SOUTHEND

10 Key Takeaways from the James LaValle Webinar,

The Current State of Peptides

What prescribing providers need to know after the FDA's Pharmacy Compounding Advisory Committee (PCAC) recommended six peptides for 503A compounding eligibility.

From Southend Pharmacy's educational webinar with Dr. James LaValle
Below are the 10 takeaways **prescribing providers** asked about most:

01 The FDA's PCAC recommended six peptides for the Category 1 bulk substances list.

BPC-157, KPV, TB-500, MOTS-c, Epitalon, and Semax were all recommended for 503A compounding eligibility, three years after the first group of peptides was removed from the list.

02 This is a recommendation, pending final FDA action.

The FDA and HHS still need to complete rulemaking before any of these six peptides are actually eligible for 503A compounding again. Compounded medications are never FDA-approved, and this vote doesn't change that.

03 The bar for inclusion isn't a clinical trial standard.

Dr. LaValle explained that the committee evaluates documented molecular identity, established testing methodology, a history of use through licensed 503A pharmacies, and organized adverse event reporting, a different bar than the one the FDA uses to approve a new drug.

04 Real-world, provider-reported usage data was central to the case.

According to Dr. LaValle, the volume of prescriptions filled through licensed 503A pharmacies with organized adverse event tracking was a major factor the committee weighed. Southend has not independently verified the specific figures presented at the hearing.

05 Not every peptide made the cut.

DSIP (delta sleep-inducing peptide) was reviewed alongside the other six and did not receive a committee recommendation, a reminder that inclusion is evaluated peptide by peptide, not as a category.

06 Taking peptides off the compounding list in 2023 didn't reduce demand.

Dr. LaValle told attendees it shifted demand into the unregulated research-use-only market, where independent testing has turned up missing or inadequate active ingredient, heavy metal contamination, residual solvents, and endotoxin presence.

07 Each of the six peptides has a distinct research profile.

BPC-157 is a synthetic peptide studied in preclinical models for its potential role in tissue-protective and regenerative signaling processes. KPV (inflammatory signaling, derived from melanocyte-stimulating hormone without pigmentation effects), TB-500 (connective tissue research, and on WADA's prohibited list for competitive athletes), MOTS-c (mitochondrial signaling research, not a substitute for GLP-1/GIP therapy), Epitalon (circadian and pineal gland signaling research, the longest observational history of the six), and Semax (cognitive and stress-related signaling research).

08 Sourcing and testing matter as much as the molecule.

Dr. LaValle emphasized that identity verification, contaminant testing (heavy metals, endotoxin, residual solvents), and FDA-registered active pharmaceutical ingredient suppliers are what separate a compliant 503A product from gray-market research product.

09 Complex patient histories still require case-by-case clinical judgment.

The hearing didn't resolve every open question. Patients with a current or prior cancer diagnosis, pregnancy, or anticoagulant use should be evaluated individually by their treating provider, not by a blanket rule.

10 The regulatory pathway is still moving.

Final rulemaking from the FDA and HHS is still pending. Providers should watch for the final rule, not the committee recommendation, before treating any of these six peptides as compounding-eligible.