STATEMENT

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Interested Party Statement
Ohio HB 324
3rd Hearing (Opposition and Interested Party)
October 7, 2025

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") is respectfully submitting an interested party statement on Ohio HB 324. HB 324 ignores FDA's framework for managing risks, and its restrictions could have a sweeping impact on the availability of a broad set of U.S. Food & Drug Administration ("FDA")-approved prescription drugs for Ohio patients.

The FDA has a framework to manage risks associated with prescription drugs

No drug is without risk, and many prescription drugs for the most serious diseases come with the risk of serious side effects. FDA manages the inherent risks associated with prescription drugs by, among other things, approving appropriate labeling, regulating advertising and promotion, and monitoring and evaluating adverse events. In some cases, FDA implements risk evaluation and mitigation strategies or "REMS" to require education, testing, and other prerequisites before patients can take a drug. In addition, informed consent is a cornerstone of the practice of medicine. Under Ohio law and basic tenets of medical practice, physicians are required to educate the patient about the nature and purpose of any treatment, including a prescription drug, as well as the treatment's risks, benefits, and alternatives.

HB 324 could lead to access restrictions

HB 324 proposes to impose onerous access restrictions for any drug that the Director of Health concludes "cause[] one or more severe adverse effects in greater than five per cent of the drug's users," including a complete ban on mail-order pharmacy dispensing for drugs on the Director's list. The scope of the bill is so broad that it could adversely impact access to a variety of types of prescription drugs, including those indicated for patients with cancer and other serious diseases.

This bill vests the Director of Health with making highly technical risk determinations based on a 5% threshold that is not rooted in science or medicine, and the bill does not specify the methodology through which the director of health would use to make the determination. Causal determinations are complex, especially for the adverse events defined as "severe" in section 3715.39(A)(3) in the proposed bill. To the extent the Director of Health's causation determinations contradict FDA's causation determinations—which are made by experts at FDA who review data and information not available to the Director of Health—this conflict could create issues around labeling and REMS implementation. Moreover, incorrect or inappropriate determinations by the Director of Health would have enormous adverse consequences for prescribers, patients, insurers, and prescription drug manufacturers. Prescribers may be reluctant to prescribe listed drugs, patients could lose access to them, even when those drugs are medically necessary to treat their condition, and insurers may decide not to cover listed drugs. Prescription drug manufacturers could also be subjected to lawsuits about listed drugs based on an incomplete understanding of the scientific landscape.

PhRMA is particularly concerned about patients who receive prescription drugs from specialty pharmacies.

By banning all dispensing by mail, HB 324 would effectively prevent specialty pharmacies from operating in Ohio for listed drugs, leaving patients to receive drugs from brick-and-mortar pharmacies that may not stock or otherwise be equipped to dispense those prescription drugs more commonly dispensed by specialty pharmacies.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.