**House Health & Human Services**

**03/10/2026 Upon Adjournment**

**HB26-1262 Patient Access to Compounded Medical Items**

**Typed Text of Testimony Submitted**

| **Name, Position, Representing** | **Typed Text of Testimony** |
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| Brian Logue<br><br>For<br><br>themself | Dear Members of the Committee,<br><br>I am writing to express my strong support for HB26-1262, legislation that helps preserve patient access to compounded medical treatments in Colorado.<br><br>Compounded medications play an essential role in modern healthcare. They allow licensed pharmacists and providers to prepare customized medications for patients whose needs cannot be met by commercially manufactured products. Many patients require individualized formulations due to allergies, dosage requirements, delivery mechanisms, or medication shortages.<br><br>HB26-1262 appropriately clarifies that licensed pharmacies, FDA-registered 503B outsourcing facilities, and licensed healthcare providers may compound, supply, obtain, dispense, and administer compounded medications when doing so in accordance with federal and state law. By doing this, the bill protects access while maintaining existing safety frameworks already established by federal regulation and state oversight. ï¿¼<br><br>Equally important, the bill prevents the state board of pharmacy from adopting rules that are more restrictive than existing federal and state law regarding compounding. This provision helps |

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| | ensure that regulatory barriers do not unintentionally limit access to medically necessary treatments for Colorado patients.<br><br>For many patients, compounded medications are not a luxuryâ€”they are the only viable therapeutic option. These treatments are critical for individuals who require specialized dosing, preservative-free formulations, alternative delivery methods, or medications that are otherwise unavailable due to manufacturing shortages.<br><br>Supporting HB26-1262 means supporting patient-centered care, medical innovation, and the ability of healthcare professionals to meet the unique needs of the people they serve.<br><br>I respectfully urge you to vote YES on HB26-1262 and help ensure that Coloradans continue to have safe and reliable access to compounded medications.<br><br>Thank you for your time and consideration.<br><br>Sincerely,<br>Brian Logue<br>Clinical Pharmacist<br>Highlands Ranch CO |

March 9, 2026

**Eli Lilly and Company**

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The Honorable Lindsay Gilchrist
House Health and Human Services Committee
Colorado House of Representatives
200 East Colfax Avenue Denver, CO 80203

**Re: Colorado HB26-1262 – Colorado Patient Access and Compounding Clarity Act**

Dear Representative Gilchrist:

I write on behalf of Eli Lilly and Company ("Lilly") to comment on Colorado House Bill 26-1262. As a pharmaceutical manufacturer founded in Indianapolis in 1876, Lilly has been at the forefront of drug innovation and drug quality for more than 150 years. At Lilly, patient safety is at the heart of everything we do. We believe our commitment to patient safety aligns with Colorado's longstanding dedication to health and the effective regulation of drug compounding.

Colorado patients deserve access to safe, high-quality medications. Unfortunately, enforcement actions brought by the Food and Drug Administration ("FDA") right here in Colorado tell a troubling story: patients received compounded drugs with inconsistent dosages, facilities cited for foreign contaminants in clean rooms where testosterone pellets were compounded, syringes of compounded ketamine found to contain particles, and drugs rendered adulterated due to manufacturing violations.[1] In one case, a Colorado compounder dispensed drugs without even receiving valid prescriptions.[2] These are not abstract regulatory concerns—they are real risks to the health and safety of Coloradans. It is against this backdrop that Lilly writes to oppose Colorado House Bill 26-1262 in its current form.

