January 12, 2026

The Honorable André Carson
U.S. House of Representatives
2135 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Carson,

On behalf of the Alliance for Safe Biologics Medicine (ASBM), we write to express our gratitude for your sponsorship of the **Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act of 2025** along with Congressman Rudy Yakym (R-IN-02), to reinforce patient safety and preserve the integrity of the U.S. drug approval system.

Founded in 2010, ASBM is a diverse group of stakeholders including physicians, pharmacists, patients, researchers, and manufacturers working together to advance patient-centered health policy in the U.S. and worldwide. ASBM understands that patients and providers depend on the Food and Drug Administration (FDA) to ensure that prescription medicines meet rigorous standards for safety, quality, and effectiveness. Federal law appropriately requires FDA review and approval before drugs can be marketed. Compounding serves as a limited and important exception to this framework—intended only to meet the specific clinical needs of individual patients when approved therapies are unavailable or unsuitable, or during acute drug shortages.

Unfortunately, that narrow exception has increasingly been exploited. In recent years, some compounders have used perceived loopholes in current law to mass produce and promote unapproved drugs that pose significant risks for patients. These products are often made in facilities that are not routinely inspected by the FDA and may rely on active pharmaceutical ingredients sourced from foreign manufacturers that are unregistered and unregulated. This erosion of safeguards puts patients at unnecessary risk and undermines the standards that protect public health.

Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act were designed to establish clear boundaries for compounding. However, experience has shown that ambiguities in these provisions will be exploited. The SAFE Drugs Act, which the Alliance for Safe Biologics Medicine (ASBM) supports, addresses these weaknesses by strengthening existing guardrails, ensuring appropriate oversight of compounding activities, and equipping the FDA with the resources it needs to carry out its responsibilities effectively.

Specifically, the legislation clarifies that compounded drugs containing the same active ingredient as an FDA-approved medicine are considered “essentially copies” unless a modification results in a clinically meaningful difference for a specific patient. This clarification will help prevent circumvention of the law through superficial changes that do not improve patient care. The bill also sets a clear numerical threshold for the limited production of such copies by 503A compounders, replacing vague statutory language that has led to inconsistent enforcement and unnecessary litigation. In addition, it establishes a clear definition of “commercially available drug product” to prevent large-scale replication of approved medicines under the guise of compounding.

The SAFE Drugs Act further strengthens oversight by requiring greater transparency from compounders that ship significant quantities of products containing active ingredients found in approved drugs across state lines. It also ensures that outsourcing facilities are inspected before engaging in large-scale compounding and are subject to regular reinspection, helping to identify and address risks before patients are harmed.

Finally, the legislation modernizes FDA resources by updating the outsourcing facility user fee structure to support timely, routine inspections. Adequate and predictable funding is essential for effective oversight and for maintaining confidence in the safety of compounded drugs.

While the lead lobbying group for the mass compounding industry claims the SAFE Drugs Act seeks to limit legal compounding, we do not believe that to be the case. Our expert analysis of the bill allows us to say with authority that it strikes an appropriate balance—preserving patient access to legitimate compounded medicines while closing loopholes that threaten safety and undermine the legitimate FDA drug approval pathway. We again express our gratitude for your sponsorship of this important legislation and demonstrating your commitment to protecting patients and upholding the integrity of our nation's drug supply.

We would welcome the opportunity to serve as a resource to you or your staff.

Sincerely,

Ralph McKibbin, MD FACP FACG AGAF
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Cc: Rep. Rudy Yakym
Rep. Diana DeGette
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