CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

August 1, 2024

The Honorable Larry Bucshon, M.D.
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Diana DeGette
U.S. House of Representatives
Washington, D.C. 20515

Dear Representatives Bucshon and DeGette:

As you look to build upon the 21st Century Cures Act and Cures 2.0, the Consumer Healthcare Products Association (CHPA), welcomes the opportunity to provide suggestions for your consideration. CHPA is the 144-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system more than $7, contributing a total of $146 billion in savings each year. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. We would like to highlight a few areas of interest:

First, the reauthorization of the **Over-The-Counter Monograph Drug User Fee Program (OMUFA)**: After seven months of negotiations, the FDA, and industry, led by CHPA, reached agreement, which has been supported by the CHPA Board of Directors, that would a) increase transparency and attention to fees and those in arrears; b) increased focus on risk and c) provide follow-up opportunity, and greater clarify in meetings procedures with the agency. The reauthorization of the law, originally passed in March 2020 as part of the CARES Act, will need to pass Congress by the end of fiscal year 2025 to avoid a lapse of the law.

Second, **Rx-to-OTC Switch**: It is well established that the public health is benefitted when consumers have greater access to nonprescription drugs. CHPA is pleased with the intent behind FDA's pending *Nonprescription Drug Product With an Additional Condition for Nonprescription Use* (ACNU) rule that could facilitate new non-prescription medicines coming to market. However, we remain extremely concerned with a provision in the proposed rule that would allow the same drug to be available simultaneously as both a prescription and nonprescription medicine. We believe such treatment would lead to significant consumer confusion, undermine the economic foundation of Rx-OTC switches, and is likely in conflict with the Food, Drug, and Cosmetic Act. The FDA should be extremely cautious of unnecessarily obstructing the Rx-OTC switch pathway, and we therefore hope the FDA strikes this provision when it issues its final ACNU rule. CHPA agrees with the points raised in a letter dated September 6, 2023, by Reps. Bob Latta, Debbie Dingell, and Dan Crenshaw that urged the FDA to remove the simultaneous marketing provision from its final rule, as it poses a threat to both consumers and the entire U.S. healthcare system by undermining the Rx-to-OTC switch process.

Next, **FDA Modernization Act 3.0**: This bill by Rep. Buddy Carter would encourage and incentivize use of non-animal testing methods in drug development, and CHPA is supportive of the legislation either as a standalone or as part of your efforts.

Lastly, modernizing the **Dietary Supplement Health and Education Act (DSHEA)**: Dietary supplements are regulated under the Dietary Health & Education Act of 1994 (DSHEA). The Act defines requirements for Current Good Manufacturing Practices (CGMPs), product labelling, and a process for new dietary ingredients. DSHEA provides a smart regulatory framework, but modernization is needed to protect today's consumer who has access to an ever-expanding dietary supplement marketplace.

CHPA looks forward to working with Congress, regulators, others in industry, and public health stakeholders on a modernized regulatory structure to protect the public health and safety of consumers, while reinforcing the quality and trust of the dietary supplement category in the healthcare system.

A modernized DSHEA must include:

- Increased FDA visibility into the market with mandatory product listing, which would make it easier for FDA to identify and more quickly remove illegitimate and illegal products from the market, provide important transparency for consumers and retailers, and help FDA make more efficient use of its resources.
- A master file concept to help support and encourage submissions of New Dietary Ingredient Notifications (NDINs), conduct studies that enhance public safety, and spur product innovation and investment in science and clinical research.
- Expanded use of third-party audits at manufacturing facilities and to ensure manufacturers are meeting high-quality standards.
- The internet must be included and defined under the promotion versus independent information criteria for materials which are not used to promote products.
- Additional resources to support FDA oversight and enforcement of the category, with a clearer definition of "Dietary Ingredient."

We appreciate the opportunity to provide our views and welcome opportunities to discuss them further at any time.

Sincerely,

Scott Melville
President and CEO