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[1] *See, e.g.*, FDA Form 483 to Thrive Health Solutions (Apr. 3, 2025) (stating the 503A compounder provided compounded drugs with inconsistent dosage to patients); FDA Warning Letter to Wise Pharmacy (Apr. 15, 2021) (warning a 503A compounder that its drugs were adulterated due to manufacturing violations); FDA Form 483 to BSO LLC (Mar. 11, 2021) (identifying nonconformances related foreign contaminants in a Clean Room where testosterone pellets were compounded); FDA Form 483 to STAQ Pharma Inc., (Sept. 3, 2020) (finding that 7 syringes of compounded Ketamine contained "particles"); FDA Form 483 to Good Day Pharmacy (Jun. 17, 2019) (stating that a 503A compounder did not sanitize equipment between compounding hormone and non-hormone drugs); FDA Untitled Letter to BSO LLC (Jan. 10, 2019) (stating manufacturing failures rendered drugs compounded at the facility adulterated in violation of the FDCA).

[2] FDA Untitled Letter to ITC Compounding and Natural Wellness Pharmacy (Aug. 18, 2020) (stating that the 503A compounder "did not receive valid prescriptions for the individually-identified patients for a portion of the drugs" compounded at the facility).

**Summary of Concerns Regarding HB 26-1262**

- Exposes Coloradans to unsafe drugs by conflicting with federal safety requirements that protect patients from substandard compounded medications;
- Strips Colorado regulators of local control by preventing the Board of Pharmacy from adopting rules tailored to protect Colorado patients, even when documented safety problems demand a stronger response; and
- Enables consumer fraud by allowing bad actors to sell unapproved, research-grade chemicals labeled "investigational use only" directly to Colorado consumers for injection or administration.

Lilly urges Colorado legislators to protect patients by amending HB26-1262 in line with the recommendations herein.

## I. HB26-1262 Is Inconsistent with Federal Drug Compounding Law

Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA") establish minimum requirements for compounding in pharmacies and outsourcing facilities, respectively. *See* 21 U.S.C. §§ 353a, 353b. Those minimum requirements apply to all compounding in the country and cannot be waived by the states. However, the federal requirements establish a floor, not a ceiling. States can and have chosen to implement their own requirements that go above the federal minimum in the name of patient safety. As written, HB-26 1262 purports to eliminate two core federal requirements by (1) allowing pharmacies and outsourcing facilities to compound medical devices, and (2) allowing pharmacies to compound drugs for office stock.

***First, federal law does not permit pharmacies or outsourcing facilities to compound medical devices.*** Section 3 of HB26-1262 would provide that "a licensed person may compound a drug *or device* in the state, including the compounding of a drug *or device* in a sterile or nonsterile environment." (emphasis added). However, federal law requires devices to be cleared or approved by FDA in accordance with their risk classification. 21 U.S.C. § 360c; *see also* 21 U.S.C. §§ 360(k), 360e. Devices also must be appropriately labeled, manufactured in registered establishments, manufactured in establishments that follow FDA's quality management system regulation ("QSMR") and engage in required materiovigilance activities. 21 U.S.C. § 360j(f). There are no compounding exceptions to any of those requirements. And by their terms, FDCA sections 503A and 503B only apply to the regulatory requirements for prescription drugs. Section 3 of the bill must be revised to remove references to medical devices.

***Second, pharmacies cannot legally compound drugs for office stock.*** Section 3 of HB26-1262 would add section 12-280-120(1.5)(a)(II) allow "a state-licensed resident pharmacy, licensed resident 503B outsourcing facility, state-licensed nonresident pharmacy, or nonresident

503B outsourcing facility may supply a compounded drug or device to a licensed health-care provider, pharmacy, facility, or organization." It is appropriate and consistent for *outsourcing facilities* to sell drugs to health care providers for in-office administration (although not for further resale—reselling any compounded drug is illegal under federal law, *see* 21 U.S.C. 331(ccc)(1)).

But section 503A only exempts pharmacy-compounded drugs from new drug approval, labeling, and manufacturing requirements when a pharmacy prepares a drug for an "individual patient based on the receipt of a valid prescription." 21 U.S.C. § 353a(1). As FDA has explained, although the prescription requirement allows pharmacies to compound limited quantities of a drug in advance of a receiving prescription, the drug cannot be dispensed until a prescription has been received.[3] Section 3 must be revised to remove references to pharmacies supplying compounded drugs for office stock.

