THE WEIGHT TRUTH

Compounding, Counterfeits and Confusion: Confronting the Infodemic of Disinformation on Obesity Treatments

A Report of the National Consumers League

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Preface

In the United States today, we are now confronting two obesity-related epidemics.

The first is the epidemic of obesity, a disease that now affects over 100,000 million adult Americans and is commonplace in all 50 states, the District of Columbia and the US territories.[1] Classified as a serious chronic disease requiring treatment,[2] obesity not only impacts almost every aspect of a person's health, but it worsens the outcomes of more than 230 medical conditions,[3] is directly linked to approximately 400,000 premature deaths each year,[4] and costs the US economy an estimated $1.72 trillion annually.[5]

But what makes obesity especially perplexing is that the disease remains largely undertreated by healthcare providers, even though recent scientific advances have led to a new class of anti-obesity medicines called "glucagon-like peptide-1 receptor agonists" or GLP-1s that control appetite and cravings to achieve significant weight loss. Additionally, recent advances in technologies and non-invasive approaches have made bariatric surgery safer with faster recovery times.

To understand why the health system works against people with obesity, in 2021 the National Consumers League (NCL) and the Obesity Care Advocacy Network (OCAN) convened a panel of experts who determined that effective treatment is being impeded by several "human obstacles"—incorrect beliefs about obesity, prejudice toward people due to their size, lack of training for health providers, access barriers, and outdated government policies. NCL then issued *A New Patient-Centered Obesity Action Agenda* in 2022 based on these findings and on January 31, 2024, we released the first *Obesity Bill of Rights* for the nation with the National Council on Aging (NCOA) and leading obesity experts. Intended to transform obesity care at every level, the bill of rights establishes eight essential rights, so people with obesity will be screened, diagnosed, counseled, and treated according to medical guidelines.

The good news is these initiatives are starting to have an influence. More Americans now recognize that obesity is a disease, the number of doctors seeking certification in obesity medicine is rising,[6] and there is a growing trend of health providers prescribing GLP-1 medications for weight loss and diabetes management.

Yet, there is a dark side to this story. The promise of GLP-1s has caused demand for these drugs to surge, leading to a shortage of the branded drugs from late 2022 through late 2024. During the shortage, the US Food and Drug Administration (FDA) allowed licensed compounding pharmacies to sell non-comparable versions of GLP-1 drugs under specific rules that make clear that compounded GLP-1s are not reviewed by FDA for safety, effectiveness, and quality. Thus, these products are not FDA-approved. FDA also issued a warning that compounded versions of GLP-1s may cause health problems due to dosing errors if patients measure and self-administer incorrect doses of the drug.

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

[2] Obesity Medicine Association. June 19, 2013. "AMA House of Delegates Adopts Policy to Recognize Obesity as a Disease. Accessible at https://obesitymedicine.org/blog/ama-adopts-policy-recognize-obesity-disease

[3] Obesity Care Advocacy Network. Fact Sheet: Obesity Care Beyond Weight Loss

[4] Hurt Rt, et al. Obesity epidemic: overview, pathophysiology, and the intensive care unit conundrum. J Parenter Enteral Nutr. 2011 Sep;35(5 Suppl):45-135

[5] Milken Institute (October 2018), "America's Obesity Crisis: The Health and Economic Costs of Excess Weight."

[6] American Board of Obesity Medicine. Number of ABOM Diplomats Continues to Grow Rapidly. October 2024. Accessible at https://www.abom.org/abom-announces-october-24-test-results

However, it became clear that compounded GLP-1s are a lucrative business, especially when consumers seek cheaper alternatives because their insurance does not cover these injectable drugs. Thus, what was meant as a temporary solution during a drug shortage turned into a largely unregulated marketplace where some online sellers, including illegal online pharmacies and companies promoting patches or oral supplements, continue to promote alternatives to FDA-approved GLP-1 medicines with unsubstantiated claims of safety and ease of use.

The situation has created America's second obesity epidemic—in this case, an escalating "infodemic" of false information and misleading claims about compounded GLP-1 drugs that is leading Americans to tune out the advice of the FDA and leading medical societies and opt for "cheap, easy and doctor-approved" GLP-1 drugs that may cause harm or could be fakes.

As defined by the World Health Organization (WHO), an "infodemic" is a tsunami of information, some accurate but most misleading or false, that spreads online at lightning speed and is intended to deceive. Adding to the problem, infodemics are amplified by social media, where rumors, falsehoods and conspiracy theories spread farther and faster than a virus, drowning out hard, clear facts and affecting health decision-making.

We have witnessed infodemics before. They have spread false information that caused patients in the US and globally to deny evidence-based treatment. And now an infodemic is sowing distrust in health institutions and the manufacturers of FDA-approved GLP-1 medicines while promoting compounded versions as equivalent to FDA-approved drugs and new forms, such as patches and sublingual forms, without evidence these products even work.

Recognizing what is at stake, the National Consumers League is calling for collective action to combat the epidemic of false and misleading claims about weight loss drugs, leading to the widespread availability of timely, accurate, and easy-to-understand information on GLP-1s from trusted sources. Countering the infodemic about weight loss medicines is a priority that cannot wait.

Executive Summary

Compounded drugs are an important part of the nation's drug supply. Representing about 1 to 10 percent of the prescriptions written in the US, compounded drugs allow people to take prescribed medications when they need a different dosage, have an allergy to an ingredient, or may need the medicine in a different form. And because they are usually one-of-a-kind modified drugs, the Food and Drug Administration (FDA) does not approve these medicines and state licensed compounding pharmacies are not required to conduct safety tests, provide information about side effects, or report serious health problems to FDA.

The problem comes during a national shortage of a popular, widely used drug, like GLP-1 weight loss medicines, when FDA allows licensed compounding pharmacies to sell large quantities of compounded alternatives to FDA-approved drugs under a regulatory framework intended for individualized compounded drugs. The unintended consequences played out between 2022 and 2024 when the popularity of GLP-1 drugs caused high demand for these medicines, created a supply shortage, and prompted FDA to allow compounding pharmacies to fill the supply gap with compounded versions on a temporary basis.

Because booming consumer demand for GLP-1s was a primary reason for the shortages, it was a gold rush situation for compounders and the telehealth companies and med-spas that sold compounded GLP-1 versions directly to consumers online at a lower cost. Thus, profits soared, and some online sellers of compounded GLP-1 products took advantage of regulatory shortcomings and insufficient enforcement to build a large market with widespread advertising that touted the benefits of GLP-1s without disclosing the risks and made inferences that their compounded drugs were the same as the FDA-approved versions.

On March 5, 2025, FDA declared that the shortage of GLP-1 products was over, triggering the withdrawal of compounded versions from the market. However, the problem has not been resolved. Today an exploitative market has emerged where non-compliant sellers, such as rogue online pharmacies and companies promoting patches or oral supplements, continue to hype their GLP-1 products as alternatives to FDA-approved GLP-1 medicines when FDA has warned that these products "can be risky for patients."

Additionally, state attorneys general report that online retailers are illegally selling the active ingredients in GLP-1 drugs to consumers online as an inexpensive way to take a GLP-1 drug, although these ingredients come from undisclosed sources and could be contaminated with bacteria. There is also the very serious problem that rogue online pharmacies are selling counterfeit GLP-1s without prescriptions on hundreds or even thousands of websites using brand names, descriptions, and images of FDA-approved drugs. The National Association of Boards of Pharmacy (NABP) estimates there are 35,000 active online pharmacies and 95 percent of them operate unlawfully, including not requiring a prescription.

Underscoring the potential health consequences from dosing errors and exposure to the wrong ingredients, FDA has received over 775 adverse event reports for compounded GLP-1 drugs as of February 28, 2025, which includes reports of 17 deaths and over 100 hospitalizations. Moreover, poison control centers report nearly a 1,500 percent increase in calls since 2019 related to overdosing or side effects of injectable GLP-1 usage. Importantly, because most compounding pharmacies are not required to report adverse events from compounding drugs, the FDA indicates it is "likely that adverse events from compounded versions of GLP-1 drugs are underreported."

