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ASOP Global Warns HHS Peptide Policy Risks Expanding Access Without Addressing Illegal Online Sales

WASHINGTON, D.C. (October 28, 2026) — The U.S. Department of Health and Human Services (HHS) has announced an enforcement-discretion policy covering six peptide bulk drug substances: BPC-157, epitalon, KPV, MOTS-c, Semax, and TB-500. Under the policy, HHS says it does not intend to take enforcement action against specified pharmacies, federal facilities, and licensed physicians compounding drugs using these substances while the FDA develops its list of bulk drug substances eligible for compounding under Section 503A.

Although HHS says the policy is intended to expand patient access, compounded drugs are not FDA-approved, and FDA does not review their safety, effectiveness, or quality before they are marketed. ASOP Global's position is consistent with concerns about the available evidence supporting the safety and effectiveness of these substances.

Permission does not automatically protect patients. Enforcement against unlawful, unsafe compounding is already insufficient, with patients receiving contaminated products. This new enforcement-discretion policy invites new market entrants but adds no new resources (inspectors, investigators, enforcement officials) to police their activity to ensure compliance with the stated 10 enforcement discretion conditions.

The online market is already flush with illegal actors who now can more easily hide amongst the masses with limited risk of getting caught. Without enhanced and consistent new enforcement of the market, today's policy will allow criminals to hide amongst the newly compliant. Data from the ASOP Global Foundation's Rx Watchdog platform illustrates the risk. Even before the release of the interim enforcement discretion policy, Rx Watchdog tracked 20,982 online listings for emerging peptide molecules across 330 websites, including 8,807 listings for BPC-157 alone.

"Expanding access is not a substitute for evidence of safety and effectiveness, nor is it a solution to the illegal online market," said Dr. Leigh Verbois, Board Chair of ASOP Global and former Director of the FDA's Office of Drug Security, Integrity and Response. "Compounded drugs are not FDA-approved, and a policy of enforcement discretion does not establish that these peptides are safe or effective. Policymakers must maintain evidence-based safeguards while taking meaningful action against illegal online sellers that put consumers at risk."

ASOP Global has urged policymakers to prioritize patient safety and strengthen enforcement against illegal online drug sellers. The organization will continue to advocate for evidence-based policies that protect consumers across both legitimate medication channels and the broader online marketplace.

Learn more at buysaferx.pharmacy.

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About ASOP Global

The Alliance for Safe Online Pharmacies (ASOP Global), a 501(c)(4) non-profit organization headquartered in Washington, D.C., with activities in the U.S., Canada, Europe, Latin America, and Asia, is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers. Learn more at buysaferx.pharmacy.