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NCL Urges FDA and Consumers to Take Action As GLP-1 Shortage Ends, but "Infodemic" Continues

May 22 Conclusion of Mass Compounded GLP-1s Should Bring Clarity but Confusion Reigns

Washington, DC: May 22, 2025 – Despite the end of the GLP-1 shortage and May 22 FDA-issued deadline for companies to stop mass compounding of the products, the National Consumers League (NCL) is concerned that the epidemic of GLP-1 misinformation will continue to confuse consumers with fake products that can put their health at risk. Both the U.S. Food and Drug Administration (FDA) and consumers have roles to play in responding to the "infodemic."

According to the FDA, as of today, companies should no longer mass-produce compounded GLP-1s. If they do, they will be in violation of the Food, Drug, and Cosmetics Act and may be subject to penalties, recalls, and other sanctions. While NCL understands the role of compounded drugs as customized medications created by pharmacists or physicians in individualized cases that combine, mix, or alter ingredients to meet a specific patient's needs, like a swallowing disorder, they are not appropriate for mass production and distribution. They also pose more potential risks to patients.

Because compounded drugs do not have the guardrails, nor have they been tested in large populations, there are risks associated with them, and they therefore should never be produced on a mass marketing basis except in very limited situations where the FDA has declared a shortage of drugs in high demand. That was the case with shortages of GLP1 drugs from 2022 to several months ago, to meet the high demand.

The May 22 deadline should provide clarity for consumers who need GLP-1 medications. After this date, only products that are "FDA-approved" or have been through the FDA process and are proven safe and effective in large populations and prescribed by a medical professional should be on the market. We must ensure compounders abide by the FDA's rules. However, NCL is concerned that the marketing of compounded and other nonlegal weight loss products will continue beyond the deadline and continue to confuse consumers and patients who are managing chronic diseases like obesity.

Our concerns are not unfounded: We recently released a <u>national survey</u> of perceptions of compounded GLP-1 products sold online, showing that there is significant confusion about GLP-1 products amongst women. Key findings include that more than 70% believe compounded GLP-1s are only on the market if they have been tested and proven safe, and more than half (53%) think compounded GLP-1s have received FDA-approval. Neither of these claims is true.

For the sake of consumers across the country, we urge the FDA to enforce federal law and its long-standing safety-guided standards for compounded products now that GLP-1 products are no longer in shortage. We also call on consumers to take the following steps to learn the facts about GLP-1s and understand what's FDA-approved, what's fake, and what might put their health at risk:

1. If a product says, "Doctor Approved," and not "FDA-Approved," it is likely a compounded versions of GLP-1s that are not permitted after May 22: if you see them, it's a red flag.

- 2. Educate yourself by going to The Weight Truth website (https://nclnet.org/weight-truth/),
- 3. Be aware that FDA-approved GLP-1s are not available in gummy, chewable, patch, nasal, or sublingual forms.
- 4. Ask the healthcare provider or company selling you the GLP-1 if it's the FDA-approved brand product. You can also reach out to the FDA-approved manufacturers to determine whether you have authentic medicine.
- 5. Report fake GLP-1s to us through The Weight Truth website (https://nclnet.org/weight-truth/).

In addition to raising awareness amongst consumers about the misinformation surrounding compounded GLP-1s, NCL is also reiterating its appeal to Congress to pass the Treat and Reduce Obesity Act (TROA), a critical piece of legislation that will allow more older Americans to be treated with FDA-approved anti-obesity medications under the Medicare program.