However, what makes these challenges so confounding is the deluge of false information circulating now about GLP-1 medicines that is causing consumers to tune out the advice of the FDA and leading medical

societies and opt for drugs that may cause harm or could be fakes. The World Health Organization (WHO) calls this disinformation overload an "infodemic," and it is still happening now, flooding the market with falsehoods and misleading claims about GLP-1s that are causing confusion, leading to risk-taking behaviors, and perpetuating fraud.

Documenting the reach of these false claims, a 2025 analysis of online advertising reported in the JAMA Health Forum found "alarming" levels of misleading information from some online sellers of compounded GLP-1s, including exaggerated claims for efficacy and failing to include risks of side effects or contraindications. The volume of this disinformation is further underscored by a 2024 study that estimated a 1200 percent increase in "violative or problematic" GLP-1 related ads between 2022 and 2024 (the time when FDA-approved GLP-1 drugs were in shortage).

Yet, the most persuasive data comes from a new National Consumers League (NCL)-commissioned survey of 1,500 women ages 18-55 fielded by Dynata, LLC in March 2025, which finds that 85 percent of women with obesity believe the false claims made in online ads. Reinforcing these viewpoints, 71 percent of the women polled said they believe compounded GLP-1s are only on the market if they were tested and proven safe, and more than half (53 percent) think these medications received FDA-approval. These perceptions are not accurate.

Infodemics are dangerous—which is why now is the time to confront the exploitation of regulatory shortcomings and the disinformation that allow illegitimate markets to flourish. Accordingly, NCL has launched an ambitious national anti-disinformation effort called The Weight Truth to help the public decode misinformation about weight loss medicines. Additionally, NCL worked with leaders in obesity management, patient safety, disinformation strategies, and law enforcement organizations to consider ways to overcome the infodemic of false information on GLP-1s and think prospectively about improving the regulation of compounded drugs during and after national drug shortages, so exploitative markets do not occur when there is a large mass market for these drugs. Toward this end, NCL's blueprint identifies nine priorities for action:

1. **Make Combating Infodemics a National Priority**
   The growing threat of disinformation requires a unified national response, and NCL's anti-disinformation initiative, The Weight Truth, can be the model for educating consumers and being a platform for clinicians, advocates, and policymakers to advance policy changes to protect consumers.

2. **Increase Coverage and Affordability of FDA-Approved GLP-1 Weight Loss Drugs**
   Because increasing coverage of FDA-approved GLP-1 drugs is the best way to put a damper on a exploitative market for these products, NCL and many advocates are working to secure coverage through Medicare and state Medicaid programs and private insurers in order to reduce patients' out-of-pocket costs.

3. **Enforce Existing Drug Advertising Rules**
   During the national shortage of GLP-1 drugs, online advertising proved effective in convincing consumers that compounded versions were essentially generic versions of branded drugs. Thus, FDA can help stem the infodemic by monitoring content online and enforcing existing prescription

drug advertising regulations.

4. **Explore a New Role for the Federal Trade Commission**
   The Federal Trade Commission (FTC) has a strong regulatory framework to address deceptive marketing and ensure that advertising claims are truthful and substantiated, including health claims. Since FTC is taking aim at food companies that are developing "GLP-1 friendly" products, there is an opening for the FTC to take enforcement actions against companies that make false or misleading claims about GLP-1 drugs and to assert that supplements, gummies, patches, and related products are not forms of GLP-1s.

5. **Increase Pharmacovigilance of Online Pharmacy Websites**
   During the national shortage of GLP-1 drugs, illegal online pharmacies were actively selling semaglutide without a prescription and shipping unregistered and falsified products. These pharmacies pose a major threat and should be a focus for enforcement efforts by the FDA and state boards of pharmacy.

6. **Intensify Federal and State Efforts to Protect Consumers from Counterfeiters**
   Counterfeit products are entering the US supply chain, as identified by the FDA, the Federal Bureau of Investigation (FBI), and many state attorneys general, key areas for enforcement are sellers using online app-based platforms to supply consumers with GLP-1 products containing insulin or "animal grade" ingredients and illegally selling the active pharmaceutical ingredient (API) in GLP-1s directly to consumers.

7. **Implement Labeling Rules for Compounders**
   Not having labeling information on side effects, contraindications, and possible adverse events leads patients to underestimate the risks of compounded drugs and potential dosing errors. Given the millions of consumers who may take compounded drugs, the same labeling rules should apply to both branded and compounded copycat drugs during a shortage.

8. **Require Compounders to Submit Adverse Reaction Reports to FDA**
   Adverse event reports are often the way the FDA learns of safety issues with compounded drugs, which is why the Agency should have accurate information on safety issues during a national drug shortage.

9. **Require Compounders to Disclose Information on the Composition and Distribution of Compounded Drugs**
   Currently, compounders are not required to disclose the source of their active pharmaceutical ingredient (API), the main ingredient in making compounded GLP-1s, nor report the number of doses sold. Having access to this information during a national shortage will improve surveillance efforts and build trust in the integrity of compounded products.

Introduction

Among Western countries, the obesity epidemic we see today traces back to the US, when researchers realized that the obesity rate had jumped to 15 percent of adult Americans between the years 1976 to 1980, then rose to 23.3 percent during 1988 to 1994 and increased to 30.9 percent in 1999-2000.[7]

To understand what had happened, researchers used data from the National Health and Nutrition Examination Survey (NHANES), a program of the Centers for Disease Control and Prevention (CDC), to assess people's physical activity levels, food consumption trends, and lifestyle habits. What they found was the abundance of ultra-processed foods, especially sugar intake through sugar-sweetened beverages, was the key factor driving increases in obesity. Thus, the research findings became a call-to-action for releasing the first *Dietary Guidelines for Americans* in 1980[8] and shaped the initial thinking among clinicians that obesity can be addressed through changes in diet and exercise.

Based on this early history, the first obesity treatment guidelines define obesity as "a complex chronic disease in which abnormal or excess body fat (adiposity) impairs health, increases the risk of long-term medical complications and reduces lifespan."[9] However, a new scientific understanding of obesity now links the disease to disruptions in brain signaling that cause people to feel hungry and overeat. This discovery led to a new class of injectable Food and Drug Administration (FDA)-approved weight loss drugs called "glucagon-like peptide-1 receptor agonists," or GLP-1s, that mimic a natural hormone in the body to reduce appetite, slow digestion, and control food cravings. Considered game changers in obesity treatment, GLP-1s can lead to significant weight loss, ranging from 5 percent to 15 percent of body weight over 12 to 72 months.[10]

Yet, the popularity of GLP-1 drugs caused high demand for these medicines, creating supply shortages and prompting consumers to seek alternative ways to obtain these drugs because many health plans do not cover GLP-1s. Therefore, when FDA allowed compounding pharmacies to fill the supply gap with compounded versions of GLP-1s during a shortage period (2022-2024), the profit motive for selling cheaper compounded drugs to consumers produced a multi-billion-dollar industry where online retailers aggressively marketed products that are not FDA-approved. This means FDA did not review the drugs for their safety, effectiveness, and quality before the products entered the market, yet many consumers believed this was the case due to disinformation and misleading advertising claims.

On March 5, 2025, FDA declared that the shortage of GLP-1 products was over,[11] triggering the withdrawal of compounded versions from the market. However, the problem has not been resolved. Today an exploitative market has emerged where non-compliant sellers, such as rogue online pharmacies and

[7] Casas R, et al. The Origins of the Obesity Epidemic in the USA- Lessons for Today. Nutrients. 2022 Oct 12;14(20):4253

[8] US Department of Agriculture. History of the Dietary Guidelines. Accessible at: https://www.dietaryguidelines.gov/about-dietary-guidelines/history-dietary-guidelines

[9] World Health Organization. Obesity. https://www.who.int/health-topics/obesity#tab=tab_1

[10] Rao,M et al. Prescribing GLP-1 Agonists for Weight Loss: Wrestling with Our Philosophical Angst. October 2024.Am Fam Physician. 2024;110(4):340-341

[11] Food and Drug Administration. FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize. March 10, 2025. Accessible at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

companies promoting patches or oral supplements, continue to hype their GLP-1 products as alternatives to FDA-approved GLP-1 medicines when FDA has warned that these products "can be risky for patients."

