Collaborative for Evidence-Based Medicines Warns Against FDA Peptide Policy That Would Circumvent Safety Guardrails and Put Patients At Risk

Provider-led organization warns that allowing the compounding of untested, poorly characterized peptides sidesteps FDA's evidence standards; Patient safety requires rigorous federal and state enforcement.

WASHINGTON, D.C. — October 26, 2026 — The Collaborative for Evidence-Based Medicines ("CEBM" or "the Collaborative") raises serious concerns about an FDA policy under consideration to permit the compounding of certain peptides discussed at the agency's July 2026 Pharmacy Compounding Advisory Committee (PCAC) meeting. FDA is considering an "interim" policy to permit compounding of certain peptide substances that have not undergone a thorough assessment by FDA through the agency's established process for deciding which substances meet the standards to be compounded. Bypassing this process undermines the guardrails that ensure that patients receive medicines they can trust, backed by evidence of safety and effectiveness and subject to quality and manufacturing requirements. While CEBM is hopeful that ongoing advocacy work will persuade the Administration against taking this step, reports that this policy is forthcoming soon have caused us to raise the alarm now.

The Administration is considering an unprecedented policy to permit the compounding with certain peptide substances, circumventing FDA's normal processes for assessing whether patients should receive medication that lack FDA approval. A policy to let substances be compounded despite a lack of rigorous evidence would move unresolved questions of safety, effectiveness, dosing, and quality out of controlled research and into routine patient care, effectively turning patients into test subjects.

"Compounding has an essential place in patient care, but cannot become the default pathway for escaping regulatory oversight and accountability," said John B. Hertig, PharmD, MS, CPPS, FASHP, FFIP, Chair of the CEBM Board of Directors. "Opening compounding to unapproved and poorly characterized peptides that FDA's own reviewers flagged for significant safety risks sidesteps the process designed to protect patients. Patients deserve medicines they can trust, and that trust has to be earned through evidence."

"As a physician, I need reliable information to counsel my patients on risks and benefits, and for these peptides, that information simply does not exist," said Dr. Adonis Saremi, MD, MS, DABOM, CEBM Board Member. "Patients should not be first real test of whether a substance is safe or has the effect it claims to have."

Some have argued that an interim enforcement discretion policy is warranted to respond to consumer demand for these peptide substances, with the aim of moving this current black market to be more legitimate. This is a fantasy. Even the most nuanced and carefully written enforcement discretion policies cannot escape the challenges of being implemented in a market that is and will be dominated by bad actors who will continue to flout the law. Regardless, illicit demand for a substance is not, and should not be, a proxy for safety.

“There will be no putting this genie back in the bottle,” Hertig said. “And the rampant growth of illegal and untested peptides available today provides no comfort that any ‘guardrails’ that FDA may try to impose as part of an interim policy will have the intended impact. Instead, the results of this policy are entirely predictable: bad actors will seize the opportunity to claim that FDA has condoned the use of these peptides, and a large and dangerous market for these peptides will grow larger and more dangerous.”

“The responsible approach to peptides is to develop rigorous evidence supporting their safety and effectiveness, then evaluate their eligibility for compounding under the existing regulatory framework,” said Michael Stepanovic, PharmD, MS, Vice Chair of the CEBM Board. “Lobbying for special carve-outs for peptides that have not demonstrated they meet established FDA standards is politics at its worst, not patient care at its best.”

The peptide substances reportedly under consideration for this interim policy include those that were discussed at the agency’s July 2026 PCAC meeting. Ahead of that meeting, FDA career scientists concluded that such substances should not be added to the 503A Bulks List (which would permit compounding using such substances) because the substances are not supported by sufficient evidence of safety and effectiveness to allow them to be given to patients. While the PCAC voted to recommend that six peptide substances be added to the 503A Bulks List, significant questions remain regarding conflicts of interest among PCAC members and the extent to which the Committee’s judgement should be given weight by FDA. Nonetheless, FDA is still assessing these substances and has taken no action to conclude that the substances meet the requirements to permit them to be added to the 503A Bulks List for compounding.

In its July 9 comment letter to the FDA docket, CEBM supported FDA's own preliminary assessment that the peptides under review should not be added to the 503A Bulks List. FDA had earlier placed these peptides in a category reserved for substances that present significant safety risks. FDA cited possible immune reactions, impurities, and difficulty in properly characterizing the ingredients. The evidence for these peptides rests largely on laboratory and animal studies, with little or no adequate human data. For four of the seven peptides, no known clinical studies have assessed safety in humans by any route of administration. FDA has identified immune-reaction risk, including the potential for life-threatening anaphylaxis, for six of the seven. Six of the seven are used mainly or only for injection, a route that carries heightened risk.

The contemplated policy poses particular challenges for state regulators, like boards of pharmacy, that lack sufficient regulatory infrastructure to oversee the widespread use of such unproven peptides. CEBM reminds states that this new policy would not change state law. Any new enforcement discretion policy from FDA does not limit the authority of state Boards of

Pharmacy, Medicine, and Nursing, or of state Attorneys General, to stop untested and violative peptides from reaching patients. States can still enforce their own pharmacy practice and sterile compounding standards, discipline licensees, investigate misleading marketing, and take action against products that endanger the public. CEBM urges state regulators to use their full authority needed to protect patients in their state. CEBM will continue working with state policymakers, as it has in jurisdictions across the country, to strengthen oversight over compounding.

In the event that the Administration moves forward with such a policy, CEBM implores FDA, the Department of Justice, and state regulators to back up any policy change with strong and timely enforcement. In a world where FDA condones access to certain peptides based on certain quality, safety, and other requirements, those requirements must have real teeth. At minimum, such guardrails should include:

- enhanced inspections and quality benchmarks for sterile peptide compounding;
- sustained collaboration between FDA and state Boards of Pharmacy;
- enforceable requirements for ingredient quality and sourcing;
- specific testing standards for identity, purity, potency and sterility;
- mandatory adverse event reporting; and
- a termination date for the policy.

For more information or to get involved see www.CollaborativeEBM.org.

About CEBM

The Collaborative for Evidence-Based Medicines: Putting Patient Safety First ("CEBM" or "the Collaborative") is a national provider-led organization advancing evidence-backed medicines, safe compounding, and stronger oversight and accountability to protect patients. Led by a Board of pharmacists, doctors, and regulatory professionals, the Collaborative brings together allies including providers, patient advocates, academics, consumer groups, manufacturers, and other stakeholders committed to putting patient safety first. CEBM's policy positions are set exclusively by its Board of Directors, whose members serve in their individual professional capacities.

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