



The Honorable Kyle Diamantas

Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas,

We, the undersigned organizations, representing a diverse group of stakeholders across the provider and patient advocacy communities, respectfully urge you to take immediate and decisive action against the illegal promotion and distribution of retatrutide. This investigational drug, which has not yet received Food and Drug Administration (FDA) approval, is being aggressively marketed and sold to consumers through online black markets, telehealth platforms, wellness clinics, and medical spas—putting unsuspecting patients at serious and documented risk.

Criminal Sellers Have Built a Thriving Black Market for an Illegal Drug

Retatrutide is a triple receptor agonist that targets GIP, GLP-1, and glucagon receptors simultaneously. It is currently being evaluated in Phase 3 clinical trials for the treatment of obesity and other conditions. While early trial data has generated significant interest, retatrutide has not yet completed the clinical development process nor has it been reviewed by the FDA for safety or efficacy. Any sale of retatrutide to the general public is currently illegal.

Despite this, a rapidly expanding network of online sellers, medical spas, and telehealth platforms have created a shadow market promoting illegal retatrutide. These sellers routinely make false or misleading claims about the drug's safety, efficacy, and regulatory status—including suggestions that it is superior to FDA-approved medicines or that it has undergone rigorous clinical review.^{1,2} Some sellers even use “research-grade” disclaimers to suggest legitimacy—when in actuality, it means the product was manufactured strictly for laboratory experiments, not for human use.

Because retatrutide has not yet received FDA approval, the products sold to consumers are largely sourced from unregistered foreign facilities operating outside of the United States regulatory framework. They are not held to the same manufacturing standards as FDA-approved products, with distributors having no obligation to even report adverse events or contaminations to the FDA. Simply put, consumers are essentially receiving a mystery vial, with no assurances of what is in the product, where it came from, or if it is even safe.

¹ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/peptide-partners-llc-735063-08242026>

² <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mile-high-compounds-llc-721600-03312026>



A Supply Chain Built on Foreign Dependence Has a Real Human Cost

Of particular concern is the source of illegal retatrutide being sold through these channels. Across online platforms, such as Discord, Reddit, and TikTok, consumers are being directed to Chinese chemical suppliers and peptide factories—many of which have not been inspected for compliance with U.S. manufacturing standards and have no obligation to disclose the composition or purity of their ingredients to consumers. One third-party testing facility discovered that of the 18 vials of counterfeit retatrutide they tested, about 30 percent had higher concentration, another 30 percent had lower concentration, and one vial did not contain any retatrutide.³ Additional analysis found that in most of the tested peptides, 90 percent of vial components contained unaccounted for substances—meaning consumers are potentially being exposed to unknown compounds whose safety, toxicity, and interaction profiles have never been studied.³ ^{above}

The reach of this illegal supply chain extends far beyond just individual consumers purchasing directly online. Chinese-based vendors are also supplying American medical spas and wellness clinics who then dispense these unregulated products to patients under the guise of legitimate medical care. In April, a federal grand jury indicted a Utah physician who had allegedly sold vials of retatrutide and other unapproved peptides to more than 200 patients. According to the indictment, the physician created his own labels and failed to disclose to patients that the drugs had been ordered online at a “deeply discounted price” from a Chinese lab.⁴ In Ohio, the state Board of Pharmacy took action against several medical spas who were found to be distributing illegal retatrutide, with one medical spa receiving a violation for purchasing “multiple dangerous drugs” from a Chinese website and affixing unlabeled vials with their own “GRT Peptide” and “Research Use Only” labels.⁵

These cases are not isolated incidents, but rather a window into a dangerous distribution system that begins with unregistered foreign manufacturers, flows through online procurement platforms, social media channels and medical spas, and ends in the hands of unsuspecting patients who do not know and cannot verify the origin of what they are receiving. While the full scale of this market is difficult to quantify because it operates outside of any regulatory reporting framework, what data does exist is alarming: a Partnership for Safe Medicines analysis found that hundreds of thousands of retatrutide doses flowed into the country in May and June 2026 alone.⁶

The risks posed by the illegal retatrutide market are already manifesting in emergency rooms and poison control centers. Since the beginning of 2026, poison center reports involving retatrutide have increased 265 percent compared to the final four months of 2025.⁷ A *CBS News* investigation revealed that one 25-year-old man had to go to urgent care three times after he injected retatrutide obtained from an online vendor, while multiple others have been hospitalized.

The allowance of this illegal supply chain stands in direct contradiction to the administration’s own stated priorities. The Trump administration has rightly identified foreign dependence on active pharmaceutical ingredients as a national security threat and pledged to confront China’s role in the U.S. drug supply chain. Yet Chinese-sourced, unregistered peptides are flowing into American exam rooms and medical spas with little meaningful intervention—putting consumers at serious risk. An “America First” pharmaceutical policy cannot coexist with this reality.

³ <https://www.abc.net.au/news/2026-08-28/black-market-peptides-dangerous-doses/107059092>

⁴ <https://www.justice.gov/usao-ut/pr/utah-licensed-osteopathic-physician-indicted-allegedly-receiving-misbranded-drugs-china>

⁵ <https://pharmacy.ohio.gov/dddquery/pdfs/0260003555.pdf>

⁶ <https://www.safemedicines.org/2026/08/may-june-freight-fraud.html>

⁷ <https://www.cbsnews.com/projects/2026/experimental-weight-loss-drug/>

Specific Actions Are Needed to Address the Retatrutide Black Market

Beyond endangering American consumers, the mass distribution and proliferation of illegal retatrutide threatens the integrity of our drug approval system as well as undermines FDA's authority. When consumers are led to believe that an unregulated product is equivalent to an FDA-approved medicine, and when that belief goes uncorrected by meaningful enforcement, it erodes the public trust that underpins the entire regulatory framework the FDA was designed to protect. Every illegal retatrutide sale that goes unaddressed sends a message to consumers, bad actors, and foreign suppliers alike—that those standards are optional.

While we recognize that the FDA has taken initial steps to address the proliferation of illicit retatrutide, warning letters that are not followed by strong enforcement will not meaningfully shut down this dangerous black market. To that end, we urge FDA to coordinate with state and federal regulatory bodies take stronger action against criminal sellers and distributors, which includes, but is not limited to:

- Leveraging a cross-government response—coordinating with federal agencies including the Department of Justice and Customs and Border Protection, and state bodies including law enforcement and boards of pharmacy—to carry out seizures and injunctions that stop illegal retatrutide at the border and dismantle the domestic distribution channels already operating within the country; and
- Working with the Federal Trade Commission and other federal agencies to shut down illegal online sellers, compel social media platforms and payment processors to remove illegal ads, and pursue enforcement action against shipping carriers and any other business facilitating illegal trade.

Americans for Safe and Effective Medicines along with the 19 undersigned organizations and physicians stand ready to work alongside you to protect consumers from this illegal market, strengthen the integrity of the U.S drug supply chain, and ensure that the FDA's authority is enforced with the urgency that this crisis demands.

Respectfully,

Americans for Safe and Effective Medicines

Alliance for Aging Research

Alliance for Safe Biologic Medicines

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