April 23, 2026

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Re: Patient Harms Associated with Compounded GLP-1 Drugs

Dear Members of the California State Board of Pharmacy:

I am writing to share growing evidence of patient harm associated with mass-compounded GLP-1 products and to emphasize the importance of establishing clear, enforceable safeguards for compounding, particularly regarding the quality of active pharmaceutical ingredients (APIs) and appropriate testing for identity, strength, purity, and sterility. Over the last several years, there has been a surge in compounding—particularly of GLP-1s. As one obesity medicine expert said, the proliferation of compounded GLP-1s amounts to "the largest uncontrolled, unconsented human experiment of our lifetime."[1] And as reports of serious adverse events continue to accumulate, we respectfully urge support for legislation that mitigates these risks by requiring API quality standards and testing requirements consistent with those outlined in AB 1990, which is pending consideration in the California Legislature.

There is a growing body of scientific evidence identifying concerning impurities, including peptide-related impurities, in GLP-1 API used for compounding as well as finished compounded GLP-1 products.[2] FDA has warned that such peptide-related impurities in drug products can pose significant safety and immunogenicity risks to patients, including anaphylaxis, severe system-wide inflammation, and non-acute immune reactions.[3] And recent peer-reviewed research has found that these impurities can result in the formation of anti-drug antibodies that can make semaglutide medicines ineffective for patients or even neutralize a patient's own native GLP-1.[4]

Mass-compounded GLP-1 drugs have been linked to more than 1,500 adverse event reports—including 372 hospitalizations and 30 deaths.[5] The number of annual adverse events associated with compounded GLP-1s has also steadily increased over the last several years. And FDA has warned that "adverse events from compounded versions of these drugs are underreported" as FDA does not require pharmacies to

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[1] The Obesity Society, *FDA-Approved vs. Compounded GLP-1s: Comparing Safety, Quality, and Transparency* (Mar. 24, 2025), https://www.youtube.com/watch?v=BJ5DU6u6rZI.
[2] *See* Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-on GLP-1 Polypeptide Drugs*, PHARM. RSCH., Table IV at 7-8 (Oct. 8, 2024), https://link.springer.com/article/10.1007/s11095-024-03771-6.
[3] *See* FDA, *ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that Refer to Listed Drugs of rDNA Origin: Guidance for Industry*, at 7 (May 2021), https://www.fda.gov/media/107622/download; *see also* FDA, *Immunogenicity Assessment for Therapeutic Protein Products, Guidance for Industry* (Aug. 2014), https://www.fda.gov/media/85017/download.
[4] *See* FDA, *Immunogenicity Assessment for Therapeutic Protein Products* at 3 (Aug. 2014), https://www.fda.gov/media/85017/download.
[5] *See* FDA, *FDA Adverse Event Reporting System (FAERS)*, (last visited Mar. 13, 2026), https://www.fda.gov/drugs/surveillance/fda-adverse-event-reporting-system-faers. Analyses of FAERS data have challenges that can limit conclusions, including case classification issues and lack of robust reporting for compounded drugs in general.

surveil for or report adverse events to the FDA.[6] These incidents underscore that variability in sourcing, formulation, labeling, and handling can translate into increasing real-world patient harms, particularly for sterile injectable products that require stringent controls.

A peer-reviewed analysis of FAERS data from 2018 to 2024 found that compounded GLP-1 drugs may be associated with a higher probability of adverse events, including suicidality, than non-compounded formulations. It also found higher odds of contamination and compounding/manufacturing issues, prescribing and preparation errors, and hospitalization related to adverse events.[7]

In addition, numerous, serious patient harms have been reported publicly by the media. For example:

- A Texas woman reportedly died in April 2024 after using a compounded GLP-1 product, and her family has filed a wrongful death class action lawsuit against the pharmacy, alleging that the product and related instructions contributed to her death.[8] The complaint alleges that the pharmacy misled consumers regarding its sterile manufacturing practices and the quality of ingredients used in its compounded products.
- A Kentucky patient reportedly developed acute liver failure after several weeks of using a compounded GLP-1 injection and was hospitalized, placed on the transplant list, and advised she was at risk of death without intervention.[9]
- An Illinois patient reportedly became violently ill and required hospitalization after taking a compounded GLP-1 injection from a telehealth provider; physicians reportedly advised that he might have died without timely care. Reports associated with this matter also describe visible particulate contamination in vials and inadequate cold-chain/shipping controls.[10]
- A North Carolina patient reportedly was hospitalized for approximately 72 hours due to severe vomiting and dehydration after an overdose associated with a compounded GLP-1 obtained through a virtual prescribing service, raising concerns about concentration differences, dosing instructions, and patient education for compounded injectables.[11]

Beyond patient narratives, enforcement and inspection records reinforce the need for stronger guardrails. When compounded products are prepared from APIs of uncertain origin or quality or when finished

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[6] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Sept. 25, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[7] *See* 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 (Apr. 26, 2025), https://www.bohrium.com/en/paper-details/safety-analysis-of-compounded-glp-1-receptor-agonists-a-pharmacovigilance-study-using-the-fda-adverse-event-reporting-system/1124276537776930825-11808.

