AMERICANS FOR SAFE & EFFECTIVE MEDICINES

Key Takeaways from the Behavioral and Educational Strategies for Avoiding Falsified Exposure (BESAFE) Annual Conference

At the September 23 BESAFE Annual Conference at the Johns Hopkins Bloomberg School of Public Health, Dr. Richard Dolinar, a clinical endocrinologist and Americans for Safe and Effective Medicines (ASEM) advisor, discussed illegal copies of GLP-1s and patient-safety risks of compounded weight-loss products.

Here are key takeaways from the discussion:

- **The success of GLP-1 medications has fueled rapid growth in compounded weight-loss products.** In 2022, federal law temporarily allowed compounders to produce versions of semaglutide and tirzepatide when the drugs were in shortage. The U.S. Food and Drug Administration (FDA) has since declared those shortages resolved, ending the shortage-based pathway for widespread compounding of GLP-1 copies. Although compounding remains appropriate for patients with a documented, individualized medical need, adding ingredients such as vitamin B12 or making minor dosage changes does not automatically justify mass production.

- **Clear labeling is needed between FDA-approved medications and compounded products.** Online advertising and celebrity promotion of GLP-1s can leave patients unsure which products have undergone FDA review for safety, effectiveness, and quality. Promotional materials should explain that compounded drugs are not FDA-approved and may carry additional risks, including dosing errors. With these products rising everywhere from med spas to convenience stores, Dr. Dolinar encouraged caution, saying that legitimate medications should be provided "by doctors, nurses, and PAs; not by spas."

- **Unapproved obesity medications, including retatrutide (or "reta"), should not be marketed or distributed to patients before FDA approval.** Clinical research is necessary to establish safety, effectiveness, and appropriate dosing, and the FDA states that retatrutide cannot be used in compounding under federal law. Dr. Dolinar quickly pointed out that we don't yet know the proper dosage for retatrutide, given its ongoing clinical trials. It's also important people understand that labeling a product as "research grade" does not guarantee its safety.

- **Protecting patients calls for stronger regulatory and legislative enforcement against illegal or unsafe drug distribution.** No single agency can fully address the growing complexity of today's drug supply chain. Close coordination across FDA, Department of Justice, Customs and Border Protection, Federal Trade Commission, state law enforcement, and boards of pharmacy is critical to stopping illegal products at the border, disrupting unlawful distribution channels, and holding bad actors accountable. Legislative action can close oversight gaps and give regulators greater visibility into emerging risks. Current proposals like the **Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act (H.R.6509/S.3794)** would improve adverse-event reporting, transparency, and oversight of large-scale compounding, helping regulators identify risks sooner and intervene before unsafe products reach more patients. Effective enforcement, backed by clear standards and sustained cross-government collaboration, is essential to protecting patients and preserving the integrity of the U.S. drug supply.

- **Health care providers and pharmacists are essential sources of clear, practical guidance for patients.** Health care experts can explain whether a medication is FDA-approved, why a compounded product may or may not be considered for an individual patient, and what risks or dosing instructions require attention. They can also encourage patients to use state-licensed pharmacies and to ask questions about when a product's source, packaging, or claims seem suspicious. When asked what Dr. Dolinar would tell a patient inquiring about compounded GLP-1s, he remarked, "I tell them the truth."

Please don't hesitate to reach out to media@safeandeffectivemeds.org if we can be a resource.

About Americans for Safe and Effective Medicines

Americans for Safe and Effective Medicines (ASEM) is a non-partisan 501(c)(4) non-profit organization dedicated to combating illegal mass compounding, counterfeit products, and misleading marketing practices. ASEM advocates for robust Food and Drug Administration enforcement and legislative and regulatory accountability on behalf of patients.

For more information, please visit safeandeffectivemeds.org and follow us on LinkedIn, X, Instagram, Facebook, and TikTok.