



February 9, 2026

The Honorable Jim Banks (R-IN)
US Senate
303 Hart Senate Office Building
120 Constitution Ave NE
Washington, D.C. 20002

The Honorable Martin Heinrich (D-NM)
US Senate
709 Hart Senate Office Building
Washington, D.C. 20510

RE: Letter of Support for the SAFE Drugs Act

Dear Senators Banks and Heinrich:

As an organization with a long track record of education and advocacy to improve patient safety and protect consumers from untested, unapproved drugs and counterfeit medications, the National Consumers League (NCL) is concerned about the threats posed by compounding pharmacies, med-spas, wellness centers, online retailers, and other manufacturers marketing and purporting to sell novel GLP-1 agonists.

Accordingly, the National Consumers League applauds the introduction in the US Senate of the Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act, which would provide critical statutory clarity and strengthen oversight to protect patients from unsafe, unapproved, and mass-marketed compounded drugs that FDA has warned can cause serious health problems.

The need for legislation to ensure that all medications are safe, contain high-quality ingredients, and are held to rigorous production standards could not be more urgent. While federal law permits limited compounding under specific circumstances — including to address temporary shortages of FDA-approved medicines or to meet individualized clinical needs — those exceptions were never intended to support ongoing, large-scale commercial production of copies of FDA-approved drugs. Yet this is the situation now with compounded GLP-1 weight loss drugs where the FDA announced the end of a national shortage in March 2025, set May 22 as the last day when compounded versions could be sold, but the mass marketing of these products continues.

Thus, what exists today is what NCL calls “America’s second obesity crisis,” a largely unregulated and exploitative market existing mostly online where telehealth companies and other sellers mass-produce and widely promote compounded GLP-1 drugs containing a different source of the active pharmaceutical ingredient (API), meaning the compounded versions are not the same and according to the FDA, could contain incorrect doses, too much or too little of the active ingredient, and possibly contaminants and bacteria.

Underscoring the potential health consequences from dosing errors and exposure to the wrong ingredients, in September 2025, the FDA reported receiving 1,150 reports of adverse events associated with compounded GLP-1 drugs, including hospitalizations and some deaths.¹ Additionally, poison control centers reported a nearly 1,500 percent increase in calls since 2019 due to overdose or side effects.²

Also of concern, the FDA and medical societies continue to warn the public about illegal online pharmacies selling counterfeit GLP-1s and companies selling so-called GLP-1 products (patches, liquids, and gummies) in forms that do not contain actual GLP-1 ingredients. Moreover, the FDA and state attorneys general have issued alerts about bad actors selling the API directly to consumers via the Internet both in powder form labeled as “not for human consumption” or as vials labeled as a “research chemical” along with dosing instructions. This illegal practice is extremely dangerous, but sellers advertised on social media that giving consumers access to the API is an easier, more affordable way to obtain GLP-1 drugs.

Yet, even as these disturbing practices put consumers’ health and possibly their lives at risk, regulators continue to play whack-a-mole because marketing dollars and the desire for GLP-1 drugs are so much greater than the resources given to the FDA and other agencies to respond aggressively.

Therefore, just prior to the introduction of the SAFE Drugs Act in the Senate, NCL went public with a national alert that raised alarm bells about so-called “personalized” compounded GLP-1s, which represent the newest marketing trend. Issued on February 3, NCL’s alert relayed FDA’s warnings about compounded GLP-1s in microdoses and non-standard formulations with added vitamins before several telehealth companies aired glossy ads during the 2026 Super Bowl touting the benefits of these practices. Specifically, our alert stressed that microdosing is not an approved regimen and can cause side effects and complications, such as not getting enough of the drug for a therapeutic benefit. Similarly, the alert informed consumers that adding ingredients like B vitamins may affect the safety, absorption, or effectiveness of the GLP-1 medication.

Then, on February 5, the telehealth company Hims & Hers pushed the envelope even further by launching a compounded copy of the first GLP-1 pill, which the FDA had only approved two months earlier. This prompted a national protest not seen before as advocates like NCL, obesity medicine leaders and even former FDC Commissioner David Kessler challenged the legality of violating the patents protecting the new FDA-approved pill and questioned whether the Hims pill would even work as the branded version is formulated with a proprietary “SNAC” technology that makes its possible to turn injectable drugs into oral doses.

The fierce backlash had quick and desired results: on February 6, FDA Commissioner Dr. Marty Makary announced that the agency would take decisive action to stop Hims from marketing a knock-off compounded GLP-1 pill, which was followed by the top lawyer for the Department of Health and Human Services (HHS) referring Hims to the Justice Department for potential

¹ Food and Drug Administration. [FDA Adverse Events Reporting System Public Dashboard](#), data on compounded September 9, 2025

² America’s Poison Centers. [“America’s Poison Centers - GLP-1,”](#) 2025.

violations of federal law. Thus, on February 7, Hims bowed to the pressure and announced the withdrawal of its compounded GLP-1 pill.

For advocates like the National Consumers League, this is a happy ending to an egregious situation that, if handled differently, could have served as a precedent for weakening the FDA drug approval process and the rigorous drug safety rules required for branded and generic drug manufacturers. Accordingly, NCL applauded FDA's quick intervention on behalf of the 40 percent of adults with obesity,³ many of whom seek treatment with a safe and effective GLP-1 weight loss drugs.

Now, with the introduction of the SAFE Drugs Act in both the House and the Senate, Congress has an important opportunity to address the growing, exploitative market for copycat GLP-1 weight-loss products and create a pathway for a holistic federal response.

Of special importance to NCL, the bill draws a clear line between legitimate compounding and the large-scale production of unapproved drug copies by clarifying what constitutes an unlawful "essentially a copy" product. This will increase transparency when compounded drugs are shipped across state lines and require FDA inspections before high-volume facilities begin producing new compounded drugs. At the same time, provisions in the bill will strengthen FDA oversight, close dangerous regulatory gaps, and help ensure that active pharmaceutical ingredients used in compounded drugs come from registered, inspected facilities that meet safety and quality standards.

Enacting the SAFE Drugs Act will not solve all the problems consumers face when navigating the shadowy market for untested, unapproved GLP-1 products but it is an important step forward in protecting the health and safety of millions of Americans. Accordingly, NCL supports the SAFE Drugs Act and will work to ensure the passage of this needed bipartisan legislation.

Thank you for your efforts on behalf of consumers.

Sincerely,



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³ Emmerich, SD et al. Obesity and Severe Obesity Prevalence in Adults: United States, August 2021-August 2023. NCHS Data Brief No. 508, September 2024