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Center for Medicine in the Public Interest

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CONTACT: Lindsey Shaw
410-419-5554
lshaw@obesity.org

New CMPI Report Finds FDA Inaction on Illegal GLP-1 Compounding Threatens U.S. Patients

Calls Grow for Immediate Enforcement as Unapproved Knockoffs Flood Market

WASHINGTON, D.C. — July 22, 2025: A new report from The Center for Medicine in the Public Interest (CMPI) warns that regulators are failing to stop the illegal mass production of compounded GLP-1 drugs despite mounting evidence of patient harm and urges the U.S. Food and Drug Administration (FDA) to use its enforcement powers to end GLP-1 mass compounding practices to protect patients.

The report, **"FDA Regulatory Failures in Enforcing Limits on GLP-1 Compounding**," authored by CMPI President and former FDA Associate Commissioner **Peter J. Pitts**, documents how mass compounding pharmacies are importing dangerous foreign ingredients and misleading patients into using unapproved, untested weight-loss and diabetes drugs, including semaglutide and tirzepatide.

The findings, to be presented today at a Congressional briefing hosted by The Obesity Society, shine a light on the growing public health threat posed by compounded GLP-1 medications. The event will explore how mass compounding pharmacies are exploiting the health system and deceptively marketing GLP-1s to vulnerable populations, address the urgent need to restore the credibility of U.S. regulatory institutions, and discuss actionable solutions to this growing problem.

"The FDA is allowing a black market of pharmaceutical-grade knockoffs to thrive right under its nose," said Pitts, who also serves as a visiting professor at the University of Paris School of Medicine. "This is not just regulatory negligence—it's a public health crisis in the making."

Key Findings from the Report Include:

- **FDA Shortage is Over – but the Copycats Haven't Stopped.** Compounders continue to sell unapproved versions of GLP-1s under the false claim of "personalization" – often adding unnecessary ingredients or adjusting dosage – to avoid existing laws.
- **Compounded GLP-1s are Often Made with Ingredients from Unregistered Suppliers in China.** These unapproved drugs frequently rely on unregulated active pharmaceutical ingredients (API) from foreign sources (primarily China), many of which are not registered or inspected by the FDA. Research indicates that the vast majority of foreign API in the U.S. comes from suppliers outside the country that are unregistered drug establishments, meaning the FDA does not know it should be inspecting them.
- **Patient Harm is Real.** Safety events tied to compounded GLP-1s include overdoses, hospitalizations, and contamination. Poison control calls related to GLP-1 drug overdoses rose 1,500% since 2019.
- **False Marketing is Widespread.** Misleading advertising is pervasive – from social media testimonials to TV advertisements to "health spa" promotions. These ads characterize compounded products as safe or FDA-approved. A majority of surveyed consumers wrongly believe compounded drugs are tested by the FDA.

"We've seen this story before—from the deadly New England Compounding Center fungal meningitis outbreak to countless smaller tragedies," Pitts said. "This time, the warning signs are flashing, and we have the laws in place to prevent it. What's missing is regulatory enforcement."

CMPI's Policy Recommendations Include:

1. **FDA Must Enforce Current Law** by ending phony "personalization" schemes and requiring compounders that act like manufacturers to register as such.
2. **Block Illegal API imports**—FDA and U.S. Customs and Border Protection must reject shipments from unregistered or unsafe foreign suppliers.
3. **Enforce the 5% Rule** limiting interstate compounding sales—Congressional intent is clear, but enforcement is lacking.
4. **Resource the FDA properly**—Congress must increase funding and mandate oversight to protect patients and uphold regulatory credibility.

More Than a Dozen Organizations and Policymakers Have Raised Concerns about Compounded GLP-1s, and the Number Continues to Grow

Today's report is the latest and most explicit indictment of compounders' egregious behavior. Over the past six months, more than a dozen government and non-profit organizations including consumer, physician and patient advocacy groups, federal and

state agencies and Members of Congress, have raised concerns about the patient safety risks associated with compounded GLP-1 medications.

Concerns have been raised by:

- **Senator Thom Tillis (R-NC) Leads Efforts to Protect Patients from Counterfeit GLP-1 Medications,** June 10, 2025
- **North Carolina Reps. Brad Knott (R) and Deborah Ross (D)** send letter requesting federal authorities end the sale of "counterfeit, research-grade and illegal copycats" of GLP-1 medications, June 11, 2025
- **US Chamber of Commerce**: Standing Up for Patients: Why Protecting Innovation Matters | U.S. Chamber of Commerce, May 30, 2025
- **National Consumers League (NCL):** Obesity Medication Misinformation Crisis Won't End with FDA Deadline, May 22, 2025; NCL urges FDA and consumers to take action as GLP-1 shortage ends, but "infodemic" continues, May 21, 2025
- **U.S. Food & Drug Administration (FDA):** FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, May 16, 2025
- **Truth in Advertising (TINA):** What You Should Know about Telehealth Companies Selling Compounded Drugs, April 8, 2025
- **Obesity Action Coalition (OAC) & The Obesity Society (TOS)**: Obesity Action Coalition & The Obesity Society Send Letter to FDA on Behalf of More Than 20 Leading Organizations & Providers Urging Enforcement of Compounding Regulations, March 24, 2025
- **Obesity Action Coalition (OAC)**: Why OAC Warns Against Compounded GLP-1 Medications, March 24, 2025
- **The Obesity Society (TOS):** Scientific and Regulatory Briefing – Virtual Toolkit, March 19, 2025
- **Personalized Medicine Coalition (PMC):** Proven Personalized Medicine, March 19, 2025
- **Alliance for Sleep Apnea:** Beware of Compounded Tirzepatide, March 13, 2025
- **FBI Issues Consumer Alert:** Safety Concerns Related to Fraudulent Compounding Practices Associated with Weight Loss Drugs, February 28, 2025
- **National Association of Attorneys General (NAAG) letter by bipartisan coalition of 38 attorneys general:** State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs, February 19, 2025

About CMPI

The Center for Medicine in the Public Interest (CMPI) is a nonprofit, nonpartisan health policy think tank committed to promoting evidence-based medicine, pharmaceutical innovation, and patient safety. To learn more, visit **cmpi.org**.

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