April 13, 2026

Chair Marc Berman
Vice Chair Natasha Johnson
Committee on Business and Professions
California State Assembly

Dear Chair Marc Berman, Vice Chair Natasha Johnson and committee members:

The undersigned individuals and organizations representing health care professionals, including physicians and pharmacists, patient advocates, and consumer groups, aim to ensure that all American patients receive medicines that are safe, effective, and manufactured according to the highest quality standards. We are deeply concerned by the rampant provision to patients of untested, largely unregulated drugs that are of, at best, unknown quality. We strongly support steps to better protect patients from the growing risks posed by mass marketed compounded drugs.

Compounding can meet the needs of specific patients who cannot take FDA-approved medicines due to a known allergy, the need for dosage and form changes (like turning a pill into a flavored liquid) for pediatric patients, or to address a similar clinical need. Unfortunately, inappropriately compounded medications have become a widespread and escalating challenge, threatening the safety of American patients. Mass manufacturing unproven drugs while calling it personalized medicine exploits patients instead of empowering them. Compounding—especially by traditional state-licensed 503A pharmacies—is now occurring at massive levels never intended under the law. There are two categories of compounding under the federal framework: compounding by traditional state-licensed pharmacies under Section 503A, and compounding by outsourcing facilities under Section 503B. 503B facilities are subject to requirements that do not apply to 503A pharmacies—like registration with FDA, complying with Current Good Manufacturing Practices (CGMPs), and other restrictions—because it was envisioned that they would compound drugs at higher volumes than 503A facilities and under different circumstances, such as to address shortages. But these limits are being pushed further than ever intended, especially by the pharmacies that operate under 503A and that traditionally were licensed and primarily regulated by states. Action at the state level is needed to protect patients from these growing and problematic practices.

Quality and Transparency Guardrails for Active Pharmaceutical Ingredients to Protect Pharmacies and the Patients They Serve

The undersigned support state legislation aimed at improving the quality and transparency of active pharmaceutical ingredients ("API") used in compounded drugs. Today, a significant number of compounded drugs are produced using substandard APIs sourced from foreign manufacturers, including in China, that are not subject to FDA or other regulatory oversight.[1] The use of these

[1] The Partnership for Safe Medicines, "New Report Reveals Illegal Ingredients for Knockoff Weight Loss Drugs Flooding Into U.S. From Foreign Sources, Endangering Patient Safety", Feb. 20, 2025,

substandard APIs puts patients at risk for exposure to drugs with inconsistent potency, as well as harmful contaminants.

- FDA's most recent report on pharmaceutical quality noted a "concerning trend" whereby API manufacturers (largely in China and India) that exclusively supply compounders represented 72% of FDA compliance actions while accounting for just 18% of all registered API manufacturers.[2]
- Moreover, FDA has described the "shell game" played by some distributors and repackagers to hide the (often foreign) sources of APIs that fail to meet basic quality standards.[3]

When poor-quality, foreign-made API makes its way into the U.S. drug supply chain and eventually into compounded drugs given to patients, this puts Americans at serious risk.[4] This isn't hypothetical. Alarmingly, one recent research study found that compounded weight-loss drugs were associated with significantly higher rates of contamination and manufacturing issues and were 2.5 times more likely to result in hospitalization.[5]

Safe drugs require safe ingredients, and patients deserve common-sense safety standards to ensure that the drugs they receive are made with high-quality ingredients—standards that most people already assume are in place to make sure their medicines are safe. To this end, clear requirements are needed for the sourcing and quality documentation of APIs (also known as "bulk drug substances").

- APIs should always meet basic requirements like being pharmaceutical grade and appropriate for use in humans--not research or industrial grade materials produced under less stringent quality controls, which can harbor dangerous impurities, heavy metals, or other hazardous contaminants that pose a direct threat to patient safety.
- Moreover, pharmacies need documentation to ensure that APIs have been subject to adequate quality control testing and come from FDA-registered facilities that are not

---

https://www.safemedicines.org/2025/02/new-report-reveals-illegal-ingredients-for-knockoff-weight-loss-drugs-flooding-into-u-s-from-foreign-sources-endangering-patient-safety.html (last accessed Jan. 27, 2026); 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) ("In addition, for FY2024, API manufacturers represented 25% of quality-related import alert additions (this was only 2% in FY2023). This FY2024 increase in quality-related import alerts for API manufacturers was primarily due to API manufacturers supplying bulk product to domestic compounding pharmacies…").

[2] 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).

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

[4] U.S. Food & Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss", https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (last accessed Jan. 30, 2026).

[5] Kenneth L. McCall, et al., "Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system" (Expert Opinion on Drug Safety 2025), https://doi.org/10.1080/14740338.2025.2499670.

subject to unresolved actions from FDA for failing to comply with federal requirements, including current Good Manufacturing Practice ("cGMP") requirements.

These are simple, common-sense safety measures that patients should be able to expect. Establishing clear requirements for ingredient sourcing and documentation will help level the playing field for responsible pharmacies and stop bad actors who put patients at risk with shoddy ingredients. With more robust due diligence and compliance measures, regulators can better trace the API supply chain to stop bad ingredients, protect pharmacies from fraud, and work to ensure that only high-quality, legitimate APIs are used in compounded drugs. The fact that these quality and transparency measures are not in place today is shocking and unacceptable. This needs to be fixed without delay.

Strengthening Advertising Integrity and Consumer Transparency

Beyond the safety of ingredients, the undersigned are deeply concerned by the deceptive marketing practices currently targeting California consumers. The proliferation of direct-to-consumer platforms has created an environment where compounded medications are often mass-marketed in ways that mislead patients, leading the proliferation at unprecedented scale of drugs that have not undergone the same rigorous review as FDA-approved drugs.

These unapproved drugs are often promoted with false or misleading claims that deceive patients about the origins and quality of such drugs and fail to convey the lack of safety or efficacy evidence and important information about relevant risks. As illustrated through recent FDA enforcement activity, many advertisements for compounded drugs make false statements, explicitly and implicitly, including that compounded drugs are FDA-approved or are equivalent to the FDA-approved medications they purport to copy. And unlike FDA-approved drugs, ads for compounded drugs are not required to provide any information about the relevant risks with such drugs, such as potential warnings or side effects. Advertisements for compounded drugs should be subject to common-sense requirements that such ads be truthful, not misleading, and provide consumers with basic risk information.

*****

The undersigned urge the California Assembly to take steps to restore trust, protect public health, and ensure that patients receive safe, effective, and high-quality medicines. We stand ready to assist legislators in implementing these reforms and building a safer health care system for all.

Sincerely,

John Hertig, PharmD
Michael Stepanovic, PharmD
Adonis Saremi, MD