

Patient Safety at Stake: The Urgent Need for Mass-Compounding Oversight

Wrap-up Report | February 2026



Event Overview

Leaders from the clinical, pharmacy, and patient advocacy communities convened for a virtual discussion, **Patient Safety at Stake: The Urgent Need for Mass-Compounding Oversight.**

The conversation focused on how the evolving compounding landscape is affecting patients and the policy solutions needed to restore clarity and safeguards.

Date: February 27, 2026

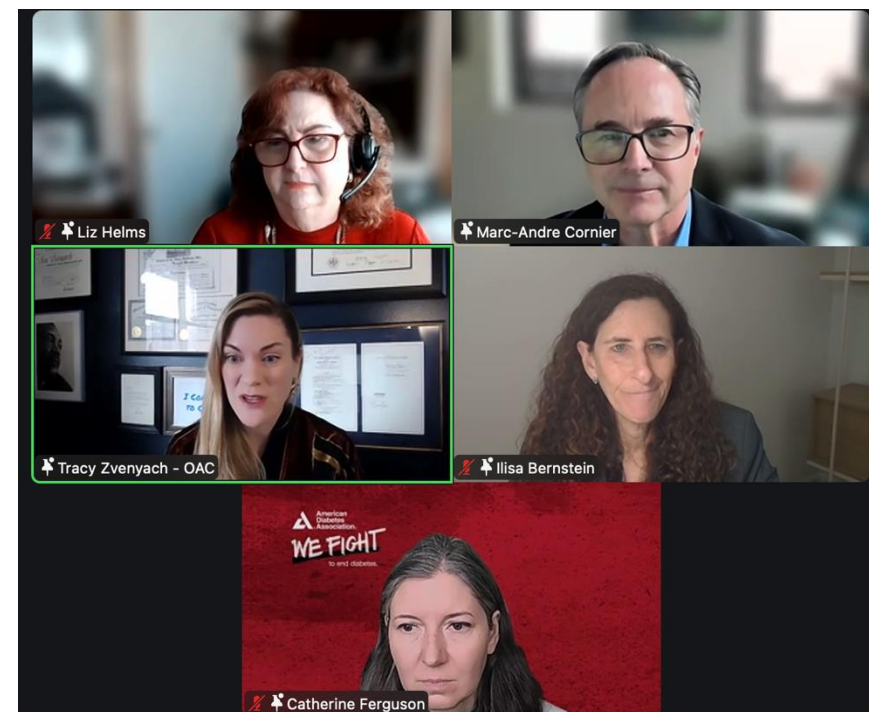


Featured Speakers:

- **Marc Andre-Cornier, MD:** Immediate Past President, The Obesity Society (*moderator*)
- **Ilisa Bernstein, PharmD, JD, FAPhA:** ASOP Board Member; President, Bernstein Rx Solutions, LLC
- **Liz Helms:** President & CEO, California Chronic Care Coalition
- **Catherine Ferguson:** Vice President, Federal Advocacy, American Diabetes Association
- **Tracy Zvenyach, PhD, MS, RN:** Director of Policy Strategy and Alliances, Obesity Action Coalition

Webinar Takeaways

- 1. Compounding Has a Limited but Patient-Specific Role:**
Intended for individual clinical needs – not mass-market substitutes.
- 2. Mass Compounding Bypasses FDA Safeguards:**
Not subject to FDA review for safety, effectiveness, or manufacturing quality.
- 3. This Is Bigger Than GLP-1s:**
Mass compounding is expanding across therapeutic areas.
- 4. Enforcement Gaps and Misleading Marketing Put Patients at Risk:**
Look-alike products can blur lines for patients and clinicians.
- 5. The SAFE Drugs Act Restores Guardrails:**
Protects patient-specific compounding while preventing large-scale distribution of unapproved drugs.



Quotes

*Compounding has played a long-standing role in American medicine to serve unique, clinically diagnosed needs – such as when a patient has a documented medical need that cannot be met by an FDA-approved product. **However, as the compounding landscape has evolved, concerns have emerged about scale, oversight, and patient safety.** While FDA has taken some steps to address these concerns, including issuing guidance and providing additional clarity, many stakeholders agree that more consistent oversight is needed to ensure patient safety remains the priority.*

– **Marc Andre-Cornier, MD | Immediate Past President, The Obesity Society**

*“Continuity of care for patients depend on trust and confidence that therapies meet clear, consistent standards. FDA approval remains the gold standard and we want to stay with that to ensure safety, effectiveness, and quality. That's what we're about with our patients. We want to be sure people are getting access to safe, affordable, quality healthcare...Coverage is key. Affordability is key. And uptake of FDA-approved therapy, so patients are not forced to choose between cost and safety. **It's about the safety of the product. And it's about not driving people to an open market where they don't know what it is that they're getting.**”*

– **Liz Helms | President & CEO, California Chronic Care Coalition**

Quotes

*"We recognize that we're living in unprecedented times, where this type of compounding is happening in a system that isn't supporting the patient community. So, the health system in general is really failing the patient community living with obesity. We want to ensure that if a patient is receiving a compounded product, that they're being followed by a qualified and trained medical provider, that there's clear transparency about what medication they're getting. **We also want to see that there's reporting and accountability...and then lastly, people should know what they're getting, right?** There should be more information about the medication that they receive in their home or from the pharmacy."*

– Tracy Zvenyach, PhD, MS, RN | Director of Policy Strategy and Alliances, Obesity Action Coalition

*"What does good enforcement look like? It's ensuring that what's used in your compounded products are ingredients that are legally allowed to be used. **Curbing this mass compounding of copies under the guise of personal prescriptions, coordination among state and federal authorities, and transparency and accountability of what's happening in the marketplace is needed, so there can be more targeted oversight of compounders.**"*

– Ilisa Bernstein, PharmD, JD, FAPhA | ASOP Board Member; President, Bernstein Rx Solutions, LLC

Quotes

*"What the Safe Drug Act would do would is increase reporting for certain entities that are doing things like transporting prescriptions across state lines if they're compounding, above a certain number of prescriptions. They would need to report that to the FDA annually, so we'd have some additional oversight about what's really happening on the ground...I think, **this lack of oversight that we currently have, the lack of awareness about these ingredients, including the active ingredients and where they're coming from, is why we really need to give our public safety institutions, both at the state and federal level, the proper transparency into what's happening, as well as the ability to do inspections to ensure that these products are being made in a safe way for patients.**"*

– Catherine Ferguson | Vice President, Federal Advocacy, American Diabetes Association