At the same time, state attorneys general report that online retailers are illegally selling the active ingredients in GLP-1 drugs to unwitting consumers intended "for research purposes only" or are "not for human consumption."[12] Although FDA has warned that these ingredients come from undisclosed sources and could be contaminated with bacteria, bad actors nonetheless advertise them online as an inexpensive way to take a GLP-1 drug and offer to provide dosing instructions. There is also the very serious problem that rogue online pharmacies are selling counterfeit GLP-1s without prescriptions on hundreds or even thousands of websites using brand names, descriptions, and images of FDA-approved drugs. The National Association of Boards of Pharmacy (NABP) estimates there are 35,000 active online pharmacies and 95 percent of them operate unlawfully, including not requiring a prescription.[13]

However, what makes these challenges so confounding is the deluge of false information circulating now about GLP-1 medicines that is causing consumers to tune out the advice of the FDA and leading medical societies and opt for drugs that may cause harm or could be fakes. The World Health Organization (WHO) calls this disinformation overload an "infodemic," and it is still happening now, flooding the market with falsehoods and misleading claims about GLP-1s that are causing confusion, leading to risk-taking behaviors, and perpetuating fraud.

To be clear, the infodemic regarding GLP-1s represents a serious health hazard for Americans hoping to benefit from obesity treatment with these medicines. According to FDA, compounded GLP-1 drugs may contain too much or too little of the active ingredient and the Agency has received reports of overdoses, with cases of people administering 5 to 20 times more than the intended dose of semaglutide.[14] Besides compounded drugs, health professionals worry about dosing errors and the presence of possibly dangerous ingredients in illegal GLP-1 products, such as the substitution of insulin for the common active ingredients in FDA-approved versions.

Confronting these problems requires reaching consumers online with empowering messages and factual science-based information. It also means addressing the regulatory gaps that produced the exploitative market for GLP-1 drugs during the national shortage and aggressively enforcing existing laws that prohibit false or misleading claims in pharmaceutical advertising and promotion.

Taking on this challenge is necessary for all Americans, which is why there is widespread support from medical societies and law enforcement agencies for a new mobilization to drive meaningful change. Towards this end, National Consumers League (NCL) conferred with leaders in obesity, disinformation and law enforcement to understand how the unregulated marketplace for GLP-1s operates, what messages are reaching the public, and what can be done both to arm people with the facts about GLP-1s and to protect the public through legal and regulatory efforts. As such, this report represents a blueprint for action and is intended as a catalyst for moving forward.

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[12] US Food and Drug Administration. FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss. March 17, 2025. Accessible at: www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

[13] National Association of Boards of Pharmacy. Rogue Rx Activity Report. Disrupting Illegal Online Pharmacies: Lock-and-Suspend as a Tool to Protect Consumers. October 2022. Accessible at: nabp.pharmacy/wp-content/uploads/2022/10/Rogue-Rx-Activity-Report-Disrupting-Illegal-Online-Pharmacies-2022.pdf

[14] DiStefano MJ, et al. Compounded glucagon-like peptide-1 receptor agonists for weight loss: the direct-to-consumer market in Colorado. J Pharm Policy Pract. 2024 Dec 24;18(1):244-1220

The Unregulated Marketplace for Compounded and Counterfeit GLP-1 Products

To understand why the GLP-1 infodemic is flourishing, NCL worked with obesity leaders, disinformation experts, and law enforcement and regulatory specialists to assess the current state of the GLP-1 market and identify the factors influencing consumer decision-making. The following is a current look at the marketplace for GLP-1 drugs and the ramifications for obesity care.

GLP-1s: A New Class of Drugs

Since the 1930s, Americans have been exposed to a long line of medical obesity treatments,[15] most of which achieved weight loss but were pulled due to troubling side effects. Thus, there was little excitement for the discovery in 1984 of glucagon-like peptide-1 (GLP-1), a type of peptide hormone that can stimulate the pancreas to produce more insulin after meals.

However, in 2023, *Science Magazine* named GLP-1 drugs the "science breakthrough of the year."[16] Originally approved by the FDA in 2005, GLP-1 receptor agonists have revolutionized the treatment of obesity, according to the magazine, and are challenging outdated notions about the disease. This is because these medicines—which are mostly injectable drugs—mimic the function of the naturally occurring GLP-1 hormone in the body. When activated, the hormone triggers GLP-1 receptors in the brain and the gut to decrease appetite and produce feelings of fullness.

Currently, FDA has approved 10 GLP-1 drugs,[17] seven to treat type 2 diabetes and three to treat obesity (liraglutide, semaglutide and tirzepatide) and expanded the eligibility requirements so adults with weight-related conditions, such as type 2 diabetes, high blood pressure and high cholesterol, can get treated, regardless of their BMI. While there are differences in these drugs, studies show these medications achieve significant weight loss, typically ranging from 5 percent to 15 percent of body weight over 12-72 months.

FDA Approved GLP-1 Drugs

- Ozempic (semaglutide) injection – for type 2 diabetes
- Wegovy (semaglutide) injection – for obesity
- Rybelsus (semaglutide) tablets – for type 2 diabetes
- Victoza (liraglutide) – for type 2 diabetes
- Saxenda (liraglutide) – for obesity
- Mounjaro (tirzepatide) – for type 2 diabetes
- Zepbound (tirzepatide) – for obesity
- Trulicity (dulaglutide) – for type 2 diabetes
- Byetta (exenatide) – for type 2 diabetes
- Bydureon (exenatide extended release) – for type 2 diabetes

GLP-1 weight loss medicines, while effective, can cause side effects, primarily gastrointestinal problems like nausea,

[15] Innovative Rx Strategies. Rx History: The Rise of GLP-1s. January 25, 2024. Accessible at: https://innovativerxstrategies.com/rx-history-glp1s

[16] American Association for the Advancement of Science. Science's 2023 Breakthrough: GLP-1 Agonists Show Promise Against Obesity-Associated Disease. December 15, 2023, Accessible at: https://www.aaas.org/news/sciences-2023-breakthrough-glp-1-agonists-show-promise-against-obesity-associated-disease

[17] Harvard Health Publishing. GLP-1 diabetes and weight-loss drug side effects: "Ozempic face" and more. February 2024. Accessible at: https://www.health.harvard.edu/staying-healthy/glp-1-diabetes-and-weight-loss-drug-side-effects-ozempic-face-and-more

vomiting, diarrhea, and constipation, as well as more serious problems like pancreatitis, rare thyroid cancer, sudden kidney injury, and worsening diabetes-related retina damage.

Demand for GLP-1s Is Surging but Insurance Is a Major Barrier

When NCL issued the agenda-setting report, *A New Patient-Centered Obesity Action Agenda*, in 2022, only about 2 percent of Americans eligible for treatment with an anti-obesity medication had been prescribed these drugs[18] and lack of insurance coverage was one of the key reasons why.

Fast forward three years and GLP-1 agonist drugs are generating levels of enthusiasm that have rarely been seen in medical practice. According to a 2024 survey of 3,000 adults commissioned by the professional services firm PWC, between 8 percent and 10 percent of US adults are currently taking GLP-1s.[19] Using Census Bureau estimates of 258.3 million adults living in the US in 2020,[20] this translates into as many as 25 million Americans who are now being treated with these medicines. Based on this increased interest, some analysts project that global sales of GLP-1s will reach $150 billion by the early 2030s.[21]

The PWC research also finds that 41 percent of adults with obesity are opting not to take an FDA-approved GLP-1 drug based on the cost of these drugs. Estimates using June 2023 data put the US list price for a month's supply of a GLP-1 drug at between $936 and $1,349 without insurance,[22] although manufacturers of the branded drugs have dropped their prices to prices to approximately $350 to $500 a month. If health insurers covered GLP-1s for weight loss the same way health plans cover these drugs for people with type 2 diabetes, consumers would have a co-pay as low as $25 a month.

