NATIONAL ASSOCIATION OF Manufacturers

April 1, 2026

The Honorable Bill Cassidy, M.D.
Chair
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Bernie Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Brett Guthrie
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Cassidy, Chair Guthrie, Ranking Member Sanders, and Ranking Member Pallone,

On behalf of the National Association of Manufacturers (NAM) and the 13 million people who make things in America, thank you for your continued commitment to patient safety.

We write to express manufacturers' strong support for the Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act (H.R. 6509/S. 3794), sponsored by Reps. Rudy Yakym (R-IN) and Andre Carson (D-IN) and Sens. Jim Banks (R-IN) and Martin Heinrich (D-NM). The SAFE Drugs Act would protect patient safety by increasing oversight of compounding pharmacies, and we respectfully request that your committees consider this important legislation. The SAFE Drugs Act is an important step toward protecting patients from underregulated compounding pharmacies' production of potentially unsafe drugs that have not been approved by the Food and Drug Administration (FDA).

Manufacturers have a deep commitment to providing health benefits to their workers and want to be sure that manufacturing employees and their families have access to the FDA-approved medications they need. Health benefits are an integral part of manufacturing DNA—even with the consistent challenge of rising health care costs,[1] 95% of manufacturing employees are eligible for health insurance benefits, and 80% of those participate in a workplace health care plan.[2]

The SAFE Drugs Act targets a rising problem within the American health care system—the rapid expansion of compounded medications that are not FDA-approved and do not meet FDA's rigorous standards for safety and efficacy. These compounded drugs may be unsafe due to unsterile manufacturing conditions, may have incorrect potency or dosing, may contain active pharmaceutical ingredients (APIs) from unregulated and uninspected foreign facilities, and may contain APIs that are research- or animal-grade instead of human-grade. Worker safety is manufacturers' top priority, which is why the steep increase in adverse events from mass-compounded drugs is particularly concerning. Not only are mass compounders ignoring patents and intellectual property rights, the lack of oversight of their behavior has led to compounded medications harming patients. Mass

[1] National Association of Manufacturers, Q1 2026 Manufacturers' Outlook Survey (March 12, 2026). Available at https://nam.org/wp-content/uploads/securepdfs/2026/03/NAM_Q1_2026_Outlook_Write_Up.pdf

[2] Kaiser Family Foundation, *2025 Employer Health Benefits Survey* (Oct. 22, 2025). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2025-Annual-Survey.pdf

production and distribution of compounded drugs without rigorous FDA oversight has given patients access to medications that may harm them more than help them.[3]

As an example, the FDA has received thousands of reports of adverse events associated with compounded GLP-1 drugs, with patient symptoms ranging from vomiting, sepsis, anaphylaxis, and liver failure to hospitalization and death. Since 2022, over 75,000 vials and syringes of compounded GLP-1s have been recalled due to safety concerns. With limited oversight and enforcement mechanisms, FDA has been unable to adequately tamp down on unsafe compounded drugs to protect patients. Manufacturers appreciate the efforts taken by FDA to reprimand these bad actors; however, the agency needs additional authority to ensure patient safety with respect to compounded medications.

The SAFE Drugs Act would give FDA stronger oversight and enforcement capabilities with respect to compounding pharmacies, which would lead to greater patient safety. Specifically, the bill would codify the definition of "essentially a copy," closing a loophole that compounders have used to make illegal copycat drugs of branded medications; restrict the number of drugs that are "essentially a copy" that a compounder can produce each month; institute reporting requirements for compounding pharmacies that ship a certain amount of compounded medications out-of-state; require FDA inspection of outsourcing compounding facilities; and increase the base outsourcing facility user fee rate to fund increased FDA inspections.

Given the threat to patient safety posed by mass compounders, manufacturers request that your respective committees hold mark-ups on the SAFE Drugs Act, and we look forward to working with you to subsequently move the legislation to the House and Senate floor. As we continue to raise awareness about this issue, we ask that you act with the urgency necessary to get this bill to the President's desk and signed into law.

Manufacturers have significant patient safety concerns with regard to compounded medications, and we appreciate your attention to this issue. We hope you consider the NAM a resource as you move this bill through the legislative process. Manufacturers look forward to continuing to work on our shared health care priorities to ensure manufacturing workers, and all Americans, have access to safe and effective medications.

Sincerely,

Jess Wysocky
Director, Health Care Policy

Jake Kuhns
Vice President, Domestic Policy

cc: The Honorable Rudy Yakym
The Honorable Andre Carson
The Honorable Jim Banks
The Honorable Martin Heinrich

[3] U.S. Food and Drug Administration, FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (February 2, 2026). Available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss