Biotechnology Innovation Organization
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August 5, 2025

Arkansas State Board of Pharmacy
322 South Main Street
Suite 600
Little Rock, AR 72201

Dear Members of the Arkansas Board of Pharmacy:

The Biotechnology Innovation Organization (BIO) would like to express our significant concerns regarding the recent passage of AR HB 1531, codified in § 20-64-105, which places significant restrictions on pharmaceutical manufacturers that utilize limited distribution networks. The law has troubling implications for all entities in the supply chain, especially patients, and raises significant legal concerns that are currently the subject of ongoing litigation, as detailed in the complaint and preliminary injunction motion filed in *Novartis Pharmaceuticals Corporation v. Griffin*. Given the unresolved nature of these legal challenges, we believe that rulemaking and implementation of the law should be deferred until pending litigation has been resolved. Please note that our concerns below should not be interpreted as endorsing the law, and BIO's position remains that the law is unconstitutional.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

BIO strongly maintains that this law violates the dormant Commerce Clause of U.S. Constitution by attempting to regulate interstate commerce to prop up in-state businesses. The law attempts to insert local in-state pharmacies into a pharmaceutical drug supply chain that is largely contained by out-of-state manufacturers for a variety of reasons — most of which are to ensure patient safety and adequate supply, as outlined below. BIO also believes the law violates the federal Medicaid statute and the federal Food, Drug, and Cosmetic Act. The Courts must weigh in prior to any rulemaking.

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Clinical and Logistical Standards that Manufacturers Use to Determine Limited Distribution Networks

Manufacturers use limited distribution networks in a range of circumstances to protect patients and ensure effective delivery of care. The law fails to consider the clinical and logistical standards that manufacturers uphold in their use of limited distribution networks for certain medications, as follows:

High-Touch Patient Services and Monitoring: Limited distribution networks are commonly used for therapies intended for small or ultra-rare patient populations, where the expertise required to safely manage these medications is highly concentrated. Many therapies placed in limited distribution require close monitoring of patients, including frequent dosage adjustments, patient education on administration (e.g. for injectable or infused therapies), monitoring for adverse events, and adherence support. These services are critical to ensuring safe, effective use of the therapy and achieving the intended clinical outcomes. Limited Distribution Networks ensure patients receive specialized medications from pharmacies with expertise in handling those specific drugs, including the necessary counseling and monitoring. It is frequently not feasible- clinically or economically- to replicate this depth of expertise across a wide network of specialty pharmacies.

Inventory Uncertainty: Limited networks are often aimed at driving inventory efficiency and helping to ensure availability, particularly for products that serve small patient populations. It is both operationally inefficient and financially unsustainable for pharmacies to maintain same day access for drugs that serve small patient populations. Open access would strain inventory levels, raise risks of drug shortages, negatively impact inventory stability, and undermine business continuity and emergency response plans. Moreover, pharmacies with one or a small number of patients are unlikely to need full case quantities, yet their case orders will divert inventory from other patients in need and lead to excess carrying costs and significant product waste, as the drugs have limited shelf lives and will expire without being used. It is evident that the law's "same day access" requirement will add significant costs and inefficiency to the entire healthcare system.

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Patient Safety and Risk Mitigation: Certain drugs carry serious risks and require additional safeguards to prevent misuse or improper administration. The FDA's Risk Evaluation and Mitigation Strategies (REMS) program[1] mandates that some high-risk medications only be dispensed through a restrictive pharmacy network. This is done to ensure that prescribers, pharmacists, and patients adhere to strict safety guidelines, such as required laboratory monitoring or patient education protocols.

Special Handling and Storage Requirements: Many medications require strict temperature control, specialized packaging, or other handling protocols to maintain their stability and effectiveness. Distributing these drugs through a select network of pharmacies and distributors helps ensure that storage conditions meet necessary safety standards, preventing potential loss of efficacy or potential harm to patients.

Distribution Logistics: Limited networks are designed to optimize inventory management and dispensing/fulfillment responsiveness. The selected pharmacies have stock on hand and therefore don't need to order upon receipt of a patient's script. For patients who may live far from specialty medical centers or have difficulty traveling, limited distribution networks often include direct-to-patient shipping options. This improves equity and access, ensuring that patients are not denied timely treatment simply because of geographic or socioeconomic barriers.

Preventing Drug Diversion and Abuse: Some medications have high potential for abuse or diversion into the illegal drug market. A controlled distribution model allows manufacturers to track inventory more closely, reducing the risk of unauthorized access or illicit resale. Unrestricted distribution could make it easier for bad actors to exploit vulnerabilities in the supply chain, potentially exacerbating issues such as opioid abuse.

Maintaining Drug Integrity in the Supply Chain: Limiting distribution to a controlled network helps to prevent counterfeit or substandard products from entering the supply chain. Expanding distribution indiscriminately increases the chances of supply chain disruptions, contamination, or improper handling that could compromise patient health and safety.

[1] Risk Evaluation and Mitigation Strategies | REMS. Retrieved from: https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

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Adverse impact on patient populations: The law would adversely impact patient populations requiring complex or rare disease treatments that need specialized handling. For example, patients with hemophilia depend on clotting factor therapies that must be stored and dispensed under strict conditions to ensure safety and efficacy. Individuals with pulmonary arterial hypertension rely on medications that require continuous monitoring and coordinated care with specialty centers. Patients undergoing treatment for oncological indications often require pharmacies trained in managing severe side effects and ensuring timely delivery. Similarly, those with enzyme deficiencies need biologic infusions that have limited shelf lives and require cold-chain handling. Pharmacies that do not understand the nuances of the product, its fulfillment, and relevant payer requirements will create significant delays and uncertainty as they navigate these issues while a patient is waiting for the product.

It is evident that the law imposes a major risk of disrupting established systems that support complex treatment regimens and vulnerable patient populations. BIO respectfully urges the Board of Pharmacy to defer any rulemaking efforts until all litigation is fully resolved. We also welcome the opportunity to further engage with the Board of Pharmacy at a later date as it considers these outstanding issues.

Sincerely,

Patrick J. Plues
Senior Vice President, State Government Affairs