DIANA HARSHBARGER
1ST DISTRICT, TENNESSEE

167 CANNON HOUSE OFFICE
WASHINGTON, DC 20515

COMMITTEE ON ENERGY & COMMERCE

205 REVERE STREET
KINGSPORT, TN 37660
PHONE: (423) 398-5186

1501 E. MORRIS BLVD., STE 12
MORRISTOWN, TN 37813
PHONE: (423) 254-1400

Congress of the United States
House of Representatives

November 10, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Kennedy:

As both a pharmacist and a Member of Congress, I write to urge the U.S. Food and Drug Administration (FDA) to exercise enforcement discretion with respect to the compounding of certain peptides for patients.

Peptides — short chains of amino acids that serve as signaling molecules, hormones, and biological regulators — are critical to processes such as metabolism, immune response, and tissue repair. Synthetic peptides, or active fragments of naturally occurring peptides, are increasingly being studied and applied in areas such as endocrinology, neurology, immunology, and regenerative medicine. Despite promising evidence and strong patient demand, FDA-approved peptide therapies remain limited. In the absence of commercial options, patients and their prescribers are turning to licensed compounding pharmacies to access therapies that are essential to health and quality of life.

Promising Clinical Evidence

Clinical and preclinical research supports the therapeutic potential of a number of peptides, including:

- **BPC-157**: Promotes wound healing, musculoskeletal recovery, and gastrointestinal protection, with anti-inflammatory and angiogenic properties.
- **CJC-1295**: A growth hormone–releasing hormone analog with sustained biologic activity for muscle wasting, metabolic dysfunction, and age-related decline.
- **Ipamorelin**: A selective ghrelin receptor agonist that safely stimulates growth hormone release without elevating cortisol or prolactin.
- **Thymosin alpha-1**: Immune-modulating peptide with evidence of benefit in infectious disease and oncology, though no FDA-approved formulation exists.
- **Thymosin beta-4 fragments (e.g., TB500)**: Studied for wound healing, tissue repair, and anti-inflammatory properties.
- **GHK-Cu**: Demonstrates wound healing and regenerative potential, with both topical and injectable uses of interest to prescribers.

Yet FDA policy significantly restricts compounding of these peptides — even where no FDA-approved alternative exists — leaving patients without safe, regulated access. This has driven patients to seek unregulated gray-market sources, exposing them to preventable risks.

Compounding Quality and Oversight

Licensed compounding pharmacies operate within rigorous quality and regulatory frameworks:

- Raw materials sourced only from FDA-registered, GMP-compliant suppliers;
- Validated procedures, standardized formulations, and testing protocols ensuring identity, quality, and consistency;
- Controlled facilities overseen by FDA or state regulators.

Such standards provide patients with safe, reliable access — in contrast to unregulated markets — and allow prescribers to guide appropriate use. Importantly, compounding offers timely access to therapies in months, rather than the years required for traditional drug approval.

Policy Request

I respectfully urge the FDA to give full and fair consideration to:

1. **Reevaluate the six peptides referenced above through an improved Pharmacy Compounding Advisory Committee (PCAC) process** that prioritizes *safety and quality* over evidence of clinical efficacy. Compounded preparations are inherently individualized and not subject to the same clinical trial models as manufactured drugs; there are no double-blind, placebo-controlled studies for these types of personalized therapies. The agency should therefore assess substances for inclusion on the 503A Bulk Drug Substances List based on their safety profile and suitability for compounding, rather than on whether a manufacturer has pursued traditional pharmaceutical approval.
2. **In the interim**, exercise enforcement discretion to permit compounding of additional clinically justified peptides under the following conditions:
    - APIs are sourced only from FDA-registered, cGMP-compliant facilities;
    - Compounding occurs solely in FDA-registered outsourcing facilities or state-licensed 503A pharmacies;
    - Dispensing requires a prescription for an identified patient to ensure clinical appropriateness; and
    - FDA maintains ongoing engagement with PCAC to evaluate emerging safety data on a case-by-case basis.

This approach balances **patient access, public safety,** and **regulatory oversight**, ensuring peptide use occurs through trusted, licensed channels rather than unsafe gray-market sellers. FDA has precedent for using enforcement discretion in areas of pressing clinical necessity, and peptides represent such a case today.

As U.S. Senator Tommy Tuberville noted in his July 30, 2025 letter to your office, restricting physician-guided compounding risks driving patients into unsafe markets. I share his concern and urge FDA to act swiftly to clarify policy, in collaboration with Congress, providers, and patients.

Thank you for your leadership and attention to this important matter. I stand ready to work with you and your staff to establish a responsible framework that prioritizes both patient access and patient safety.

Sincerely,

Diana Harshbarger

Diana Harshbarger, Pharm.D.
Member of Congress

cc: The Honorable Martin A. Makary, M.D., M.P.H.,
Commissioner, U.S. Food & Drug Administration