July 21, 2026

The Honorable Bill Cassidy, M.D.
Chairman
Senate Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Bernie Sanders
Ranking Member
Senate Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Cassidy and Ranking Member Sanders:

The undersigned organizations represent patients, clinicians, researchers, professional societies, employers, and advocates committed to improving the health and well-being of people living with obesity.

We write to express our support for the Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act of 2025 (S. 3794) and respectfully urge the Senate Committee on Health, Education, Labor, and Pensions (HELP) to advance this legislation during its upcoming healthcare markup.

Obesity is a complex, chronic disease that affects millions of Americans and increases the risk of diabetes, cardiovascular disease, certain cancers, obstructive sleep apnea, and numerous other serious health conditions. Recent advances in obesity treatment, particularly FDA-approved GLP-1 receptor agonists and related therapies, have transformed care and provided new opportunities to improve health outcomes. As organizations dedicated to advancing obesity prevention, treatment, research, and patient support, we believe patients deserve access to therapies that meet rigorous standards of safety, effectiveness, and quality.

Obesity-focused organizations are weighing in on this issue because the unprecedented demand for GLP-1 medications has created unique patient-safety and treatment-continuity challenges in obesity care. Patients and clinicians need confidence that medications used to treat obesity are produced under appropriate safeguards, clearly distinguished from unapproved or unlawfully mass-produced copies, and supported by a regulatory framework that protects patients while preserving legitimate access when individualized care is medically necessary.

Pharmaceutical compounding serves an important purpose within the healthcare system. Compounded medications can help meet the unique needs of individual patients when an FDA-approved product is not clinically appropriate for many health-related conditions. Preserving

access to legitimate patient-specific compounding remains important, and we support policies that ensure patients can continue to receive individualized care when medically necessary.

At the same time, we are increasingly concerned by the rapid growth of large-scale production and distribution of compounded copies of FDA-approved obesity medications. Compounding was established to address individual patient needs—not to operate as an alternative manufacturing pathway for products that closely resemble FDA-approved treatments. When compounding extends beyond its intended patient-specific purpose, it may expose patients to avoidable safety risks and undermine confidence in the healthcare system.

Unlike FDA-approved medicines, compounded drugs are not reviewed by the U.S. Food and Drug Administration for safety, effectiveness, or quality before they reach patients. The FDA has repeatedly noted that compounded products carry greater risks than approved medicines because they are manufactured outside the regulatory safeguards and quality standards that govern approved drugs. In addition, some compounded products may include ingredients, concentrations, formulations, or delivery methods that differ from approved therapies and have not been evaluated by the FDA for safety or effectiveness.

The need for stronger oversight is becoming increasingly clear. FDA has reported nearly 2,000 adverse events associated with compounded GLP-1 products as of July 2026 and has cautioned that the true number is likely much higher because many compounders are not required to report adverse events. These reports raise significant concerns about patient safety and reinforce the need for enhanced transparency and accountability.

Publicly reported cases further illustrate these concerns. In Kentucky, Jimmie Wilson reportedly experienced acute liver failure requiring an emergency liver transplant after receiving a compounded tirzepatide product. In Texas, the family of Shawna Stash has alleged in ongoing litigation that she died after using a compounded semaglutide product. While individual circumstances may vary, these reports underscore the potentially serious consequences that can occur when patients receive medications that have not undergone the same review and oversight as FDA-approved therapies.

We are also concerned about reports regarding the sourcing and quality of ingredients used in some compounded products. The FDA has identified recurring quality concerns involving certain suppliers of active pharmaceutical ingredients used in compounded medicines. Maintaining public confidence in obesity treatment requires ensuring that medications are produced under robust quality standards and appropriate regulatory oversight.

The bipartisan, bicameral SAFE Drugs Act offers a balanced and targeted approach to addressing these concerns while preserving access to legitimate patient-specific compounding. The legislation would clarify the definition of a “copy” of an FDA-approved drug to help prevent unlawful mass compounding; require reporting to the FDA when compounded copies are distributed at scale across state lines; and strengthen FDA oversight through inspections of large-scale compounding facilities before they begin producing new products.

These provisions would help reinforce the distinction between traditional patient-specific compounding and large-scale production of compounded copies of FDA-approved medicines. In doing so, the legislation strengthens patient protections while preserving access for individuals who genuinely require compounded therapies.

As organizations dedicated to improving the health of individuals living with obesity, we believe patients should be able to trust that the medications they receive are produced under consistent safety and quality standards. Strengthening oversight of large-scale compounding is an important step toward protecting patients, supporting evidence-based care, and maintaining confidence in the nation's drug supply.

We appreciate your leadership on this important issue and respectfully urge the Committee to advance the SAFE Drugs Act during its upcoming legislative work.

Sincerely,

Advocates for Responsible Care
Aimed Alliance
Alliance for Women's Health & Prevention
Alliance of Sleep Apnea Partners (ASAP)
American Association of Clinical Endocrinology
CancerCare
Caregiver Action Network
Caring Ambassadors Program
Choose Healthy Life
Color of Gastrointestinal Illnesses
Endocrine Society
Gerontological Society of America
ICAN, International Cancer Advocacy Network
Obesity Medicine Association
League of United Latin American Citizens (LULAC)
Loom for Lupus
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Consumers League
National Council on Aging
National Hispanic Health Foundation
STOP Obesity Alliance
The Obesity Society