congress-boosts-funding-fda-dietary-supplement-office>

- **Support a mandatory product listing requirement for all supplement products marketed in the US.** At a minimum, supplement manufacturers should be required to tell the agency what products they are selling, the ingredients they contain, and provide a copy of the label. Such a reform already has strong public support—Pew’s survey of supplement users found that 95 percent supported a mandatory product listing requirement.⁸
- **Clarify FDA’s authority to mandate the recall of supplements tainted with active pharmaceutical ingredients.** The agency currently maintains that it does not have mandatory recall authority over supplement products that contain drug ingredients. This raises serious public safety concerns. One study found that, between 2007 and 2016, the FDA identified more than 700 supplement products that contained active pharmaceutical ingredients⁹—given the agency’s limited resources, it is likely that the true number of tainted products on the market is higher. FDA should be able to pull all dietary supplements, including those with pharmaceutical ingredients. If FDA continues to assert that it lacks the authority to do so, then Congress should grant it this authority in legislation.
- **Strengthen the New Dietary Ingredient pathway.** The New Dietary Ingredient Notification process is critically important to the safety of dietary supplements because it is the only premarket authority the FDA can invoke to prevent a potentially unsafe product from reaching the market. However, the NDI pathway is underused, owing in part to a lack of enforcement.¹⁰ The agency should take steps to encourage greater use of this pathway, including finalizing its NDI guidance and more robustly enforcing the NDI notification requirements.

The FDA is responsible for protecting the public from potentially harmful supplement products and they should have adequate authorities and resources to be able to do so. The Pew Charitable Trusts has been a longstanding champion of dietary supplement regulatory reform, and we stand ready to work with you and your colleagues on these important issues. Please do not hesitate to reach out with any questions.

Sincerely,



Elizabeth Richardson
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The Pew Charitable Trusts

⁸ <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/12/americans-support-requiring-supplement-makers-to-tell-fda-about-their-products>

⁹ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2706496>

¹⁰ <https://www.pewtrusts.org/-/media/assets/2019/07/pew-comments-fda-responsible-innovation-dietary-supplements.pdf>