NATIONAL CONSUMERS LEAGUE
1701 K Street, NW, Suite 1200 Washington, DC 20006
Main: (202) 835-3323 Fax: (202) 835-0747 www.nclnet.org

September 17, 2025

The Honorable Rick Scott
Chair, Senate Select Committee on Aging
G16 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kirsten Gillibrand
Ranking Member, Senate Select Committee on Aging
628 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Scott and Ranking Member Gillibrand:

The National Consumers League (NCL) is a private, nonprofit consumer organization that, since its founding in 1899, has been a vocal advocate for policies to improve the health and well-being of Americans. Thus, we write to thank the Select Committee for holding the hearing, *Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans,* and to offer our perspective on a critical safety issue affecting many seniors today – the serious health risks posed by compounded GLP-1 medicines made with unregulated active pharmaceutical ingredients (API) from foreign sources (primarily China), many of which are not registered or inspected by the Food and Drug Administration (FDA).

On May 1, 2025, the NCL launched The Weight Truth, a national anti-disinformation effort to alert consumers to the warnings from the FDA and medical societies that compounded GLP-1 drugs are not reviewed for safety, effectiveness or quality by the FDA,[1] are not approved medicines, and "can be risky for patients"[2] because compounded versions differ in ways that may increase the risk of medication errors. Among the differences, compounded GLP-1 drugs may contain too much or too little of the API, be at a different dosage level, and have drug quality problems, such as contamination with bacteria or a harmful substance – all of which can be detrimental to patient safety.

Underscoring the potential health consequences from dosing errors and exposure to the wrong ingredients, as of September 9, 2025, the FDA has received 1,424 reports of adverse events associated with compounded GLP-1 drugs, 329 hospitalizations, and 23 deaths.[3] Moreover, poison control centers have seen a nearly 1,500 percent increase in calls since 2019 related to overdose or side effects of injectable weight loss drugs, and have managed 3,633 GLP-1 agonist-related exposure cases as of April 30, 2025.[4]

[1] Food and Drug Administration. Human Drug Compounding Laws. December 17, 2024. Accessible at: https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws

[2] Food and Drug Administration. FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss. September 5, 2025. Accessible at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

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

[4] America's Poison Centers. Glucagon-Like Peptide-1 (GLP-1) Agonists.

However, older adults face added safety challenges when taking a compounded GLP-1 drug. Compared to younger adults, seniors metabolize drugs differently due to age-related physiological changes, such as reduced liver and kidney function. These age-related changes increase the likelihood that a dosing error from taking a compounded GLP-1 medicine will lead to a severe adverse effect, like pancreatitis, gallbladder issues, and gastroparesis.[5] Additionally, older adults may be more susceptible to the medication's known side effects, such as muscle mass loss and dehydration, and are at higher risk for harmful drug interactions due to taking multiple medications.

These concerns are especially relevant as the Select Committee considers the risks to seniors from compounded GLP-1 drugs that rely on foreign sources for the supply of API. Federal law requires that API used in any product sold in the U.S., including compounded drugs, must be sourced from entities that are properly registered with the FDA. However, a recent report citing publicly available data finds that most of the API used in making compounded GLP-1 drugs are from entities that are either not registered with the FDA or have never been inspected by the FDA to ensure compliance with good manufacturing practices and other safety requirements.[6] Moreover, an analysis from the Brookings Institution detailed that the vast majority of these foreign API shipments come from China and have not been inspected for safety or quality.[7]

To address this situation, on September 5, the FDA announced the establishment of a "green list" import alert that will include GLP-1 APIs from facilities the agency has inspected or evaluated and, according to the agency, "appear to be in compliance" with the FDA's standards that apply to all API's manufactured in the U.S. Further, the FDA has stated that APIs from other sources are subject to detention without physical examination. NCL applauds this action as a proactive measure to help stop the entry of unverified foreign APIs into the U.S. Still, we remain concerned that more will need to be done to address the quality issues posed by foreign-manufactured compounded GLP-1 drugs and, more generally, to reduce pharmaceutical supply chain risks.

Speaking for America's consumers, and especially older adults who are at greater risk for harm if drugs contain potentially unsafe ingredients, NCL thanks the Select Committee for seeking solutions to reduce the serious threats posed by quality issues in foreign-manufactured pharmaceutical products. We appreciate the opportunity to share our insights and hope these comments will be helpful.

Sincerely,

Nancy Glick

Nancy Glick, Director, Food & Nutrition Policy
National Consumers League
nancyg@nclnet.org

[5] Are GLP-1 Weight Loss Medications Safe for People Over Age 65? Harbor Health. February 28, 2024. Accessible at: https://harborhealth.com/blog/health-tips/are-glp-1-weight-loss-medications-safe-for-people-over-65

[6] Center for Medicine in the Public Interest. FDA Regulatory Failures in Enforcing Limits on GLP-1 Compounding Puts Patients at Risk. July 22,2025.

[7] Brookings Institution. Wosińska, ME et al. US drug supply chain exposure to China: Myths, omissions and related insights. July 28, 2025. Accessible at: https://www.brookings.edu/articles/us-drug-supply-chain-exposure-to-china/