## II. Colorado Must Retain Local Control Over Patient Safety

The bill proposes that "in adopting rules to implement this section or otherwise regulate the compounding of drugs or devices in the state, the Board shall not adopt rules that are more restrictive than applicable federal and state law." Lilly strongly opposes this provision and recommends its removal.

This provision would strip Colorado's Board of Pharmacy of the authority to respond to local public health threats with locally tailored solutions. It prevents Colorado regulators from doing their job: protecting Coloradans. Federal minimum standards are just that—minimums. They are designed as a baseline, not a straitjacket.

Many Boards of Pharmacy around the country have adopted regulations that are stricter than federal laws on drug compounding in the interest of public safety—and for good reason. Past FDA enforcement illustrates that the quality of drugs compounded in Colorado has been a documented problem that has put patients at risk.[4] Colorado compounders have been cited for:

- Providing compounded drugs with **inconsistent dosages** to patients;
- **Foreign contaminants** in clean rooms where drugs were compounded;
- **Particles found in syringes** of compounded ketamine;

[3] FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, 10-11 (Dec. 2016).

[4] *See infra* note **Error! Bookmark not defined.** (listing examples of FDA enforcement against compounders located in Colorado).

- Dispensing drugs **without valid prescriptions** for identified patients; and
- Manufacturing violations that rendered drugs **adulterated**.

Without the ability to impose requirements tailored to Colorado's needs, the Board of Pharmacy cannot protect the residents of Colorado from potentially dangerous drugs. And it ties the Board of Pharmacy's hands to address emergent issues that may require immediate action to protect Coloradans from serious harm, particularly if they arise when the State Legislature is not in session. This is a matter of **local control**—Colorado regulators should have the flexibility to act decisively when they identify threats to public health, rather than being hamstrung by a one-size-fits-all federal floor.

Lilly strongly encourages the amendment of HB26-1262 to remove subsection (b) prohibiting the Board of Pharmacy from enacting more restrictive regulation.

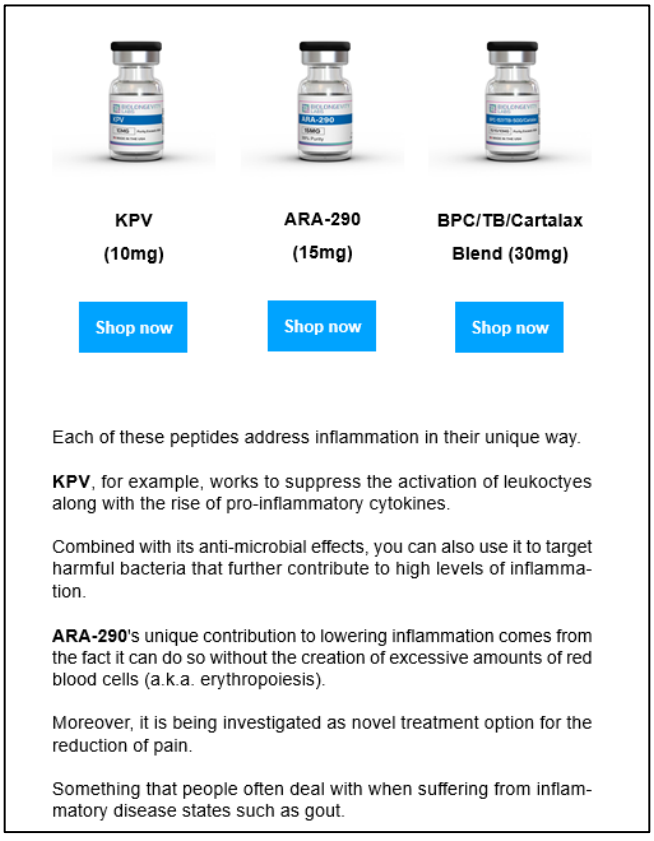
## III. Bad Actors Have Abused "Investigational Use Only" Labels and Put Patients at Risk

Section 4 would permit sales of a new drug when it "is plainly labeled to be for investigational use only." Section 4 also exempts a "compounded drug or device" from the prohibition of selling "any new drug not authorized to move in interstate commerce." The bill, as written, would perpetuate the abuse of "investigational use only" or "research use only" labeling to import and mass-distribute research-grade chemicals that put Colorado patients at risk.

