AMERICANS FOR SAFE & EFFECTIVE MEDICINES

Unapproved Peptides & Patient Safety: HHS Proposed 503A Compounding Policy

Overview
The U.S. Department of Health and Human Services (HHS) announced an interim policy allowing the compounding of six unapproved injectable peptides: BPC-157, Epitalon, KPV, MOTS-c, Semax, and TB-500. The proposal follows recommendations from the U.S. Food and Drug Administration's (FDA) Pharmacy Compounding Advisory Committee (PCAC), a group hand-picked by HHS and whose independence and composition have come under scrutiny over potential conflicts of interest. HHS is moving forward despite concerns raised by FDA scientists about insufficient clinical evidence, potential safety risks, and product quality.

HHS is accepting **public comments** through November 13, 2026, providing stakeholders an opportunity to share feedback.

KEY TAKEAWAYS FROM CONCERNED STAKEHOLDERS

Lack of Evidence and Research: FDA scientists are concerned about a lack of any human clinical evidence, as well as other safety risks associated with the six peptides. Allowing these products to proliferate without rigorous research risks undermining established drug approval standards.

Patient Harm: Allowing compounding pharmacies to prepare and sell products containing six unapproved peptides without adequate clinical evidence and FDA review could expose patients to preventable, serious harm— such as an increased risk of cancer and even anaphylaxis resulting in death.

Consumer Confusion: Patients may mistakenly assume that products prescribed by physicians or prepared by compounding pharmacies are FDA-approved, creating a false sense of safety around unapproved products.

Undermining FDA Gold Standard: Allowing the compounding of unapproved peptides without rigorous clinical testing undermines the gold-standard drug approval system that drives innovation and research, establishes safety and effectiveness, and brings proven medicines to patients. This risks normalizing the use of unapproved products and opening the door to more unsafe, black-market substances reaching patients in the future.

Regulatory Oversight Gaps: Broader compounding could strain state regulators and expose gaps in manufacturing safeguards and safety oversight, as compounding pharmacies are subject to significantly lower requirements than FDA-approved drug manufacturers.

Need for Stronger Enforcement: Federal and state authorities should prioritize enforcement and shut down illicit supply chains to prevent unsafe products from reaching consumers.

TIMELINE

February 2026: HHS Secretary Robert F. Kennedy Jr. announced plans to allow compounding pharmacies to prepare drug products using seven peptides that had not been approved by FDA for any use. These included BPC-157, TB-500, KPV, MOTS-c, Epitalon, Emideltide, and Semax. FDA had previously identified significant safety concerns associated with these substances, including potential immune reactions, impurities, and challenges in verifying ingredient quality.

June 2026: HHS hand-picked new members for FDA's Pharmacy Compounding Advisory Committee (PCAC), including clinicians and pharmacists with ties to the peptide, wellness, and compounding industries. Investigative reporting revealed that several appointees had financial ties to businesses that promote, prescribe, or sell peptides, despite concerns raised by FDA officials about potential conflicts of interest. The appointments raised serious questions about the committee's independence and whether commercial interests could influence decisions meant to protect patients. HHS claimed that members underwent standard ethics screening, but specific conflict-of-interest determinations and recusals had not been publicly disclosed at the time.

July 2026: FDA convened its PCAC to consider adding the seven peptides to the Section 503A Bulk Drug Substances List (Bulks List), which identifies certain substances that may be used in pharmacy compounding under specified conditions, without constituting FDA approval. By narrow margins, over FDA scientists' own recommendation against their inclusion, the committee recommended adding six of the seven peptides. FDA scientists cited insufficient human safety and effectiveness data, concerns about product quality and potential immune reactions, and the availability of FDA-approved treatments. The committee's votes did not resolve these scientific concerns or constitute a final regulatory determination.

October 2026: HHS released a draft interim enforcement-discretion policy under which it would refrain from certain federal enforcement actions against state-licensed pharmacies, federal facilities, and licensed physicians compounding products containing six unapproved peptides, subject to specified conditions. HHS framed the policy as providing patients with a "safer," "more regulated" alternative to peptides sold through the gray market, including products labeled "research use only." However, the policy could open the floodgates to widespread prescribing and commercial sales of these unapproved substances for a broad range of conditions, potentially exposing more patients, including children and other vulnerable populations, to serious safety risks before FDA has established their safety or effectiveness.

November 13, 2026: The public comment period on HHS's draft policy closes, marking the deadline for stakeholders to share feedback on its potential implications for patient safety.

To prevent the proliferation of unapproved peptides, patient safety advocates are urging HHS to withdraw its enforcement discretion policy and require rigorous scientific review. Federal and state regulators must also crack down on illegal sales and providers marketing unproven treatments while ensuring patients understand the risks. Patient safety depends on established clinical research and regulatory safeguards, not weakening them.

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