



ASBM Statement Commending Senator Jim Banks for Introducing the SAFE Drugs Act of 2025

February 16, 2026

The Alliance for Safe Biologic Medicines (ASBM) commends Senator Jim Banks (R-IN) for introducing the **Safeguarding Americans from Fraudulent and Experimental Drugs (SAFE Drugs) Act of 2026** in the United States Senate. We also support the bipartisan companion bill (H.R. 6509), introduced in the House of Representatives by Congressman Rudy Yakym (R-IN-02) and Congressman André Carson (D-IN-07).

The SAFE Drugs Act upholds critical patient safety protections within the Federal Food, Drug, and Cosmetic Act and strengthens oversight of drug compounding practices that have increasingly stretched beyond their intended purpose. Pharmacy compounding plays an important and legitimate role in patient care when FDA-approved therapies are unavailable or patient-specific factors make an available version clinically unsuitable. However, recent years have seen the expansion of large-scale production and interstate distribution of compounded drugs that closely replicate commercially available, FDA-approved products, but often do so without the rigorous FDA review and inspection standards that safeguard public health.

The SAFE Drugs Act addresses these concerns by clarifying the definition of “essentially a copy” of a commercially available drug product, establishing clear production thresholds, strengthening reporting requirements for interstate compounding, and enhancing inspection and oversight of large-scale compounding facilities. The legislation also modernizes FDA user fee authorities to ensure the agency has the resources necessary to conduct timely and effective inspections.

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 supports reforms that preserve access to legitimate, patient-specific compounding while closing loopholes that allow the mass production of unapproved drugs outside the FDA approval framework. We believe the SAFE Drugs Act strikes this appropriate balance.

We thank Senator Banks for his leadership in advancing policies that protect patients, reinforce regulatory integrity, and uphold the high standards of the U.S. drug approval system.

Sincerely,

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