Yet, commercial insurance plans continue to exclude or restrict access to GLP-1 weight loss drugs, despite their benefits in improved health. According to GoodRx, which tracks changes in commercial insurance coverage for in-demand medications, in 2025 the number of insured people with no coverage for tirzepatide increased by over 14 percent, which equates to 4.9 million adults.[23] Similarly, GoodRx reported that commercially insured people with no coverage for semaglutide rose by 22 percent in 2025, leaving another 1.1 million adults without access to treatment.

Reinforcing these findings, a 2024 study from the International Foundation of Employee Benefit Plans (IFEBP) finds that employer coverage of GLP-1s is still limited, with only 34 percent of corporate plans currently providing coverage for people with obesity who do not have diabetes.[24] Adding to this coverage gap, outdated Medicare Part D rules exclude FDA-approved anti-obesity medications for older adults with obesity, but not diabetes. Collectively, these trends underscore the ongoing challenge associated with

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[18] Kanj A, et al. Overcoming obesity: weight loss drugs are underused. Cleveland Clinic Journal of Medicine October 2020, 87 (10) 602-604

[19] PWC. GLP-1s have revolutionized the treatment of obesity and can compel companies to lead through disruption and reinvent themselves. Issue 10. October 2024. Accessible at: https://www.pwc.com/us/en/services/consulting/business-model-reinvention/glp-1-trends-and-impact-on-business-models.html

[20] US Census Bureau. August 12, 2021. Accessible at: https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.

[21] Reuters. Weight-loss drug forecasts jump to $150 billion as supply grows. May 28, 2024. Accessible at: https://www.reuters.com/business/healthcare-pharmaceuticals/weight-loss-drug-forecasts-jump-150-billion-supply-grows-2024-05-28

[22] Peterson-KFF Health System Tracker. How do prices for drugs for weight loss in the US compare to peer nations' prices? August 17, 2023. Accessible at: https://www.healthsystemtracker.org/brief/prices-of-drugs-for-weight-loss-in-the-us-and-peer-nations

[23] GoodRx. Live Updates: Tracking Insurance Coverage for GIP and GLP-1 Agonists Like Zepbound and Wegovy. March 4, 2025. Accessible at: https://www.goodrx.com/healthcare-access/research/tracking-insurance-coverage-weight-loss-meds

[24] International Foundation of Employee Benefit Plans. GLP-1 Drugs: 2024 Pulse Survey Report (U.S. Data). Accessible at: https://www.ifebp.org/resources---news/survey-reports/glp-1-drugs--2024-pulse-survey-report-(u.s.-corporate-data)

access to GLP-1 weight loss drugs. Without insurance coverage that gives people with obesity the same access to treatment that is now afforded to patients with diabetes and other chronic diseases, consumers will either not seek care or opt for low-cost treatment options that may put their health at risk.

Supply Shortages Paved the Way for Compounded Versions

In 2022, the increasing demand for GLP-1 weight loss drugs and growing concerns about their costs collided with a national supply shortage, ushering in a marketplace where consumers have been able to purchase less expensive compounded versions outside of traditional channels. Although there are no requirements for compounders to report the doses sold, it is estimated that between 1 million and 10 million Americans are now taking compounded GLP-1 drugs.[25]

As described by FDA in its 2018 guidance for the compounding industry,[26] "compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product." For these purposes, a health professional will write a prescription for a compounded version of a prescribed medicine and a licensed compounding pharmacy will combine or adjust the ingredients to create a form of the drug that meets the patient's medical requirements. Practitioners in hospitals, clinics, and other healthcare facilities also provide compounded drugs to patients when an FDA-approved drug is not medically appropriate to treat them. It is estimated that compounded drugs for one-of-a-kind situations represented 1 percent to 3 percent of the prescriptions written in 2024.[27]

The other purpose for compounded drugs is when the FDA-approved medicine is in a "verified shortage," which FDA defines as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[28] In these situations, the drug is placed on FDA's drug shortages list and the Agency allows the compounding and sale of versions that are "essentially a copy"—meaning the compounded version contains the same active pharmaceutical ingredient (API) as the FDA-approved drug, the API has a similar or substitutable dosage strength, and the compounded drug uses the same route of administration.

However, because compounded drugs are intended as individualized treatments or a temporary solution during a shortage, these drugs are regulated differently than traditional FDA-approved medications—although these differences are not well understood by consumers and even some health professionals. Of key importance, Congress exempts compounded drugs from undergoing the formal FDA-approval process, which is why FDA publicly states that "compounded drugs are not FDA-approved. This means the agency does not review compounded drugs for safety, effectiveness[29] As a result, there are no

[25] Obesity Action Coalition. Why OAC Warns Against Compounded GLP-1 Medications. March 24, 2025, Accessible at: Why OAC Warns Against Compounded GLP-1 Medications

[26] Food and Drug Administration. Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Food, Drug and Cosmetic Act: Guidance for Industry. January 2018.

[27] Government Accounting Office. Compounded Drugs. October 2014. Accessible at: https://www.gao.gov/assets/gao-15-85.pdf

[28] Food and Drug Administration. Frequently Asked Questions About Drug Shortages. December 18, 2024. Accessible at: https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages

[29] 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

requirements that state licensed pharmacies conduct safety tests and the labels on compounded drugs may not include important information, such as adequate directions to use the drugs safely.

Moreover, because compounded GLP-1 drugs are not the same medicines as the FDA-approved versions, these drugs may contain different ingredients and usually come in vials instead of pre-filled pens, requiring patients to measure and draw the correct dose into a syringe for self-injection. Thus, FDA issued several warnings raising safety concerns that some compounded GLP-1 drugs may contain too much or too little of the API or be at a different dosage level, increasing the risk of dosing errors. Additionally, health professionals worry that compounded GLP-1s may contain added ingredients like vitamin B-12 and B-6, which change the composition of the medication. These combinations of substances have not been studied and approved as safe and effective. [30]

Underscoring the potential health consequences from dosing errors and exposure to the wrong ingredients, FDA has received over 775 adverse event reports involving compounded versions of two GLP-1 drugs as of February 28, 2025. [31] Breaking out these adverse events, as of February 2025, FDA had received reports of 17 deaths and over 100 hospitalizations, many attributed to dosing errors. Moreover, across the country, poison control centers have seen a nearly 1,500 percent increase in calls since 2019 related to overdosing or side effects of injectable GLP-1 usage.[32] This included reports of two callers who accidentally received 10 times the recommended dose and one caller who accidentally took 20 times more than the safe level due to confusing measurement units while using the syringe. [33]

Regulation of Compounded Drugs Is Complicated

Branded and generic drugs on the market undergo a thorough safety evaluation to demonstrate their safety and efficacy. Regarding prescription medicines, FDA conducts a comprehensive review of the laboratory, animal and human clinical tests supporting a proposed new drug's safety and effectiveness, and ensures the product label (package insert) of each approved product is understandable and contains the clinical information needed for healthcare providers to prescribe the drug and patients to take the drug safely. Similarly, FDA requires generic drug manufacturers to perform bioequivalence testing to show the generic product gets into the bloodstream in the same way as the branded product and stability tests to assess how the drug changes over time under various environmental conditions.

None of these requirements apply to compounded drugs, which FDA considers "new drugs" under the Food, Drug and Cosmetic Act but are exempt from safety rules so as not to put an undue burden on compounding pharmacies and compounding pharmacists. Thus, compounded drugs are not required to undergo clinical testing, do not have an approved label defining the indications for use, and are exempt from certain requirements, such as providing information to consumers about possible side effects.

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[30] Food and Drug Administration. FDA alerts health carw providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products. July 26, 2024. Accessible at: www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded

[31] Food and Drug Administration. FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss. March 17, 2025. Accessible at: www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

[32] America's Poison Centers. Glucagon-Like Peptide-1 Agonists. February 2025. Accessible at: https://poisoncenters.org/track/GLP-1#

[33] Lambson JE, et al. Administration errors of compounded semaglutide reported to a poison control center- Case Series. J Am Pharm Assoc (2003) 2023 Sep-Oct;63(5):1643-1645

The Drug Quality and Security Act (DQSA), enacted in 2013, provides a framework for the regulation of drug compounding and the investigation of compounding-related complaints. Specifically, DQSA establishes that:

- FDA has responsibility for issuing and enforcing rules for compounding, including using bulk drug substances.

