April 9, 2026

Chair Kyle Mullica
Vice Chair Iman Jodeh
Senate Health & Human Services Committee
Colorado General Assembly

Dear Chair Mullica, Vice Chair Jodeh and members of the committee:

We, the undersigned individuals and organizations representing healthcare professionals- physicians, pharmacists, patient advocates, and consumer groups - are committed to ensuring that all American patients receive medicines that are safe, effective, and manufactured to the highest quality standards.

We are deeply concerned about the increasing availability of untested and largely unregulated drugs that may be of unknown quality. **We strongly oppose any efforts to remove critical safeguards and hamstring important public health authority this area, which could jeopardize the safety of Colorado patients.**

Colorado Public Health Agencies Needs Clear Authorities to Protect Patients

Compounding can be beneficial for patients who cannot take FDA-approved medicines due to allergies or require specific dosage forms, such as turning a pill into a flavored liquid for children. However, the misuse of compounded medications is becoming a widespread problem, threatening patient safety across the country.

One of our main concerns is the limitation on the Board of Pharmacy's regulatory authority over compounding pharmacies. Colorado has a proud history of leading in public health, and restricting the Board's ability to implement stronger safety measures would undermine the capacity and capability to respond to emerging safety issues and take effective action to protect Colorado patients. Without proactive regulatory capacity, patients will be left vulnerable to unsafe compounding practices.

Moreover, freezing the Board of Pharmacy's enforcement powers would create major public health risks by tying the hands of Colorado public health officials to protect Coloradans. As compounding practices evolve, Colorado's regulatory framework must evolve with it. A framework that cannot adapt to new risks leaves Colorado patients vulnerable to public health threats. For instance, med spas are increasingly engaging in illegal compounding practices.[1] In response, the Ohio Board of

[1] The Ohio Board of Pharmacy cites the following as the *Ten Most Common Prescriber and Medical Spa Violations*: Purchasing drugs from unlicensed sellers (ex. Facebook and other social media sites, internet sellers, and other clinics or prescribers not authorized for sale), purchasing medications marked as 'For Research Purposes Only', insanitary preparation of medication marked 'Unfinished Drug Products', Purchasing non-FDA approved medications including foreign-sourced or drugs not permitted for

Pharmacy has taken enforcement actions and implemented clear policies to ensure patient safety while allowing access to necessary compounded medications. For example, the Ohio Board of Pharmacy published *Ten Common Prescriber Clinic and Medical Spa Violations*, and *Med Spa and IV Hydration Clinics: Tips for Patients*, which provide further information about the kind of risks that the Colorado Board of Pharmacy needs the authority to address.[2] [3] Boards of pharmacy from across the country—including California[4], Kansas[5], and Nevada[6], among others—have all promulgated new rules and policies to address the public health risks from unsafe compounding. Colorado should not purposefully hamstring its own Board of Pharmacy from taking similar action in the future when needed to protect patients. Such an approach would undermine the Board of Pharmacy's role as a protector of patient safety, leading to compounded drugs entering the market without proper oversight, raising concerns about quality assurance and traceability. [7] [8]

Analogizing to Park Oversight: Colorado Should Not Cede Longstanding Authority to Protect Coloradans

Consider what it would mean if Colorado enacted a law providing that the state could take no measures to protect its parks beyond federal law — in other words, that Colorado's state parks must be governed solely by the rules that apply to national parks. Such a law would be immediately recognized as absurd. The federal framework for national parks is not a complete code for all parks, and never intended to apply to state parks. Federal law governing national parks addresses *national* parks. It does not attempt to be the definitive word on all parkland in all states. Recognizing this, Colorado has developed its own parks system, its own rules, and its own enforcement mechanisms tailored to the land it owns and the people it serves. Federal rules written for Rocky Mountain

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compounding, failure to comply with compounding standards, failure to secure controlled substances, inadequate record keeping, patient specific drugs used as office stock, labeling multidose vials, expired/adulterated drugs in active drug stock.

