SB26-066 BY SENATORS JODEH & CARSON

Regulation of Compounded Weight-Loss Medication

Concerning the regulation of compounded weight-loss medications that have not been approved by the US food and drug administration.

THE PROBLEM:

Over the last several years, an unprecedented amount of compounded weight loss drugs have flooded the market, often made from illicit, inauthentic or substandard active pharmaceutical ingredients (API). Bad actors have exploited patients' desire to be a healthy weight across the country.

Imports of APIs for use in compounded weight loss drugs are largely from China, and too often of dubious quality and safety. They may come from suppliers that have never been inspected by FDA or may have troubling and potentially dangerous impurities that are not identified in certificates of analysis (COAs).

THE SOLUTION:

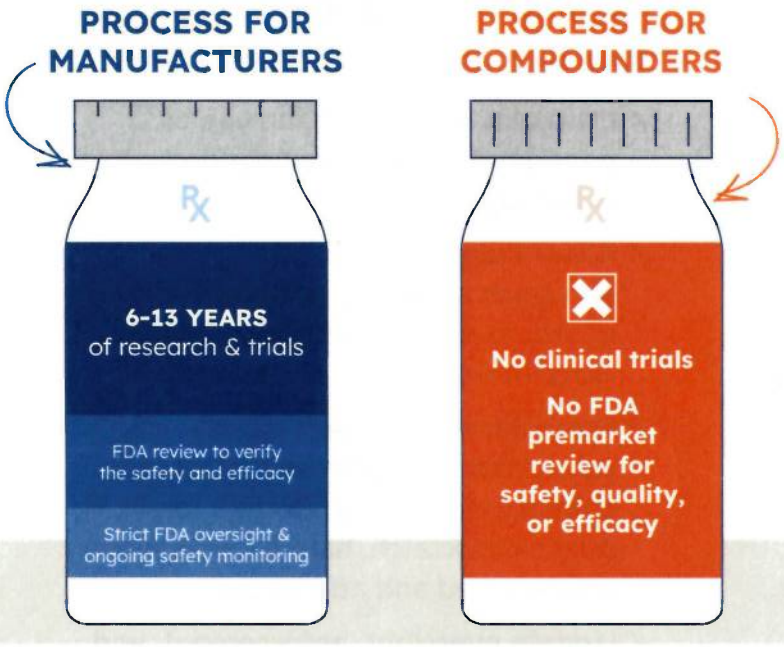
THIS BILL WILL

- ✓ **Protect patients** from the use of poor quality API in compounded weight loss drugs
- ✓ **Allow Colorado to ID bad actors and good actors** by ensuring the quality of API used in compounded weight loss drugs
- ✓ **Establish stronger API quality assurance measures** so that when compounders make a weight loss drug from scratch, harmful impurities are detected and addressed
- ✓ **Update oversight, enforcement, and recordkeeping** requirements to support oversight and compliance

THIS BILL *DOES NOT:*

- ✗ Apply to compounded drugs made from FDA-approved drugs, such as those frequently used in hospital and clinical settings
- ✗ Apply to outsourcing facilities
- ✗ Affect the ability for prescribers to determine that a compounded drug is necessary to meet a patient's individual needs

PATIENTS DESERVE BETTER



Patients deserve rigorously tested medicines that are proven to be safe and effective. This is the foundation of the "gold standard" U.S. drug-approval system.

Compounding is a narrow exception from these bedrock principles for patients who cannot be treated with an FDA-approved medication.

Compounded drugs are not FDA-approved and are not subject to the same rigorous requirements as FDA-approved medicines, putting patients at risk. That's why federal and state laws limit compounding. In situations where patients legitimately need a compounded drug, quality controls must be in place to protect patients from unnecessary risks.

Colorado has a duty to protect patients by ensuring API used in compounded weight loss drugs is authentic and of the highest quality.

The proposed amendment to SB66 is designed to address concerns raised by the Colorado Pharmacists Society, the Colorado Hospital Association, the Attorney General's Office, Novo Nordisk, and other stakeholders while reinforcing patient safety and transparency in the compounding of weight-loss medications.