- Traditional compounding pharmacies, known as 503A pharmacies, that mostly modify drugs specifically for individual patients must be state-licensed and must not compound products that are "essentially a copy" of a commercially available FDA-approved drug regularly or in inordinate amounts. 503A compounding pharmacies are also prohibited from distributing compounded drugs out of state in quantities greater than 5 percent of total prescription drugs dispensed unless their state has entered into a memorandum of understanding (MOU) with FDA.

- MOUs between states and FDA must address the interstate distribution of inordinate amounts of compounded drugs and provide for state investigation of complaints relating to interstate distribution of compounded drugs.

- FDA regulates outsourcing compounding facilities, called 503B facilities, which produce bulk quantities of compounded drugs for sale to hospitals and medical offices. These facilities may only compound using the API that FDA has placed on a list based on clinical need or to make a copy of a drug on FDA's drug shortages list. Also, 503B facilities must register with FDA, follow current good manufacturing practices, and are not required to compound pursuant to a patient-specific prescription, which enables them to produce much larger quantities.

Unfortunately, DQSA does not address a series of problems that still need to be resolved, including not requiring compounders to publicly disclose the certificates of analysis for their API, the number of compounded products dispensed that are "essentially a copy" of an FDA-approved drug, and the total number of prescription drugs dispensed. As explained in a joint statement issued in January 2024 by The Obesity Society (TOS), the Obesity Action Coalition (OAC) and the Obesity Medicine Association (OMA), [34] because FDA only approved the API from the manufacturers of semaglutide and tirzepatide and these companies did not sell their active ingredients to compounders during the shortage, compounders obtained their API from other, unapproved sources.

Similarly, advocates are calling for rules requiring compounders to report the number of compounded drugs, including GLP-1s, sold while state attorneys generals are urging FDA to ramp up enforcement against counterfeiters and online retailers directly selling the active ingredients in GLP-1s to consumers without a prescription, supposedly for "research purposes." Reinforcing these efforts, members of Congress have called on FDA to apply existing laws and regulations to online sellers of GLP-1 drugs that prohibit false or misleading claims in pharmaceutical advertising promotion, including deceptive images and text that omits safety or side effect information.

[34] The Obesity Society, Obesity Action Coalition, Obesity Medicine Association. Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives. January 9, 2024. Accessible at: www.obesityaction.org/obesity-care-organizations-issue-joint-statement-do-not-use-compounded-alternatives-to-glp-1-medications/

Inadequate Enforcement

The widespread marketing of compounded GLP-1s has drawn consumers into an unruly area with insufficient enforcement of safety protections. The consequence is a regulatory wild west where numerous actors—med-spas, illegal online pharmacies, and others—use online advertising, social media, and "patient influencers" to plug their GLP-1 versions as safe, easy to administer and "doctor-approved" while not disclosing safety and health risks in promotional materials.

This exploitative market began when FDA declared a shortage of the branded GLP-1 drugs, allowing opportunistic online retailers to gain market share and drive demand for less expensive alternative products. A key selling point was access to GLP-1 products through online weight loss programs that featured a telehealth consultant, home delivery and a GLP-1 drug at a relatively low cash price. By taking advantage of exclusions to the advertising regulations that apply to prescription drugs, companies used online advertising, social media, and "patient influencers" to plug their GLP-1 versions as safe, easy to administer and "doctor-approved" while not disclosing safety and health risks in promotional materials.

Documenting this situation, recent studies find numerous examples of misleading claims about compounded GLP-1 versions promoted online. For example, a review of 79 websites marketing or offering prescriptions for compounded GLP-1s reported in JAMA Health Forum found 37 percent of the sites stated or implied that the drugs were approved by the FDA and nearly 50 percent did not include information about the drugs' adverse effects, warnings or contraindications. Additionally, a 2024 study on the advertising practices of GLP-1 compounders found "numerous examples of misleading claims regarding the regulatory status of compounded glucagon-like peptide-1 products."

Now that the GLP-1 drug shortage is over, it is illegal to sell compounded GLP-1 drugs unless a patient needs a customized version for medical reasons. Therefore, responsible online retailers exited the market, but rogue actors remain in business. In fact, in February 2025, the FBI warned the public about the threat of online pharmacies, weight loss clinics, and med-spas engaging in fraudulent practices by unlawfully misrepresenting compounded weight loss drugs. Specifically, the FBI reported that in multiple states med-spas, pharmacies and weight loss centers sold products purporting to be compounded semaglutide, which were fakes and had unknown drug impurities. The FBI also cited a southern-based med spa and weight loss clinic that offered and sold a weight loss medication made of "animal grade" semaglutide with vitamin B-12, which is not compliant with FDA regulations.

Also of concern, NABP warns that organized criminal networks with global operations have added GLP-1s to their product offerings. According to a 2024 NABP report, the same illegal online pharmacies that sold hydroxychloroquine and ivermectin during the COVID-19 pandemic are now actively selling substances advertised as GLP-1 agonists—without requiring a valid prescription and without the required pharmacy licenses—to vulnerable patients. Many of these internet pharmacies belong to organized criminal networks that operate thousands of websites that promote the illegal sale of unapproved GLP-1 agonists, including sites that are connected to domain names that use the GLP-1 drug's brand name.

Consumer Understanding and Perceptions of Compounding and GLP-1s

When the American Medical Association (AMA) recognized obesity as a serious chronic disease in 2013,[35] a poll by the National Opinion Research Center (NORC) at the University of Chicago found that only 38 percent of Americans made this connection.[36] Less than 10 years later, a second NORC poll conducted with the American Society for Bariatric Surgery (ASMBS) showed a dramatic shift in public awareness; 81 percent of US adults in 2022 said obesity is one of the most serious health issues affecting the nation.[37]

However, awareness of a disease is not the same thing as American perceptions about treatment options when seeking care for a disease like obesity. This is especially the case for GLP-1 weight loss drugs. Public awareness of the treatment option jumped from 19 percent of adults in 2023 to 32 percent in 2024,[38] but perceptions and medicine-taking behaviors are being shaped by a flood of false and misleading claims circulating online about compounded and counterfeit versions of these medicines.

In response, the National Consumers League commissioned the first national survey of Americans to answer questions of how disinformation spreading online influences perceptions about compounded GLP-1s and how people respond to the advice of the FDA, medical societies, and law enforcement agencies about the safety of these medications. Conducted between March 19-31, 2025, by Dynata, LLC, one of the largest consumer online market research panels globally, the online survey of 1,500 women ages 18-55 showed that knowledge of compounded drugs generally does not translate into decisions about compounded GLP-1s, specifically due to the volume of misleading claims reaching consumers online.

A key takeaway is that even though 56 percent of U.S. women say they are familiar with compounded drugs and 31 report having taken one, the extensive online disinformation spread during the two-year shortage of branded medicines has affected women's decision-making about compounded GLP-1s. Consequently, 71 percent of women generally hold the view that compounded GLP-1s must be tested and proven safe to be on the market, a belief shared by 73 percent of women living with obesity. Moreover, over half of women (53 percent) believe that compounded GLP-1 drugs are FDA-approved — none of which is true.

Going deeper into the misperceptions about compounded GLP-1 drugs, the survey also reveals that:

- **Americans are paying attention to information about GLP-1 medicines.**
  Three in four women polled (76 percent) say they are aware of GLP-1 drugs. The percentage jumps to 81 percent of women living with obesity (based on BMI calculations).

[35] AMA. Recognition of Obesity as a Disease. H-440.842. June 19, 2013

[36] Associated Press. Lauren Neergaard. Poll: Few Americans know all the risks of obesity. January 6, 2013

[37] American Society of Metabolic & Bariatric Surgery & NORC. Issue Brief. Americans View Obesity As Top Health Threat. February 2022.

[38] KFF Health Tracking Poll May 2024: The Public's Use and Views of GLP-1 Drugs- May 10, 2024. Accessible at: https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs

- **Many consumers view compounded GLP-1s as essentially generic drugs.**
  According to the findings, 55 percent of women say compounded GLP-1s are as safe and effective as the branded medications, 49 percent think compounded versions have the same active ingredients, and 41 percent say the doses are the same. None of these perceptions are accurate.

- **Consumers believe compounded GLP-1 products come in many forms.**
  While 78 percent of the women polled know that GLP-1s are injectable medicines, over half (56 percent) also cited forms that are fakes: 38 percent identified weight loss patches, 32 percent cited gummy supplements, and 24 percent identified oral drops.

- **Consumers largely believe the advertising claims about compounded GLP-1 drugs.**
  Of the women polled who had seen news or advertising online about specific compounded GLP-1 products, eight in ten said they were very confident (27 percent) or somewhat confident (54 percent) in the accuracy of the information. Only 20 percent were not confident.

- **Misleading claims have been effective in shaping consumer perceptions.**
  When given a fictional ad for a compounded GLP-1 drug to review, respondents were asked to describe what the phrase "doctor approved" meant to them. The majority (54 percent) said the drug was "endorsed by medical professionals" while 31 percent said the drug was "safe to use." Additionally, 11 percent said the phrase lent "trust and credibility" and 10 percent thought the wording meant there is "general approval" for its use from health professionals.

These findings are significant, especially considering the volume of direct-to-consumer advertising promoting products offered as compounded GLP-1 drugs via television, social media, and online platforms. Although US federal law requires advertising of all prescription medications, including compounded medications, to be "truthful, non-misleading, and accurate," advertising for compounded medications has pushed the boundaries to the limit by implying that products are FDA-approved, by claiming the compounded drug has the "same active ingredient" as the FDA-approved medicine, and/or by juxtaposing images of compounded drugs with easily recognized FDA-approved products. Americans deserve better; they deserve accurate and complete information about all GLP-1 drugs.

Decoding the Infodemic and Misleading Promotion of GLP-1s

On December 10, 2020, the Secretary-General of the United Nations, António Guterres, joined with Dr. Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization, to declare the need for a global response to one of the defining public health issues in the 21st century: the "infodemic" of incorrect, misleading, and false information on diseases and treatments that can travel around the world before there is a chance to correct it.

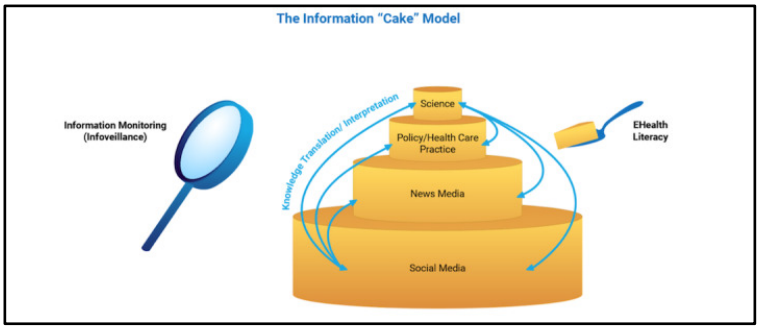
Warning that infodemics undermine trust in science, discredit medical authorities, and lead to polarization and fear, the UN and WHO leaders urged the global health community to sign a statement of commitment to confront and mitigate the harm of infodemics through actions such as:

- Recognizing that an infodemic is a tsunami of information, some accurate, most not, that spreads alongside a disease threat that cannot be eliminated but can be managed.
- Acknowledging that infodemic management can reduce public confusion and mistrust towards governments, science, and health personnel.

- Striving to make science more accessible, transparent, and understandable.
- Utilizing trusted sources to reach citizens across all information channels with evidence-based information that is customized and personalized.

As a result of this global call-to-action, there is a growing scientific field called infodemiology[39] — a term coined by the German-Canadian researcher Gunther Eysenbach in 2002 — where researchers study how information and misinformation spread in communities and online to identify areas where there is a knowledge translation gap between best evidence (what some experts know) and practice (what most people believe). Based on 20 years of infodemiology research, scientists have developed a four-stage "wedding cake" model that charts the flow of information during an infodemic.

According to this model, there are four layers of the wedding cake, starting with science as the smallest layer at the top. The next layer involves information spread by health practitioners and policymakers, which is smaller in size than the third layer, the news media. Social media is the largest and last segment of the wedding cake, representing the vast amount of largely unfiltered and uncontrolled information generated or amplified by the public.



Other behavior models emphasize that exposure to disinformation increases the odds that people will believe it and will spread it further. But it is also the case that people will share information they know is false, especially if the disinformation aligns with their viewpoints or elicits strong reactions.[40] This is why social media plays such a pivotal role in amplifying infodemics. Rapid posting and person-to-person sharing allow users to distribute misleading content quickly to large audiences, which aids the spread of falsehoods and impedes dissemination of factual corrections while algorithms push content that is sensational and spurs emotional responses.

These models are relevant to understanding the infodemic regarding GLP-1 weight loss drugs. The recommendations of health professionals and medical societies are being drowned out by the news media and social media platforms, which feature celebrity stories, the opinions of online influencers, and a flood of paid content that uses misleading language and visuals to manipulate consumers. Common tactics include suggesting that compounded GLP-1 drugs are FDA-approved, equivalent to FDA-approved versions or generic versions; and targeting especially vulnerable consumers with claims that the drug is a cheap, safe, and easy solution to achieve significant weight loss. Another frequent practice is to place the logos of scientific bodies like the National Institutes of Health (NIH) in an ad with links to scientific studies completely unrelated to the advertised substance.

[39] Eysenbach G. How to Fight an Infodemic: The Four Pillars of Infodemic Management. J Med Internet Res. 2020 Jun 29;22(6):e21820.
[40] American Psychological Association. How and why does misinformation spread? March 1, 2024. Accessible at: https://www.apa.org/topics/journalism-facts/how-why-misinformation-spreads

Documenting the reach of these false claims, a 2025 analysis of online advertising reported in the JAMA Health Forum[41] found "alarming" levels of misleading information from some online sellers of compounded GLP-1s, including exaggerated claims for efficacy and failing to include risks of side effects or contraindications. The volume of this disinformation is further underscored by a 2024 report from LegitScript,[42] a provider of healthcare product verification and monitoring services, which showed a more than 200 percent surge in "violative or problematic" GLP-1-related ads in the first half of 2024 compared to all of 2023, and an approximate 1,200 percent increase compared to all of 2022. Content that violated advertising guidelines and regulations ranged from exaggerated claims about the efficacy of the medications to the promotion of unauthorized sources and counterfeit products.

The most persuasive data comes from NCL's new poll of US women. Among the 1,500 women ages 18-55 polled, 85 percent of those with obesity are confident in the accuracy of information included in compounded GLP-1 advertisements. This includes 69 percent who believe that FDA-approved and compounded versions are similar and 60 percent who say compounded GLP-1 drugs are as safe and effective as FDA-approved GLP-1 drugs.

Dissuading consumers of these beliefs will require a comprehensive education effort to help consumers identify false claims and manipulative placements of logos, links to research data, and suggestive visuals. At the same time, there is a compelling need to address the problem at its source through policies requiring direct-to-consumer advertising and the web content for compounded drugs to meet the standards expected of FDA-approved prescription medicines.

[41] Chetty, AK. et al. Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists. JAMA Health Forum 2025;6(1):e245018.
[42] XTalks. LegitScript Finds 1200 Percent Increase in Problematic Ads for Compounded GLP-1 Meds. July 19, 2024. Accessible at: https://xtalks.com/legitscript-finds-1200-percent-increase-in-problematic-ads-for-compounded-glp-1-meds-373

The Need for Consumer Protections

It is a rare occurrence when compounded drugs replace FDA-approved medicines during a national shortage that lasts years and ushers in a largely unregulated and profitable secondary market. However, this is what happened between 2022 and 2024 when there was a national shortage of the popular GLP-1 weight loss drugs semaglutide and tirzepatide. This prompted the FDA to place semaglutide and tirzepatide on its drug shortages list and allowed compounding pharmacies to fill the supply gap with compounded versions of GLP-1s on a temporary basis.