[8] *See* Law360, *Texas GLP-1 Compounder Caused Mom's Death, Family Says*, (Apr. 13, 2026), https://www.law360.com/articles/2464464/texas-glp-1-compounder-caused-mom-s-death-family-says.

[9] *See* The Washington Post, *The U.S. Weight-Loss Boom Has a Dangerous Blind Spot* (Mar. 31, 2026), https://www.washingtonpost.com/opinions/2026/03/31/weight-loss-compounding-pharmacies/. Following that case, Kentucky lawmakers introduced "Jimmie's Law" (HB 729) to strengthen oversight of compounded injectables, including sourcing, inspection, and production safeguards. *See* WLKY, *"Jimmie's Law" Provides Stricter Regulations on Pharmaceutical Compounding* (Feb. 50, 2026), https://www.wlky.com/article/jimmies-law-stricter-regulations-pharmaceutical-compounding-kentucky/70503397; *see also* Kentucky Legislature 2026 Regular Session, *HB 729*, https://apps.legislature.ky.gov/record/26rs/hb729.html.

[10] *See* KING 5 Seattle, *Investigators Find Contamination, Untrained Workers Plague GLP-1 Drugmaker Mochi Facility* (Feb. 20, 2026), https://www.youtube.com/watch?v=CkgW5MjsQOg.

[11] *See* WCNC, *Popular, Powerful and Potentially Dangerous: Poison Control Calls Skyrocket for Injectable Weight Loss Drugs* (Feb. 6, 2026), https://www.wcnc.com/article/news/investigations/injectable-weight-loss-drug-overdose-reports-skyrocket-side-effects-health-risks/275-fb7e6d49-1e59-4e06-a73e-8f0a80310222.

products are not subjected to appropriate, risk-based testing, patients may be exposed to incorrect potency, contamination, endotoxins, or other defects that are difficult to detect until harm occurs.

- FDA issued a warning letter to a compounder—that compounds GLP-1 products—after distribution of a compounded drug with "excessive bacterial endotoxins," and reports that three patients who received the product were hospitalized with symptoms including low blood pressure, body aches, and "uncontrollable shaking." The letter also noted sanitation and hygiene deficiencies and failure to prevent microbiological contamination of products represented as sterile.[12]
- FDA issued a separate warning letter after an inspection documented a patient hospitalization following use of a compounded injectable drug and indicated that the outsourcing facility failed to submit required adverse event reporting to FDA.[13]

Public health surveillance likewise signals increasing risk. Poison center data and published analyses suggest rising overdoses and higher hospitalization rates associated with compounded GLP-1 products relative to FDA-approved versions.[14]

These events may be preventable. AB 1990's approach—requiring clear API quality standards and fit-for-purpose testing requirements—would help reduce the likelihood that compounded products are prepared from substandard or contaminated ingredients, and would promote consistent verification of identity, strength, and purity. Establishing these requirements in statute can provide clarity to regulated entities and stronger enforcement tools to protect California patients.

We respectfully request that the Board support and help advance legislative measures, including AB 1990, that strengthen oversight of compounded drugs by requiring API quality standards and testing requirements. Thank you for your ongoing efforts to protect patients and uphold the integrity of the drug supply.

Sincerely,

Gabrielle Cosel
Consultant to Novo Nordisk Inc.

[12] FDA, *GenoGenix LLC - 718739 - 01/20/2026* (Jan. 20, 2026), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/genogenix-llc-718739-01202026.
[13] *See* FDA, *MedisourceRx - 717970 - 12/12/2025* (Dec. 12, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/medisourcerx-717970-12122025.
[14] *See* KING 5 Seattle, *Washington Poison Center Calls Related to GLP-1 Diet Drugs Double since 2024* (Feb. 26, 2026), https://www.king5.com/article/news/investigations/investigators/washington-poison-center-calls-glp1-diet-drugs-double-since-2024/281-2710a947-171b-404b-adb9-10fe8da5656a.