For decades, bad actors have sought to evade all federal and state oversight by falsely claiming their unapproved drug products are not, in fact, drugs at all because they are not intended for human administration and are intended for "research use only." They know that the research-grade chemicals they sell are not safe for use as human drugs and pretend that they are selling their products to laboratories for use in experiments. But they know full well that their customers are often individual consumers who buy the chemicals for injection. Indeed, they typically sell and package these supposed "research use only" drugs with the tools needed to convert them to human use (e.g., bacteriostatic water and syringes) and use sales techniques designed to foster the belief—sometimes through less public marketing channels—that the unapproved, untested chemical will provide some therapeutic benefit.

For instance, one seller's website contains a supposed disclaimer that its products are intended for research only (https://biolongevitylabs.com/):


However, the seller markets the same supposedly "research use only" products in blast email messages to their customers and on the company's website by touring the drugs' supposed benefits for patients —even for investigational products like orforglipron that have not been approved by FDA or any other global regulator:[5]




[5] https://biolongevitylabs.com/product/biozapetite/.


This is consumer fraud, as well as the sale of complex drugs without a prescription. Federal prosecutors and state enforcement regulators have repeatedly taken action against this type of conduct. Examples include:

- A doctor pled guilty to distribution of misbranded semaglutide that "arrived packaged in a vial that contained a warning that the drugs were intended for lab research and development only";[6]
- The owner of Precision Peptides and DNA Peptides was convicted for selling misbranded drugs labeled for "research/laboratory use only";[7]
- A man was indicted for marketing unapproved and misbranded drugs to consumers as "for research use only" and "not for human use";[8]
- A medical spa was permanently closed and its owners were fined and prohibited from treating patients in any capacity for "using unapproved, research-grade chemicals on unsuspecting patients";[9] and
- Clinics lost their licenses to distribute dangerous drugs for giving patients weight-loss drugs that were labeled "For Research Use Only."[10]

[6] DOJ Press Release: Ashland Doctor Pleads Guilty to Distribution of Misbranded Semaglutide (Apr. 15, 2025) (stating that compounded semaglutide "arrived at Lewis Family Care packaged in a vial that contained a warning that the drugs were intended for lab research and development only" were misbranded).
[7] DOJ Press Release: Owner of Bodybuilding Drug Companies Sentenced for Selling Misbranded Drugs (May 9, 2016) (convicting the owner of Precision Peptides and DNA Peptides that sold misbranded drugs that were labeled for "research/laboratory use only").
[8] DOJ Press Release: Mentor Man Indicted For Selling Drugs Not Approved By The FDA (Jul. 29, 2014) (indicting a man who marketed unapproved and misbranded drugs to consumers as "for research use only" and "not for human use").
[9] Attorney General Marshall Settles Lawsuit with Cullman Clinic for Administering Dangerous, Unapproved Weight Loss Drugs (January 12, 2026) (imposing a settlement agreement on Aurora IV and Wellness and its owners after the state investigation revealed the defendants advertised their weight loss drugs as "pharmaceutical grade" though the drugs were research grade).
[10] Two Ohio Doctors and Their Clinics Disciplined Over Weight Loss Drugs (January 28, 2025) (suspending the licenses of clinics in Columbus, Cleveland, Dayton and Cincinnati for distributing patient weight loss drugs labeled "For Research Use Only" and that came from an unlicensed out-of-state seller").

