



October 26, 2026

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

Re: Renewed request to pause expansion of peptide compounding

Dear Secretary Kennedy:

We write to renew the Alliance for Safe Biologic Medicines' October 15 request to pause implementation of the Pharmacy Compounding Advisory Committee's (PCAC) recommendations expanding peptide compounding. The reported submission of an interim access policy for White House review makes that pause more urgent: access should not expand before the scientific objections and oversight gaps identified in our letter are resolved.

The risks extend across illicit sales and pharmacy production. CBS News's findings describe two deaths reported to FDA after use of illicit products sold as the as-yet-unapproved peptide retatrutide. Separately, FDA's recall record documents Apothecary Pharma's nationwide recall of compounded tirzepatide for "Lack of Assurance of Sterility." Together, these developments underscore the need to bring existing safety and oversight problems under control before expanding access further.

On October 20, Reuters reported your call for a "regulated marketplace" with accurately identified products and inspected factories. We share that objective. But inspections and accurate labeling alone cannot establish whether an experimental drug is safe or effective. FDA already has a scientific review process to address those questions. Expanding pharmacy access while leaving its scientists' objections unanswered would weaken the protections a regulated market should provide.

The recent advisory process deepens this concern. You appointed new PCAC members ahead of the July review, including advisers with ties to peptide businesses. NBC News reported that all eight new appointees voted to support BPC-157, KPV, and TB-500, providing the entire affirmative bloc in each 8–6 vote, with one abstention. Their votes supplied the majority against FDA scientists' recommendation. The regulatory system for peptides was already at work: agency scientists were evaluating the evidence and identifying reasons to withhold expanded access. Reshaping the advisory panel to secure contrary recommendations gives the appearance of subverting that system rather than supporting it. Changing the committee's membership does not change the evidence.

The inconsistency in your approach to oversight of two classes of injectable products - vaccines and unapproved peptides - is particularly striking. Your department revived a task force to strengthen safety oversight of childhood vaccines already on the market which have undergone FDA review of laboratory and clinical data. Why demand greater scrutiny of FDA-approved

injectable vaccines while easing access to injectable peptides that have not earned FDA approval and whose safety and effectiveness remain unestablished? Patients deserve consistent evidentiary standards. Simply increasing pharmacy access cannot substitute for evidence or assurance of safety.

The safety reports and surveillance failures described in our October 15 letter remain unresolved. We therefore urge HHS to hold the interim access policy and defer implementation of PCAC's recommendations until FDA publicly addresses the substance-specific scientific objections, an independent review examines advisory conflicts, and adequate adverse-event reporting, product traceability, and enforcement safeguards are in place.

The credible, regulated peptide market requires these protections before access expands.

Sincerely,

Michael Reilly, Esq.

Executive Director, Alliance for Safe Biologic Medicines

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

Philip J. Schneider, MS, FASHP

Past President, American Society of Health-System Pharmacists

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] Alliance for Safe Biologic Medicines. Letter to Secretary Robert F. Kennedy Jr. requesting a pause in expanded peptide compounding. October 15, 2026.

[2] *Becker's Hospital Review*. "2 deaths reported to FDA after people took products claiming to be Eli Lilly's retatrutide: Report." October 13, 2026.

[3] U.S. Food and Drug Administration. Enforcement Report: Apothecary Pharma LLC, Tirzepatide Injection. Recall No. D-0036-2027; initiated September 24, 2026; reported October 14, 2026

[4] *Reuters*. "Kennedy says Trump administration aims for regulated market for peptides." October 20, 2026.

[5] NBC News, via AOL. Berkeley Lovelace Jr. "FDA panel, with ties to the peptide industry, recommends easing restrictions on four of the compounds." July 23, 2026.

[6] *Reuters*. "FDA staff question peptides backed by Kennedy ahead of advisory meeting." June 30, 2026.

[7] U.S. Department of Health and Human Services. "HHS Revives Task Force on Safer Childhood Vaccines." August 14, 2025.

[8] U.S. Food and Drug Administration. "Vaccines."

[9] U.S. Food and Drug Administration. "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss."