

RogueRx Activity Report

Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients

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INTRODUCTION

Almost 75% of Americans are clinically defined as overweight or obese.¹ Therefore, it is unsurprising that glucagon-like peptide-1 receptor agonists (GLP-1 agonists) have gone viral. This class of drugs – which includes semaglutide, liraglutide, and tirzepatide – is well-known for its effectiveness in promoting weight loss. Some celebrities, including Elon Musk and Tracy Morgan, have admitted to using semaglutide for weight loss – and dozens of other suddenly-slender celebrities have vehemently denied its use. These drugs are so popular that Walmart has noted a correlated reduction in food purchases.² Meanwhile, weight-loss chain Jenny Craig filed for bankruptcy, and WeightWatchers acquired a telehealth platform that offers GLP-1 agonists.^{3,4}

GLP-1 agonists stimulate the receptor for the hormone glucagon-like peptide-1, which increases insulin production and satiety. Approved GLP-1 agonist medications are used to treat type 2 diabetes and obesity. Regarding the latter, semaglutide (under the brand name Wegovy[®]) was approved by Food and Drug Administration (FDA) in 2021 for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol).⁵ More recently, tirzepatide was approved by FDA (under the brand name Zepbound[™]) for chronic weight management in adults with obesity or overweight with at least one weight-related condition.⁶ However, other GLP-1 agonists – including Ozempic[®], Rybelsus[®], Mounjaro[®], and Saxenda[®] – are frequently used off-label for the same purpose. Most of these drugs are injectable, and they must be refrigerated prior to first use. Common side effects include nausea, vomiting, diarrhea, constipation, and abdominal pain. Currently, certain dosages of these FDA-approved drugs are on FDA's Drug Shortage List; this means that the total supply of the commercially available product cannot meet the current demand.⁷

Of course, bad actors are taking advantage of these drugs' popularity and shortage; their unlawful actions put patients at risk. In this report, NABP highlights the methods used by illegal actors to sell substandard or falsified GLP-1 agonists without holding required pharmacy licensure and without requiring a valid prescription. The Association also reports on the actions taken by government agencies around the world to prevent the illegal sale of these drugs and prosecute bad actors. Finally, NABP encourages third-party platforms to continue monitoring for these illegal products and recommends that pharmacists and patients report these illegal sellers to FDA's Office of Criminal Investigations (FDA-OCI), state boards of pharmacy, state attorneys general, and NABP.

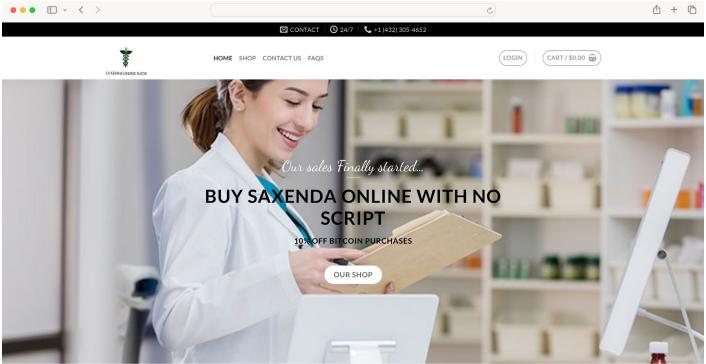
ILLEGAL ONLINE PHARMACIES CAPITALIZE ON GLP-1 AGONISTS' POPULARITY AND SHORT SUPPLY

Illegal online pharmacy operators have always been opportunists, from their heavy promotion of lifestyle drugs (eg, Viagra[®], Cialis[®], Propecia[®]) to their focus on hydroxychloroquine and ivermectin during the COVID-19 pandemic. As rational economic actors, these criminals are now actively selling GLP-1 agonists – without requiring a valid prescription and without the required pharmacy licenses – to vulnerable patients.



Illegal online drug sellers are focusing on GLP-1 agonists for many reasons. These drugs are extremely popular, expensive, and often not covered by insurance. This means that desperate patients will pay out of pocket and will be highly motivated to find cheaper options online. In addition, because several FDA-approved GLP-1 agonists are not readily available in the legitimate market, patients are more likely to explore options outside of their local retail pharmacy.

NABP has identified thousands of websites that promote the illegal sale of GLP-1 agonists. In some cases, these websites are connected to domain names that include GLP-1 agonist brand names, including Ozempic and Wegovy.⁸ An example can be found below.



Buy saxenda Online | Buy Saxenda with No Prescription

FIGURE 1: Illegal online pharmacy offering Saxenda, a GLP-1 agonist, without requiring a prescription.



Although some illegal online drug sellers, like the example in Figure 1, make it obvious that they are selling GLP-1 agonists without requiring a prescription (a clear indicator of illegality), others try to mimic legal sellers. One online seller has even copied the manufacturer's website for Wegovy. See below.

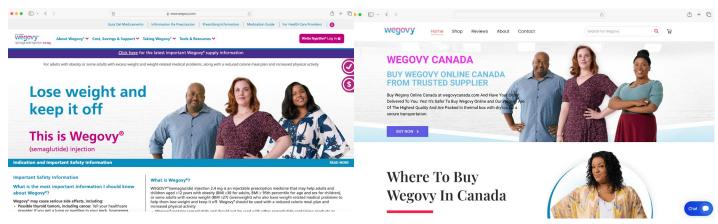


FIGURE 2: Manufacturer's website (left) versus an illegal online pharmacy (right).

As NABP has discussed in previous reports, many illegal online pharmacies belong to large, rogue online pharmacy networks. At this time, these large networks appear to be selling *only* oral semaglutide, marketed as Rybelsus; they do not sell the injectable versions, which require refrigeration prior to first use. For example, see Figure 3 below. However, many smaller networks and isolated actors do sell injectable GLP-1 agonists without requiring a prescription. That said, pharmaceutical manufacturers are actively developing new oral GLP-1s intended for weight loss, which experts predict will be cheaper to produce and will be better tolerated by patients; as such, NABP predicts that the large criminal networks will soon be promoting oral GLP-1s as actively as they currently promote erectile dysfunction drugs.9

WHAT IS A ROGUE INTERNET PHARMACY NETWORK?

Most illegal internet pharmacies belong to organized criminal networks, many of which have been the recipients of FDA warning letters. These networks are often complex, global operations that include hundreds – or even thousands – of related websites. The network operators create website templates and run back-end services (eg, payment processing and pharmaceutical shipping). They offer these templates and services to "affiliate marketers" who: (1) operate websites on behalf of the network; (2) drive traffic to those websites; and (3) take a small cut of the profits. Illegal pharmacy networks typically sell prescription-only drugs without requiring a prescription, sell unapproved drugs, and do not hold proper licensure in the jurisdictions where they offer shipping.



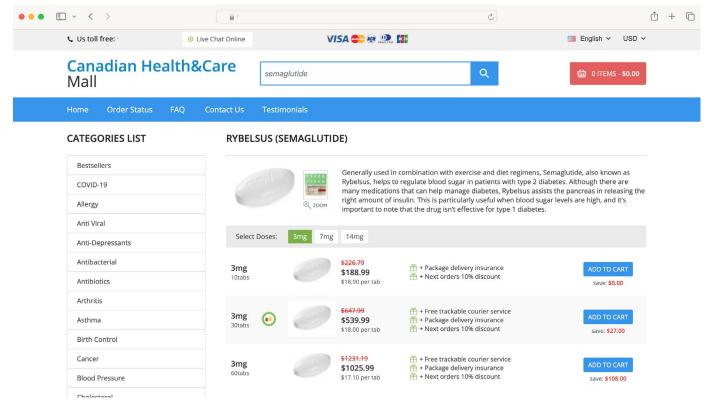


FIGURE 3: Website belonging to a large rogue internet pharmacy network that sells oral semaglutide.

Some illegal websites offer GLP-1 agonists as part of "non-delivery schemes."¹⁰ A non-delivery scheme is a financial crime where a buyer pays for goods or services online, but never receives them. NABP has received reports directly from patients regarding this issue. For example, one patient reported that a website "took my money out from my bank account and no contact. Missing \$640." Another stated, "[I]ong story short, via a series of text messages and naiveté on my part, they stole \$700 from me."

ILLICIT PEPTIDE DEALERS ADD GLP-1 AGONISTS TO THEIR PRODUCT CATALOGS

To avoid enforcement, some illegal online drug sellers advertise drug products as "peptides." Although these bad actors knowingly sell their products for consumer use, they claim that these products are for "research purposes only" and "not for human consumption." The "peptides" are typically delivered as lyophilized (freezedried) powder, and users are required to reconstitute the product with bacteriostatic water.

Illegal peptide sellers have been around long before Ozempic. They typically offer a limited product catalog of investigational new drugs, unapproved drugs, and prescription-only drugs that are popular among bodybuilders (eg, melanotan 2, CJC-1295, clomiphene). The United States Department of Justice, in collaboration with FDA-OCI, has prosecuted several of these illegal peptide sellers.¹¹



In response to consumer demand, these bad actors have recently added GLP-1 agonists – including semaglutide and tirzepatide – to their product catalogs. Because they are claiming the products are for research purposes, they do not use brand names. Instead, NABP has seen peptide websites label their products with the following names: GLP-1 analogue, GLP-1, Tirz, and Sema GLP-1. One such example can be found below.

FREE Shipping For Orders Over \$2001							
Ξ	Q & C	7					
	Sema GLP-1 so.o Countify (- 1 +) Add to cart						
SEMAGLUTIDE	Semagluide, a groundbreaking gluagon-like peptide-1 receptor agoinsi (GL-1 RA), has revolutionized the field of diabates management and holes promise in diverse health areas. This synthetic peptide has garanced global attention for its remarkable effects on blood sugar control, weight management, and potential cardiovascular benefits. Here's an in-depth overview of Semagluide - GLP-1 Receptor Activation: Semagluide mimics the action of the natural hormone GLP-1, which plays a pivotal role in glucose regulation and sativy. It acts by stimulating insulin secretion and suppressing glucagon release, resulting in improved blood sugar control. - Diabates Management Champion: Semagluide has transformed diabates management, particularly type 2 diabates. It helps lower blood sugar levels by enhancing insulin sensitivity and slowing down gastric emptying, contributing to a more stable glucose profile.	Chat					

FIGURE 4: "Sema GLP-1" is advertised on a peptide website.

In an article focusing on peptide websites selling GLP-1 agonists, the *Wall Street Journal* identified more than 50 websites selling semaglutide and tirzepatide. Nearly all of them included disclaimers that the substances were "not for human consumption."¹² These sellers likely offer, at best, research-grade versions of these drugs, which do not eliminate impurities at the same level as pharmaceutical-grade versions.¹³

In recent months, illicit peptide websites have begun offering retatrutide, a GLP-1 agonist that is currently classified as an investigational new drug.¹⁴ For example, in Figure 5 below, the seller notes, "[a]Il products purchased are for laboratory & research use ONLY, this means we cannot provide any further instructions on reconstitution and/or dosing."



According to George Karavetsos, former director of FDA-OCI, "[i]t's unprecedented to see a drug that is in latestage clinical trials being so flagrantly advertised for sale online."¹³

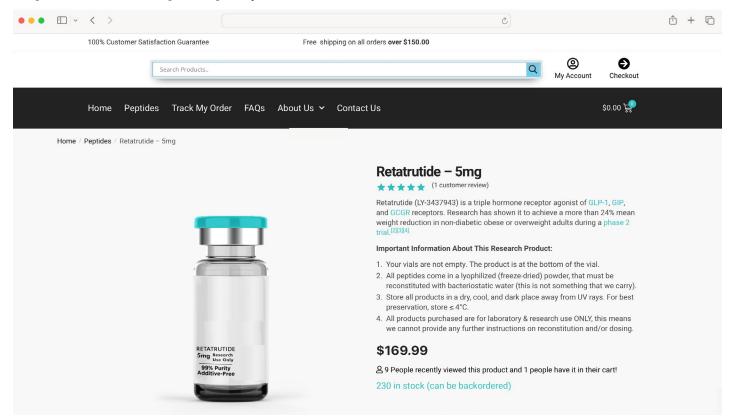


FIGURE 5: A peptide website is marketing retatrutide, an investigational new drug.

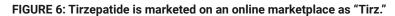
CRIMINAL ACTORS TAKE ADVANTAGE OF ONLINE MARKETPLACES AND AD PLATFORMS

Illegal online drug sellers are also taking advantage of online marketplaces to sell substandard or falsified GLP-1 agonists.

In some cases, bad actors intentionally misspell or nickname the product to avoid detection by the platform's automated compliance tools. For example, on one platform, an illicit seller described tirzepatide as "Tirz" (see Figure 6). In another example, an illegal seller intentionally placed spaces between the letters in the words "semaglutide," "Ozempic," and "Wegovy" (see Figure 7). In a third example, the word "semaglutide" is misspelled (see Figure 8).



\equiv Categories	Search for anything				Sign in t	
Back to search results	TIRZEPATIDE [10mg] For research purposes on		Exp date: 05/2026 RESEARCH PURPOSES	Ø	\$160.00 tirz 5mg & 10mg ***** • Arrives soon! • Returns & exchanges accepted Add to cart Item details	
Other reviews from this shop 🕇	★★★★★ (7)		Sort by: Suggested	•	Tirz 5mg and 10mg	
****		Item quality	5.	.0	Shipping and return policies	^
Fast shipping great product :-) Purchased item: <u>tirz 5mg & 10mg</u>		Shipping	5.	.0	*. *	
۲		Customer service	5.	.0	E Returns & exchanges accepted within 30 days	
i Helpful?					Get shipping cost 🗸	



SemaglutideWeightLoss - \$125

For sale 3 bottles of S e m a g l u t i d e (active ingredient in W a g o v y & O z e m p i c

Each 2 ML vial contains 2.5-2.5 MG/ML

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$125 a vile or $300
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Will send pics of product to email. It has been stored appropriately as recommended.

Semaglutide Description

Semaglutide is an effective, FDA-approved weight loss therapy. Medical studies show significant weight loss when Semaglutide is combined with a healthy diet and exercise. Semaglutide is also used to treat type 2 diabetes.

Semaglutide mimics the effects of glucagon-like peptide-1 (GLP-1). GLP-1 is released after eating, and it helps control blood sugar by increasing the production of insulin while suppressing the production of glucagon. By functioning in a similar way, Semaglutide positively impacts blood sugar levels and the metabolism.

Studies suggest Semaglutide can also suppress the appetite by slowing down the digestive process, so patients feel more full.

FIGURE 7: Semaglutide is promoted for sale with spaces between the letters in the words "semaglutide," "Ozempic," and "Wegovy." Wegovy is also misspelled.





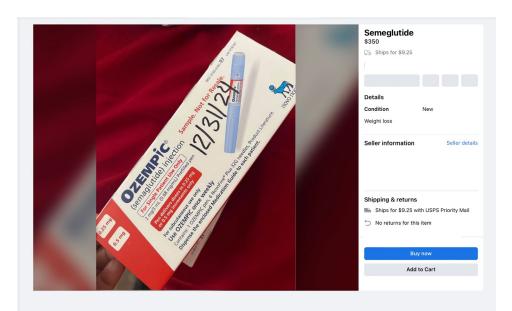


FIGURE 8: Semaglutide is misspelled, possibly to avoid detection by automated compliance solutions.

Illegal sellers have also advertised on major online ad platforms and social media.^{15, 12, 13} Often, these sellers are peptide websites that are marketing GLP-1 agonists as research chemicals.

GOVERNMENT AGENCIES IDENTIFY SUBSTANDARD AND FALSIFIED GLP-1 AGONISTS AND TAKE ACTION AGAINST ILLEGAL SELLERS

Medicine regulators around the world have identified substandard and falsified GLP-1 agonists in the supply chain. In the US, FDA has seized thousands of units of fake Ozempic.^{16,17} In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that, since January 2023, they had seized 369 potentially fake Ozempic pens. MHRA also stated that they had "received reports of fake Saxenda pens that have been obtained by members of the public in the UK through non-legitimate routes (any route that does not require a prescription from a qualified prescribing healthcare professional)."^{18,19} Germany's Federal Institute for Drugs and Medical Devices identified wholesale batches of counterfeit Ozempic 1 mg in German packaging.²⁰ Australia's Therapeutic Goods Administration also detected fake semaglutide being illegally imported into Australia.²¹ Ireland's Health Products Regulatory Authority detained 254 units of products claiming to contain semaglutide between January and September 2023, compared to just 32 units in 2022.²² According to the Partnership for Safe Medicines, substandard and falsified Ozempic has been found in at least 16 countries to date.²³

These fake medicines have resulted in patient harm. For example, in October 2023, Austria's drug regulatory authority reported that several people suffered hypoglycemia and seizures after using what was suspected to be a falsified version of Ozempic.²⁴ "Due to the untested quality of the counterfeit drug, possible impurities and unknown ingredients, these counterfeits can also be life-threatening," the Austrian agency said. In Lebanon, 11 people suffered bouts of dangerously low blood sugar, one of whom required hospitalization, after injecting



suspected fake versions of Ozempic.²⁵ According to information gained from FDA's Adverse Event Reporting System, 42 people around the world were hospitalized after being injected with substandard or falsified semaglutide. Of the reports, 28 are classified as "serious" with outcomes that include death. Three of these hospitalizations happened in the US.²⁶

Regulators are taking action to stop the unlawful sale of GLP-1 agonists. In addition to seizing fake Ozempic and alerting pharmacists and patients about fake lot numbers,¹⁶ FDA is regularly issuing warning letters to peptide website operators and illegal online pharmacy operators who engage in the illicit sale of GLP-1 agonists.^{27, 28, 29} Likewise, the European Medicines Agency is assisting European Union member states in their investigations of falsified versions of Ozempic.³⁰

Meanwhile, Canada has taken a different approach. To ensure availability for Canadian patients and to protect the legitimate supply chain, the Canadian province of British Columbia passed legislation to restrict the shipment of semaglutide to US patients.³¹ After enacting the regulation, the number of dispenses to US residents dropped by more than 99%.³²

Regulators are also collaborating internationally to take down sellers of substandard and falsified GLP-1 agonists. According to Jim Mancuso, director of the US Department of Homeland Security's Intellectual Property Rights Coordination Center (IPR Center), "[t]hese weight loss drugs are a hot topic right now because they're on TV and getting a lot of media attention. If I'm a criminal organization, that's the next opportunity I go ahead and exploit." According to Reuters, the IPR Center is "working with Europol, INTERPOL, and around 23 other law enforcement agencies on tracking weight-loss drugs to quell what they believe could become the worst tide of counterfeit lifestyle medicines since erectile dysfunction drugs like Viagra."³³

CONCLUSION

In 2023, the American Association for the Advancement of Science declared that GLP-1 drugs were the "Breakthrough of the Year."³⁴ By all accounts, these medications are critical for public health. Unfortunately, illegal actors are taking advantage of high demand and short supply in order to sell substandard and falsified versions of these products to patients around the world.

To stop these bad actors, government agencies and private actors need to stay alert, take aggressive action, and, where possible, work together. NABP applauds the work of government agencies around the world that are actively investigating illegal sellers of substandard and falsified GLP-1 agonists. NABP also supports the efforts of online marketplaces and e-advertising platforms, whose leaders are working hard to remove illegal online drug sellers from their ecosystems. To protect the supply chain and promote public health, NABP strongly encourages pharmacists and patients report illegal sellers to FDA-OCI,³⁵ state boards of pharmacy,³⁶ state attorneys general,³⁷ and NABP.³⁸

For information about NABP's RogueRx Activity Report or the Association's research and reporting capabilities, please contact Senior Digital Health & Policy Expert Niamh Lewis at <u>nlewis@nabp.pharmacy</u>.

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