Colorado should prosecute those who distribute "investigational use only" or "research use only" drugs, not encourage this dangerous behavior. Section 4 must be removed.

## IV. Drug Compounding Is Not Drug Manufacturing

Lilly opposes the proposed new C.R.S. 12-280-120(1.5)(c) because it could prohibit the Board of Pharmacy from protecting Coloradans from illegal manufacturing that occurs under the guise of compounding. While there should be an important distinction between drug compounding and drug manufacturing, the reality is there too often is not. Indeed, there is a long history of illegal drug manufacturing occurring under the guise of compounding, which has resulted in a shadow industry of unapproved drugs that are mass-produced in enormous volumes in facilities that claim to be pharmacies but are acting as drug manufacturers. Examples of mass-compounded drugs flooding the market include not just incretin drugs but also erectile dysfunction pills, hair loss medicines, controlled substances (e.g., ketamine), and hormones. The recent boom of telehealth companies selling compounded drugs and using false and misleading advertising has further fueled the problem.[11] In the interest of Coloradan patients, Lilly implores the General Assembly to preserve the Board of Pharmacy's ability to combat the illegal drug manufacturing that is occurring under the guise of compounding.

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**Summary of Requested Amendments to HB 26-1262:**
Lilly respectfully urges the Colorado legislature to:

1. **Remove references to medical devices** in Section 3;
2. **Remove pharmacy office stock provisions** in Section 3;
3. **Delete subsection (b)** restricting the Board of Pharmacy's authority to enact more protective regulations; and
4. **Remove Section 4 entirely** to prevent abuse of "investigational use only" labeling.

Lilly appreciates the opportunity to comment on these important matters. We urge the Colorado legislature to amend HB 26-1262.

Sincerely,

Brad Jordan, Ph.D.
Associate Vice President
Regulatory Policy & Strategy
Eli Lilly and Company

[11] *See generally* https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829222.

**March 10, 2026**
**Testimony in support of HB26-1262**
**LeadingAge Colorado**
**Joseph Dubroff, Director of Government Affairs**
**Colorado House Health & Human Services Committee**

My name is Joe Dubroff and I am the Director of Government Affairs for LeadingAge Colorado, the leading voice of senior living and care providers in our state. Our mission is to foster a collaborative network that leads, advocates, and shares knowledge to enrich and advance services to the aging and promote a healthy business environment for our members. Our membership includes Assisted Living Residences, Home- and Community-based Services (HCBS), Independent Senior Housing, Life Plan Communities, Nursing Homes, and Programs of All-Inclusive Care for the Elderly (PACE).

On behalf of our members, I write to express our support for HB26-1262.

Our members are responsible for caring for some of Colorado's most medically complex and vulnerable residents. In order to provide safe, effective care, they must be able to ensure that residents have access to the medications they need in the form, dosage, and formulation that works for them. Compounded medications are an important part of that care.

Many older adults cannot take medications in standard commercially available forms. Residents may require adjusted dosages, liquid formulations, topical preparations, or medications that are free of certain ingredients due to allergies or medical conditions. Compounding allows pharmacists to tailor medications to the clinical needs of individual patients when a commercially manufactured product does not meet those needs.

Access to compounded medications is particularly important in long-term care and senior living settings. Residents often take multiple medications, have complex health conditions, and require individualized medication management. Compounding provides the flexibility necessary for physicians and pharmacists to ensure residents receive appropriate treatment that helps individuals manage chronic disease, improve mobility, and maintain independence. A large number of these residents are also Medicaid beneficiaries.

Our members take medication safety extremely seriously. The residents they serve are older, medically fragile, and often living with multiple chronic conditions. Medication management in these settings is closely monitored by physicians, pharmacists, nurses, and regulatory oversight. The use of compounded medications in long-term care is not casual or experimental; it occurs within a structured clinical environment designed to protect patient safety.

For these reasons, LeadingAge Colorado respectfully asks the committee to support HB26-1262.

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