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October 7, 2025

The Honorable Jean Schmidt
Chair, House Health Committee
77 South High Street
12th Floor
Columbus, OH 43215

Re: Opposition to HB 324 – The Patient Protection Act

Dear Chair Schmidt:

On behalf of the Consumer Healthcare Products Association¹, I am writing to express our opposition to House Bill 324, which proposes new state-level regulatory authority over over-the-counter (OTC) and prescription drugs. While we share the General Assembly's commitment to protecting public health and ensuring consumer safety, this proposal raises significant concerns regarding consumer confusion, regulatory duplication, and potential conflicts with federal law.

OTC drugs play an invaluable role in our healthcare system by providing accessible and affordable treatment options to millions of Americans every day. Unlike prescription drugs, OTC medicines can be purchased without a prescription and come in user-friendly forms that help consumers safely manage minor, short-term conditions. Their accessibility helps reduce unnecessary doctor visits, lower healthcare costs, and empower individuals to care for themselves and their families.

OTC drugs are comprehensively regulated by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. Before being made available to the public, active ingredients in OTC products undergo extensive FDA review to ensure that their benefits outweigh any potential risks. The FDA-approved Drug Facts label provides standardized, science-based instructions for safe use. When used as directed, OTC medicines have a strong record of safety and efficacy, supported by decades of real-world consumer experience.

Importantly, the FDA's regulatory authority extends well beyond initial product approval, ensuring continued consumer protection long after a product reaches the market. The agency continuously monitors product safety through a rigorous post-market surveillance and recall system. If new data or adverse event reports indicate a potential risk—for example, if 5% of consumers were found to experience a severe adverse health reaction—the FDA can declare the product an "imminent hazard" and take immediate action to remove it from the market to prevent serious harm or death. This may include requesting a voluntary recall, but the agency also has stronger enforcement tools: it can issue public health warnings, pursue court orders for seizure or injunction, or suspend a drug's approval altogether. This comprehensive oversight framework ensures that any safety concern—no matter how rare—is identified and addressed swiftly through a transparent, science-based process.

Establishing a separate state-level framework for regulating OTC drugs risks undermining this strong, responsive federal system. Duplicative or conflicting requirements could confuse

¹ Consumer Healthcare Products Association is the Washington, D.C. based national trade organization representing the makers of over-the-counter medications, dietary supplements, and consumer medical devices.

consumers, create compliance challenges for manufacturers and retailers, and limit access to trusted, affordable healthcare products. Regulatory fragmentation adds unnecessary costs without delivering meaningful public health benefits.

Ohio should rely on the robust federal framework already in place to ensure the safety, efficacy, and quality of OTC medications. The FDA's comprehensive oversight—from product formulation to labeling and post-market safety monitoring—provides a proven model for protecting consumers while maintaining access to essential healthcare products.

For these reasons, I respectfully urge the House Health Committee to reject HB 324 and instead collaborate with federal regulators, healthcare professionals, and industry stakeholders to ensure that any state action complements—rather than conflicts with—federal standards.

Thank you for your attention to this matter and for your commitment to the health and well-being of Ohio residents.

Respectfully submitted,



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Cc: Members of the House Health Committee
The Honorable Representative Adam Mathews