**H.R. ___ -- Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act of 2025**

Led by Reps. Rudy Yakym and André Carson

**Issue Background**

Americans rely on the Food and Drug Administration (FDA) to ensure that prescription drugs are safe and effective. Typically, prescription drugs cannot be marketed or sold without FDA approval. Compounding is a narrow exception to that rule and is allowed only when approved medicines cannot meet a patient's unique medical needs or in times of extreme drug shortages. However, over the past several years, some compounders began abusing these narrow exceptions by mass-producing and marketing unapproved drugs. These unapproved compounded drugs are not produced in FDA-inspected facilities and often use active pharmaceutical ingredients (API) that are made in foreign, unregistered, and unregulated facilities, which only heightens the safety risk.

**Bill Summary**

Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) create basic guidelines for compounders, but these guidelines are regularly exploited. The SAFE Drug Act strengthens Sections 503A and 503B to clarify existing guardrails, require appropriate oversight of compounding facilities, and improve FDA resources.

- **Clarifying existing guardrails**
  - Clarifies that any compounded drug that contains the same active ingredient as an approved medicine is "essentially a copy" of that medicine unless a change has been made that makes a clinically significant difference for an identified patient, which will help prevent compounders from evading the law through pretextual changes (like marketing minor dose changes, mixing in additional ingredients without product testing, or creating new routes of administration that do not work).
  - Establishes a precise numerical cap on the number of "essential copies" a 503A compounder can make each month (20) to ensure consistency and avoid costly and burdensome litigation over the FDA's interpretation of the phrase "regularly and in inordinate amounts."
  - Establishes a clear definition of "commercially available drug product" so that 503A compounders cannot mass-manufacture approved medicines.

- **Establishing appropriate oversight**
  - Requires 503A compounders to report to the FDA the name and number of compounded drugs that contain an active ingredient that is an approved medicine and were shipped out of state in excess of 20 prescriptions or orders.
  - Requires the FDA to inspect outsourcing facilities before they begin large-scale compounding (defined as over 100 prescriptions filled for a particular product) and require reinspection every two years.

- **Enhancing FDA Resources**
  - Amends the FDCA to increase the base outsourcing facility user fee rate from $15,000 to an amount deemed appropriate by the Secretary of Health and Human Services to fund timely and regular inspections of outsourcing facilities adequately.

**Supporting Organizations:** American Diabetes Association, the Obesity Action Coalition, and the Partnership for Safe Medicines