
SAFE Drugs Act proposed to restrict mass compounding and strengthen FDA's oversight – December 12, 2025

Bipartisan bill introduced by Reps. Rudy Yakym (R-IN) and André Carson (D-IN); supported by the ADA, Obesity Action Coalition, and Partnership for Safe Medicines

This week, Reps. Rudy Yakym (R-IN) and André Carson (D-IN) [introduced](#) a new bill, “Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act of 2025.” See the full [legislation](#) and [one-pager](#) here.

The bill aims to address risks associated with compounded drugs, which rose in popularity during the now-resolved shortages of weight loss medications, Wegovy and Zepbound. To do so, it proposes to: (i) restrict mass compounding of “essentially cop[ies]” of FDA-approved drugs; (ii) increase transparency for interstate distribution; (iii) strengthen regulatory oversight of outsourcing facilities; and (iv) allow the FDA to change outsourcing facility user fees to expand its resources.

The bill received support from the ADA, Obesity Action Coalition, and Partnership for Safe Medicines, which raised concerns about the safety, quality, and efficacy of compounded drugs.

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Bill aims to codify illegal mass compounding and enhance FDA inspection

The SAFE Drugs Act aims to corroborate Sections [503A](#) and [503B](#) of the [Federal Food, Drug, and Cosmetic Act](#) that govern compounding practices for state-licensed pharmacists and outsourcing facilities, respectively, in the US.

To limit “illegal” mass compounding, the bill defines any compounded drugs that contain the same active ingredient as an FDA-approved medicine to be “essentially a copy” unless a clinically meaningful modification has been made for a specific patient. This would prevent compounders from circumventing the law through superficial changes, such as minor dose adjustments, addition of untested ingredients, and re-formulation of drugs into ineffective routes. The legislation also restricts the number of “essential copies” a state pharmacist (503A) can make to 20 per month, clarifying the previous language: “regularly and in inordinate amounts.”

To increase regulatory oversight on manufacturing and interstate distribution, 503B outsourcing facilities would be subject to FDA inspection before compounding a new drug at a large scale (>100 prescriptions), as well as reinspection every two years. 503A pharmacists would be required to report to the FDA if over 20 prescriptions of “essentially a copy” drugs cross state lines. To support more inspections, the bill would allow the agency to increase the base outsourcing facility user fee rate from \$15,000.

Bill to address concerns previously raised by the ADA and the FDA

The ADA released a statement in [Diabetes Care](#) in [December 2024](#), cautioning against the use of compounded GLP-1 RAs and dual GIP/GLP-1 RAs. The ADA highlighted concerns about safety, quality, and efficacy due to the lack of standard quality control measures. The statement also referred to the FDA warning about [dosing errors](#) associated with compounded products and the proliferation of counterfeit drugs.

In [September 2025](#), The FDA issued a “green list” [import alert](#) to regulate active pharmaceutical ingredients (APIs) for

GLP-1 RAs manufactured from foreign facilities. This decision was based on the FDA's investigation, which found that 21% (n=10) of 48 foreign API facilities were non-compliant with [Current Good Manufacturing Practice](#) (CGMP) standards.

Compounding gained popularity during now-resolved shortages of GLP-1 RAs

As background, [compounded drugs](#) are customized medications made by state-licensed pharmacists and FDA-registered outsourcing facilities to address patients' specific needs (e.g., allergy to ingredients, preference for smaller oral pills). Medications in [shortage](#) are uniquely eligible for compounding copies.

While shortages of semaglutide and tirzepatide were resolved in [February 2025](#) and [December 2024](#), respectively, mass compounding of "personalized" drugs has [persisted](#).

Closes Concerns' Questions

1. In practice, will this bill look significantly different than current pharmacy practices?
2. If passed, how will this bill support patients who rely on compounded therapies when FDA-approved alternatives are not available?
3. What has the debate been like surrounding this bill?

--by Kat Moon, Kayla Mathieu, Monica Oxenreiter, and Kelly Close