



October 15, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary, U.S. Department of Health and Human Services

Re: Pause implementation of PCAC recommendations expanding peptide compounding

Dear Secretary Kennedy:

On behalf of the Alliance for Safe Biologic Medicines (ASBM), we urge you to pause implementation of the Pharmacy Compounding Advisory Committee's (PCAC) July recommendations to expand peptide compounding, including the interim access policy reported by The Washington Post.[1] Mounting adverse-event reports, reported deaths involving illicit and compounded products, significant gaps in safety surveillance, and persistent enforcement challenges warrant reassessment before access expands—particularly while FDA lacks a Senate-confirmed commissioner. Since 2010, ASBM has advocated safe, affordable access to innovative medicines while preserving rigorous standards for safety, quality, and effectiveness. We ask HHS to uphold those standards by addressing FDA scientists' objections and establishing adequate safeguards before proceeding.

On October 13, CBS News reported that FDA had received two death reports involving illicit products purported to contain retatrutide.[2] These reports remain unverified and do not establish causation. Although retatrutide was not among the peptides endorsed by PCAC, its illicit market illustrates the risks of widespread access to experimental drugs outside clinical trials and reliable oversight.

Safety concerns also extend to compounded medicines. By May 31, 2026, FDA had received 990 adverse-event reports associated with compounded semaglutide and more than 730 associated with compounded tirzepatide. FDA cautions that these events are likely underreported because state-licensed pharmacies operating outside the outsourcing-facility framework are not required to report them.[3] Recent reporting also describes a wrongful-death lawsuit involving compounded semaglutide; the pharmacy disputes that its product caused the death.[4] These reports warrant investigation and stronger surveillance before access expands further.

PCAC's recommendations do not resolve the underlying scientific concerns. FDA reviewers recommended against adding any of the seven peptides under consideration to the 503A Bulks List, citing inadequate evidence of safety and effectiveness. Nevertheless, the committee endorsed six. Reporting also identified substantial peptide-industry ties among newly appointed advisers, raising questions about the independence of the process.[5] HHS should publicly explain how it would reconcile those recommendations with its own scientists' findings.

Safety and effectiveness is not established simply by changing where the unapproved product is secured. Pharmacy access is as troubling as illicit suppliers, perhaps more so because it

provides a false sense of confidence for patients. The Wall Street Journal describes enforcement against illegal weight-loss drug sellers as a game of “whack-a-mole,” with businesses resurfacing under new names and websites after being shut down.[6] These persistent challenges facing FDA and state pharmacy boards underscore the need to demonstrate adequate oversight before expanding access.

We therefore ask HHS to suspend any interim policy expanding access to these peptides and defer implementation pending review by a Senate-confirmed FDA commissioner. Before proceeding, FDA should publish a substance-specific response to its scientists’ objections, independently review potential advisory conflicts, and establish adequate adverse-event reporting, product traceability, and enforcement safeguards.

Patients deserve access to innovation supported by evidence and accountable oversight. The emerging safety signals make a pause both prudent and necessary.

Sincerely,

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Former Associate Deputy Secretary, U.S. Department of Health and Human Services

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ASBM Steering Committee Members:

Alliance for Patient Access

American Academy of Dermatology

Autoimmune Association

Association of Clinical Research Organizations

Colon Cancer Alliance

Global Colon Cancer Association

Global Healthy Living Foundation

Health HIV

International Cancer Advocacy Network

Kidney Cancer Association

Lupus and Allied Diseases Association

National Hispanic Medical Association

National Psoriasis Foundation

ZERO- The End of Prostate Cancer

Sources

- [1] The Washington Post, October 7, 2026.
- [2] Becker's Hospital Review, reporting CBS News's October 13 findings.
- [3] FDA: Concerns with unapproved GLP-1 drugs.
- [4] KING 5, September 24, 2026.
- [5] Reuters, June 30, 2026; The Hill, July 23, 2026.
- [6] The Wall Street Journal, "One State's Battle to Stop People From Taking Unapproved Weight-Loss Drugs".