Because booming consumer demand for GLP-1s was a primary reason for the shortages, it was a gold rush situation for compounders and the telehealth companies and med-spas who sold compounded GLP-1 versions directly to consumers online at a lower cost, with promises of drugs that were equivalent to FDA-approved versions in safety, efficacy, and quality. Thus, profits soared, and some online sellers of compounded GLP-1 products took advantage of regulatory shortcomings and insufficient enforcement to build a large market with widespread advertising that touted the benefits of GLP-1s without disclosing the risks, and made inferences that their compounded drugs were the same as the FDA-approved versions, only cheaper and more convenient to obtain.

FDA declared the end of the GLP-1 shortage on March 5, 2025, setting the stage for the withdrawal of compounded versions from the marketplace. Yet, the regulatory framework that allowed what former FDA Commissioner David Kessler described as a "reckless national experiment with compounded new weight loss drugs" is still in place. Therefore, the National Consumers League believes now is the time to rethink the regulation of compounded drugs during national drug shortages to protect consumers from misinformation and inferior products when there is a large mass market and high demand for FDA-approved drugs.

To set the stage for new thinking, NCL started with FDA's own interpretation of the regulatory challenges as described in the agency's guidance documents for compounders and the December 18, 2024 publication in which the agency flagged "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss."[43] Specifically, FDA states that compounded drugs are held to lower regulatory standards than FDA-approved prescription drugs due to how federal law defines FDA's authority over compounding pharmacies. Accordingly, FDA has raised key issues that impede informed and safe use of compounded drugs during shortage situations:

- Because compounded drugs do not undergo a pre-market review process to ensure safety and quality, there is an increased potential for quality issues, such as contamination, sub- or super-potency, or incorrect dosing, which can be detrimental to patient safety.
- Traditional compounding pharmacies that compound drug products under section 503A rules are exempt from federal Current Good Manufacturing Practice (CGMP) regulations, which are mandatory for all approved pharmaceutical manufacturers. CGMPs assure proper design, monitoring, and control of pharmaceutical manufacturing processes and facilities.

[43] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

- FDA does not review the labels of compounded products prior to marketing and the labeling is not standardized, unlike with FDA-approved prescription medications. The differences in the product labels of conventional manufacturers and compounders may lead to dosing errors, among other concerns.
- Federal law does not require state-licensed compounders to submit adverse event reports. This leaves a large portion of compounding activities outside the scope of mandatory reporting, potentially leading to underreporting of adverse events.
- Because compounding pharmacies subject to 503A regulations are not required to register their compounding facilities with FDA and undergo inspections, agency personnel are often not aware of potential problems with the compounding facility or practices unless FDA receives a complaint about a compounded drug.

Beyond the issues raised by FDA, position papers and policy reports from obesity medicine, chronic disease, patient safety, pharmacy, and law enforcement organizations have identified regulatory and enforcement shortcomings that allow marketers to sell and promote compounded products that FDA has described as "risky" for patients. Major concerns are:

- Compounded preparations are not required to have standard product labeling or prescribing information with instructions for safe use. Thus, consumers may not have information on side effects, contraindications, and possible adverse effects.

- Compounding pharmacies are generally not required to provide information on total drugs distributed and the names and quantities of compounded drugs delivered in state and out of state, making it difficult to know how many compounded drugs are being distributed, what proportion of total drug deliveries compounded drugs represent, whether a pharmacy is compounding products that are "essentially a copy" of a commercially available FDA-approved drug regularly or in inordinate amounts, and whether FDA enforcement action is necessary.

- A report from the Safe Medicine Coalition (SMC) reveals that a significant quantity of the bulk active pharmaceutical ingredient (API) for compounded semaglutide and tirzepatide products came from sources outside the US that are not registered with FDA. This is especially concerning because there are no explicit federal requirements that compounding pharmacies publicly disclose the names of API suppliers or certificates of analysis for the active ingredients they use.

- US federal law requires advertising of all prescription medications, including compounded drugs, to be "truthful, non-misleading, and accurate." However, advertising for compound pharmacies falls into a "regulatory gray zone." Because compounded products are considered copies of FDA-approved products, compounders can reference the FDA-approved label to attest to safety and efficacy, even though there may be differences in the manufacturing and ingredients used. Consequently, the advertising is technically legal but violates Congress' intent to support patient access to safe and effective drugs.

- Counterfeit products are now entering into the US supply chain. The demand for these products and the profit opportunities means bad actors will continue to market so-called GLP-1 products

aggressively, despite FDA's declaration that the shortage of the branded GLP-1 drugs is over.

- FDA has issued safety alerts after becoming aware of safety issues with compounded drugs, such as increased medication overdoses. However, FDA's response is often reactive after receiving adverse event reports or complaints. This suggests that FDA is insufficiently staffed and not proactively enforcing rules prohibiting false and misleading drug advertisements and sales of drugs with ingredients that have not been approved. Similarly, FDA could do more to monitor compounding pharmacies, outsourcing facilities, and their API suppliers and enforce rules disallowing the compounding of products that are "essentially a copy" of a commercially available FDA-approved drug regularly or in inordinate amounts.

- States have an important role to play, both in regulating compounding pharmacy practices and in being on the front lines to protect consumers from counterfeiting and fraud. This has been the case with GLP-1 regulation and enforcement where attorneys general and state boards of pharmacy have increased scrutiny and oversight of compounding pharmacies and been aggressive in educating consumers about illegally sold ingredients.

Along with these regulatory challenges, the obesity community makes clear that Americans will continue to respond to marketers who offer less expensive products purported to be GLP-1s because cost is the primary obstacle to taking these drugs. Accordingly, any rethinking of the regulatory landscape for GLP-1 drugs specifically must include action by the US Centers for Medicare and Medicaid Services (CMS) to finalize a proposed rule allowing Medicare and Medicaid to cover GLP-1 drugs for weight loss. Similarly, advocacy is needed to press employers and commercial health plans to cover GLP-1s for weight loss in the same way they cover treatment for other chronic diseases like diabetes and heart disease. It is a national investment that will pay off in improved health outcomes and lower rates of chronic disease.

Blueprint for National Action

Compounded drugs are an important part of the nation's drug supply. Representing about 1 to 10 percent of the prescriptions written in the US, compounded drugs allow people to take prescribed medications when they need a different dosage, have an allergy to an ingredient, or may need the medicine in a different form. Because they are usually one-of-a-kind modified drugs, FDA does not approve these medicines and state licensed compounding pharmacies are not required to conduct safety tests, provide information about side effects, or report serious health problems to FDA.

The problem comes during a national shortage of a popular, widely used drug, like GLP-1 weight loss medicines, when FDA allows licensed compounding pharmacies to sell large quantities of compounded alternatives to FDA-approved drugs under a regulatory framework intended for individualized compounded drugs. These unintended consequences played out between 2022 and 2024 when there was a national shortage of the popular GLP-1 weight loss drugs semaglutide and tirzepatide. Compounding pharmacies filled the supply gap with similar versions of GLP-1s, and the telehealth companies and med-spas who sold these products directly to consumers online at a lower cost took advantage of regulatory shortcomings to create a multi-billion-dollar market with widespread advertising that touted the benefits of compounded GLP-1s without disclosing the risks and made inferences that these drugs were the same as the branded versions, only cheaper and more convenient to obtain.

FDA declared the end of the GLP-1 shortage on March 5, 2025, setting the stage for the withdrawal of compounded versions from the marketplace. Yet, the problem is far from over. Responsible digital health companies pledged to stop selling compounded GLP-1 drugs, but an exploitative market has emerged where online companies promoting patches, shakes, and oral supplements as GLP-1 products and those illegally selling the active ingredients in GLP-1 drugs to unwitting consumers with dosing instructions continue to operate. What is worse, consumers are being inundated with false information circulating online about GLP-1 medicines that is causing consumers to tune out the advice of the FDA and leading medical societies and opt for drugs that may cause harm. The World Health Organization calls this disinformation overload an "infodemic," and it is flooding the zone with falsehoods, conspiracy theories, rumors, and misleading claims about GLP-1s that are causing confusion, risk-taking behaviors, and perpetuating fraud.

