March 16, 2026

Hon. Juan Oscar Morales Rodríguez
President
Senate Health Committee
Senate of Puerto Rico
The Capitol Hill
P.O. Box 9023431
San Juan, PR 00902-3431

Dear Honorable Juan Oscar Morales Rodríguez:

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.

Greater Oversight and Accountability Over Med Spas That Use Prescription Drugs

Our concerns about the unsafe provision of substandard drugs are especially urgent as medical spas and wellness clinics (collectively “med spas”) have quickly expanded, providing treatments that often use compounded or otherwise unapproved drugs that fall outside FDA oversight. Unlike hospitals and pharmacies, med spas in Puerto Rico typically lack meaningful regulatory supervision, regular inspections, and rigorous safety protocols. While some individual practitioners at med spas are

accountable to regulatory bodies such as medical or nursing boards, this oversight is not universal and supervision of unlicensed staff is often poor—and this does nothing to ensure that the drug compounding performed at the facility is being done properly and safely. These accountability gaps increase the risk that patients will receive unsafe sterile drugs, including compounded products that may be contaminated, or improperly prepared, stored, or administered, as well as counterfeit drugs.[1,2]

The undersigned support state legislation to give the Puerto Rico Board of Pharmacy oversight authority over med spas engaged in use of prescription drugs. The Board of Pharmacy is Puerto Rico's authority on compounding and medication safety. Board of Pharmacy oversight would help ensure that prescription drugs given to patients are sourced responsibly, prepared and handled safely, and subject to appropriate oversight. The Ohio Board of Pharmacy has long had this authority and has used it effectively to investigate, fine, and shut down med spas engaged in prohibited conduct:

- In 2025, the Ohio Board of Pharmacy summarily suspended the licenses of more than 30 clinics and med spas after determining these facilities posed a danger of immediate and serious harms to others.[3]

Puerto Rico law should also require med spas to meet basic patient safety standards, such as having a named and licensed provider responsible for the facility's operations and be open to accountability from regulators through regular reporting of serious adverse events, recordkeeping requirements, and inspections. These steps would create the accountability needed to identify unsafe practices, hold violators accountable, and help protect patients while supporting legitimate providers who already comply with the law.

The undersigned urge the Puerto Rico 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,

Obesity Action Coalition

John Hertig, PharmD

Michael Stepanovic, PharmD

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[1] Caroline Cummings. "Prior Lake Spa Owner Charged for Allegedly Selling 'Black Market' Botox." CBS News Minnesota, 16 Jan. 2024, www.cbsnews.com/minnesota/news/black-market-botox-charges-prior-lake-minnesota-spa/

[2] Marty Schladen, "Pharmacy Board Suspends Another Ohio Weight Loss Clinic's License," Ohio Capital Journal, May 5, 2025, https://ohiocapitaljournal.com/2025/05/05/pharmacy-board-suspends-another-ohio-weight-loss-clinics-license/

[3] The Ohio Board of Pharmacy, "Ten Common Prescriber Clinic and Medical Spa Violations", Dec. 8, 2025, https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/ten%20common%20prescriber%20clinic%20and%20medical%20spa%20violations.pdf (last accessed Jan. 27, 2026)