The strike below will:

- **Refine Definitions**: Adjust the definition of compounded weight-loss drugs to ensure it is precise and protects patients from illegitimate mass compounding practices, without restricting legitimate, medically necessary compounding.
- **Strengthen Wholesaler Requirements**: Mandates that wholesalers must provide compounders with clear and detailed information about the original source and quality of Active Pharmaceutical Ingredients (API), supporting transparency and traceability in the supply chain.
- **Clarify COA Provisions**: Specifies that the Certificate of Analysis (COA) should include information relevant to the content and purity of the API, equipping compounders with the details needed to ensure quality in the finished drug product.
- **Modify FDA Inspection Language**: Removes requirements relating to the timing of FDA inspections for foreign API manufacturers, recognising that compounders cannot control these processes.
- **Update Labelling Provisions**: Prioritizes the inclusion of information about the API on product labels, while allowing flexibility regarding excipients. Language about "known and unknown side effects" may be removed, provided other risk-related warnings remain.
- **Carve Outs**: Seeks to exempt hospitals, compounded drugs administered in hospitals, veterinary compounding, and long-term care pharmacies from the provisions of the bill.
- **Attorney General's Authority**: Authorizes the Attorney General's office as the regulator/enforcer of the bill under the Colorado Consumer Protection Act. The strike below also gives exclusive authority to the Attorney General, meaning there is no private right of action in the bill.

"The Reckless National Experiment With Compounded Weight Loss Drugs"

The deluge of false and misleading claims about GLP-1 medicines represents one of the most problematic forms of DTC drug advertising. A 2024 report from LegitScript found a 1,200 percent increase in "violative or problematic" GLP-1-related ads between 2022 and 2024. These ads, mostly appearing online, not only promote untested, unapproved compounded GLP-1s as virtually the same as the FDA-approved versions but target young girls and women with body image concerns and promise unhealthy, unrealistic results.

This Is What Is Flooding Social Media

Consumers Are Being Harmed Every Day

As of September 2025 , FDA had received 1,424 adverse event reports, including 329 hospitalizations and 23 deaths. THIS IS THE TIP OF THE ICEBERG because AE reporting to FDA is voluntary.

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NATIONAL CONSUMERS LEAGUE

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Why does Colorado need SB26-066?

There is overwhelming evidence of counterfeit GLP-1 compounding API in the drug supply. Over the past year, we've been studying large, freight shipments of GLP-1 compounding ingredients in the FDA's database entering the US. We've uncovered a tide of suspicious, unauthorized, and illegal ingredients for popular diabetes and obesity injectables coming into the country. FDA's import records show that between March and August 2025, just one unregistered facility in China sent over 120 kilograms of tirzepatide—the equivalent of more than 48 million starting doses of the drug Mounjaro—explicitly labeled for compounding to the U.S.

FDA confirms this problem in multiple communications.

There is overwhelming evidence that some compounders around the country have cut corners using ingredients made in non-FDA-inspected facilities.
Based on FDA warning letters, we have seen that since 2021, FDA has warned compounders in Colorado (503A), Michigan (503A), Nebraska (503B), and Pennsylvania (503B) that were illegally using substances from unvetted suppliers. And more specifically, FDA inspections in California (503A), Florida (503B), Michigan (503A), and Nevada (503B) specifically cite compounders using API from unregistered establishments.

FDA released a warning letter to Darmerica, LLC, a Florida company that characterizes itself as a "supplier of choice for compounding." The letter states that Darmerica

- purchased API from facilities that aren't FDA-registered
- distributed it to compounders before completing third-party quality testing, and
- sold substances that are ineligible for use in human drug compounding, including the as-yet unreleased retatrutide, which hasn't been approved by any drug regulator in the world.

Last week, FDA released a January warning to GenoGenix LLC, a 503B compounder that cited them for using ineligible ingredients in compounded medicines.

Have patients been harmed by poorly compounded GLP-1's?

- Yes. Maryland Poison Control just revealed that based on calls to poison control since 2020, 8,000 patients have been sickened by compounded GLP-1 medicines.
- Jimmie Wilson of Georgetown, KY took four doses of her compounded GLP-1 and then suffered liver failure requiring an emergency transplant. As a result Kentucky introduced a law regulating the safety of compounding of all medicines.
- An independent analysis of the FDA's Adverse Events database of incidents related to compounded GLP-1s show that they have more adverse events associated with them and those events are more severe.