[2] Ohio Board of Pharmacy, " Ten Common Prescriber Clinic and Medical Spa Violations", https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/ten%20common%20prescriber%20clinic%20and%20medical%20spa%20violations.pdf (last accessed Mar. 5, 2026)

[3] Ohio Board of Pharmacy, " Med Spa and IV Hydration Clinics – Tips for Patients", https://www.pharmacy.ohio.gov/Documents/Pubs/Special/IVTherapy/Med%20Spas%20and%20IV%20Hydration%20Clinics%20-%20Tips%20for%20Patients.pdf (last accessed Mar. 5, 2026)

[4] Cal. Code Regs. tit. 16, §§ 1735–1738.14

[5] Kansas Board of Pharmacy, "Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists", https://www.pharmacy.ks.gov/home/showpublisheddocument/9120/638804875360800000 (last accessed Apr. 6, 2026)

[6] Department Of Business And Industry Office Of Nevada Boards, Commissions And Councils Standards State Of Nevada Board Of Pharmacy "Notice of FDA's Declaratory Orders Resolving Shortages of Tirzepatide (Mounjaro and Zepbound) and Semaglutide Injection Products (Ozempic and Wegovy)", https://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/Notice%20to%20Compound%20Pharm%20re%20Tirzepatide%20semaglutide%20FINAL.pdf (last accessed Apr. 6, 2026)

[7] U.S. Food & Drug Administration, "FY 2024 Report on the State of Pharmaceutical Quality", https://www.fda.gov/media/188236/download (last accessed Jan. 27, 2026).

[8] U.S. Food & Drug Administration, "API Sourcing or Buyer Beware", https://www.fda.gov/media/164526/download (last accessed Jan. 27, 2026)

National Park or Great Sand Dunes were not intended to apply to Lake Pueblo or Chatfield state parks.

The analogy helps show the flaws with ceding the state's authority over pharmacy compounding. Just as state parks are owned and governed by the state, pharmacy practice is, and for well over a century has been, primarily a matter of state law. There may be additional federal rules that also apply to protecting state park land, but the primary authority over state parks is the state of Colorado. The Colorado Board of Pharmacy, not FDA, licenses pharmacists and pharmacies in Colorado. The federal compounding framework under Sections 503A and 503B of the Food, Drug, and Cosmetic Act sets a national baseline — but it was never designed to be the complete and exclusive code for pharmacy practice in every state. States have always retained the authority to impose additional requirements, just as they retain the authority to make rules for their own parks. Adopting a moratorium on new compounding authority would leave significant gaps because the federal rules were never meant to replace state-level oversight and requirements, just as federal rules over national parks were never meant to stop states from making rules about their own parks.

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The tragic consequences of past health crises serve as a stark reminder of the dangers of inadequate state oversight over compounding. [9] For example, the Maryland Poison Control Center has reported a staggering 1500% increase in calls related to compounded GLP-1 products since 2020. [10] Current trends demand swift action from regulatory bodies like the Board of Pharmacy, Board of Nursing, and Board of Medicine. **Colorado must prioritize robust safeguards to protect the health and well-being of our communities.**

We urge Colorado to take steps to protect public health and ensure that patients receive safe, effective, and high-quality medicines. We are ready to assist legislators in implementing these reforms and building a safer healthcare system for all.

Sincerely,

John Hertig, PharmD
Michael Stepanovic, PharmD
Shabbir Safdar, Executive Director, Partnership for Safe Medicines
Adonis Saremi, MD
Nancy Glick, National Consumers League

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[9] Pew Charitable Trusts, "U.S. Illnesses and Deaths Associated With Compounded Medication and Repackaged Medications" https://www.pew.org/en/research-and-analysis/data-visualizations/2017/us-illnesses-and-deaths-associated-with-compounded-medications-or-repackaged-medications (last accessed Mar. 5, 2026)

[10] Karl Hille, "FDA Cracks Down on Weight-Loss Drug Alternatives As Thousands Sickened in Maryland", The Baltimore Sun, https://www.baltimoresun.com/2026/02/23/glp-1-crackdown-fda/?clearUserState=true (last accessed, Mar. 5, 2026)

Ray Patnaude, Alliance for Safe Biologic Medicines

Note: Each signatory is signing in their personal capacity, and any credentials or organizational affiliations are provided exclusively for biographical purposes.