Infodemics are dangerous, which is why now is the time to confront the challenges that lead to exploitation of regulatory shortcomings and the disinformation that allow illegitimate markets to flourish. Therefore, the National Consumers League worked with leaders in obesity management, patient safety, disinformation strategies, and law enforcement organizations to consider ways to overcome the infodemic of false information on GLP-1s and to think prospectively about improving the regulation of compounded drugs during and after national drug shortages so exploitative markets do not occur when there is a large mass market for these drugs. The following are recommendations for moving forward on both fronts.

I. Immediate Action Steps to Curtail Disinformation About Weight Loss Drugs

1. **Make Curbing Infodemics a National Priority**
   Infodemics flourish because false information travels at the speed of light through advertising, promotional websites, and social media platforms. Today, the US has the second highest rate of

misinformation of any country,[44] which is especially troubling because studies show that medical misinformation — along with the belief in anecdotal evidence and remedies that are not backed by science — leads to the lack of trust in medical professionals, poorer health outcomes, and even higher rates of death.[45] Therefore, the growing threat of misinformation requires a unified and sustained national initiative that makes the impact of an infodemic "real" for consumers, clinicians, and policymakers and disseminates personally-relevant information that shows individuals how to separate fact from fiction.

Because an exploitative market for GLP-1 weight loss drugs is now operating in the nation and is being fueled by massive disinformation and misleading claims about these medicines, the National Consumers League is responding with a national mobilization called The Weight Truth that can serve as a model for healthcare stakeholders. Intended to counteract the infodemic at all levels, the initiative helps consumers understand what claims made online are misleading or false and which products are likely counterfeits. The initiative also mobilizes federal and state regulatory, law enforcement agencies and policymakers to enforce existing laws that protect consumers from disinformation, take counterfeits off the market, and regulate marketing practices more aggressively.

2. **Lower Consumer Costs for GLP-1 Weight Loss Drugs**
   Because increasing coverage of FDA-approved GLP-1 drugs is the best way to put a damper on a underground market for these products, the National Consumers League and many advocates are working to secure coverage through Medicare, state Medicaid programs, and private insurers in order to help reduce patients' out-of pocket costs. If people with obesity had the same insurance coverage for GLP-1s as those with diabetes, they would have a co-pay of $0 to $25 a month.

3. **Enforce Existing Drug Advertising Rules**
   During the national shortage of GLP-1 drugs, online advertising was extensive and proved very effective in convincing consumers that compounded versions were essentially generic versions of the FDA-approved drugs (which they are not). According to the findings of the consumer poll conducted for NCL in Mach 2025, 55 percent of respondents believed compounded GLP-1s are as safe and effective as the branded medications and 49 percent thought compounded versions have the same active ingredient. With an underground market now operating, FDA can help stem the infodemic of disinformation by monitoring content online of sellers promoting supposed GLP-1 products and enforcing existing prescription drug advertising regulations.

4. **Explore a New Role for the Federal Trade Commission**
   The Federal Trade Commission (FTC) has a strong regulatory and enforcement framework to address deceptive marketing and ensure that advertising claims are truthful and substantiated, including health claims. Already, FTC is scrutinizing food companies promoting products as "GLP-1 friendly"[46] to establish that claims are substantiated and not misleading. This provides an opening for enlisting FTC to take enforcement actions against companies that make false or misleading claims about the efficacy or safety of GLP-1 drugs and to assert that supplements, gummies, patches,

[44] University of Alberta. India, US account for a quarter of COVID-19 misinformation: study. December 10, 2021. Accessible at: www.ualberta.ca/en/folio/2021/12/india-us-account-for-a-quarter-of-covid-19-misinformation-study.html
[45] Ballard Brief. The Effects of Medical Misinformation on the American Public. 2024. Accessible at: https://ballardbrief.byu.edu/issue-briefs/the-effects-of-medical-misinformation-on-the-american-public
[46] National Agricultural Law Center. Regulation of Food for GLP-1 Drug Users: Off-Label Advertisements. August 1, 2024.

and related products are not forms of GLP-1s.

5. **Increase Pharmacovigilance of Online Pharmacy Websites**
   During the national shortage of two GLP-1 weight loss drugs, the online sale of compounded versions without a prescription was a significant issue. This was documented by data published in 2024 in JAMA Network Open where investigators from the University of Pécs in Hungary and the University of California San Diego found that illegal online pharmacies were actively selling semaglutide products without a prescription and shipping unregistered and falsified products.[47] These pharmacies are a major element of the underground market for GLP-1 products and should be a focus for FDA, FTC, the Federal Bureau of Investigation (FBI), US Customs and Border Protection, US Postal Service, and state attorneys general and boards of pharmacy moving forward.

6. **Intensify Federal and State Efforts to Protect Consumers from Counterfeiters**
   Counterfeit products are now entering into the US supply chain. The demand for these products and the profit opportunities means bad actors will continue to market so-called GLP-1 products aggressively, despite FDA's declaration that the shortage of branded GLP-1 drugs is over. As identified by FDA, the FBI, and many state attorneys general, key areas for surveillance and enforcement are sellers who use online app-based platforms to supply consumers with GLP-1 products that contain insulin or "animal grade" ingredients, and those illegally selling directly to consumers the active pharmaceutical ingredient (API) with dosing directions to mix the drug without a prescription. Moreover, there are increasing reports of fraudsters delivering faulty products that are missing tamper-resistant measures, mixing and matching applicators with different boxes and stated doses, and shipping needles that may be fake or unsterile.

II. Long-Term Action Steps to Protect Consumers During National Drug Shortages

New policies to prevent exploitative markets during future drug shortage situations will take time to formulate and implement. However, the recent shortage of GLP-1 drugs points to changes that can be implemented now to help patients and health professionals make informed decisions when compounded drugs are widely sold during a mass market national shortage.

1. **Implement Labeling Rules for Compounders**
   As documented during the GLP-1 national shortage, the lack of labeling for compounded drugs with information on side effects, contraindications, and possible adverse events led patients to underestimate the risks and not being aware of potential errors in dosage. Given the millions of consumers who may take compounded drugs if/when there is another large and prolonged national drug shortage, labeling is an area where compounders should be held to the same requirements as branded drug manufacturers so consumers will have access to needed safety information.

2. **Require Compounders to Submit Adverse Reaction Reports to FDA**
   Because adverse event reports are often the way FDA learns of safety issues with compounded drugs, it is important that the agency have accurate information on safety issues during a national drug shortage. Exempting compounders from requirements to track and submit adverse event reports makes sense when compounded drugs are made for individual people with special medicine needs. However, when compounded drugs are mass-marketed for millions of patients, not having access to

[47] Ashraf AR, Mackey TK, Schmidt J, et al. Safety and Risk Assessment of No-Prescription Online Semaglutide Purchases. *JAMA Netw Open.* 2024;7(8):e2428280. doi:10.1001/jamanetworkopen.2024.28280

this data leads to underreporting of safety and quality issues and hampers FDA's enforcement efforts.

3. **Require Compounders to Disclose Information on the Composition and Distribution of Compounded Drugs**

Due to rules that are not designed for the mass marketing of compounded drugs, there were no requirements that compounders publicly disclose the certificates of analysis for their Active Pharmaceutical Ingredient (API) or report total drugs distributed and the names and quantities of compounded drugs delivered in state and out of state, making it difficult to know how many compounded drugs are being distributed, what proportion of total drug deliveries compounded drugs represent, whether a pharmacy is compounding products that are "essentially a copy" of a commercially available FDA-approved drug regularly or in inordinate amounts, and whether FDA enforcement action is necessary. Having access to this information not only improves surveillance efforts, but it builds trust in the integrity of these products.

The Time is Now

Although the national shortage of two GLP-1 weight loss drugs is over, a parallel market of inferior products is now operating, mostly online, accompanied by an infodemic of disinformation that puts consumers' health (and wallets) at risk. At the same time, the GLP-1 shortage situation is not likely a black swan event. Rather, it represents a warning that without more aggressive enforcement of existing federal and state regulations and strategies to address regulatory and enforcement shortcomings, we may be at the same place the next time there is a national shortage of a popular drug with widespread demand for access.

Thus, it is hoped that the issues raised in this report and the recommendations posed will be a starting point for a national discussion about exploitative markets, infodemics, and more targeted regulatory efforts to keep people safe and needed information flowing.