AMERICANS FOR SAFE & EFFECTIVE MEDICINES

November 13, 2026

The Honorable Robert F. Kennedy, Jr.
U.S. Department of Health & Human Services
200 Independence Avenue SW, Washington, D.C. 20201

Re: Docket No. HHS-OASH-2026-0496

Opposition to HHS's Draft Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

Dear Secretary Kennedy:

We, the undersigned physicians, nurses, and other health care professionals, strongly oppose the Department of Health and Human Services (HHS) draft enforcement discretion policy permitting the compounding of six non-FDA-approved injectable peptides. This policy risks exposing patients to contaminated injections, dangerous dosing errors, and inadequately studied treatments while placing additional demands on an already strained health care system.

Failures in sterile compounding have already had devastating consequences: contaminated steroid injections from the New England Compounding Center caused a nationwide fungal meningitis outbreak that killed over 100 people. The U.S. Food and Drug Administration (FDA) has also reported dosing errors involving compounded semaglutide, with patients administering five to 20 times the intended dose and some requiring hospitalization. These incidents demonstrate the serious harm that can result when compounded medicines are contaminated or administered incorrectly.

As licensed health care professionals, we share a fundamental obligation to do no harm.

FDA has specifically identified concerns about immune reactions and peptide-related impurities for BPC-157, along with insufficient safety information to determine whether it could harm people. Patient demand and online popularity cannot substitute for the clinical evidence needed to justify treatment.

We share HHS' concern about illicit online sellers marketing unapproved drugs under "research use only" disclaimers. In February 2025, FDA warned USApeptide.com about unlawful sales of unapproved semaglutide and tirzepatide products, including sales without prescriptions. The agency cautioned that drugs bypassing regulatory safeguards may be contaminated, counterfeit, or contain incorrect or entirely different ingredients. These practices demand stronger enforcement. They do not establish that allowing compounding of other unapproved products is safe, let alone that it will displace illegal sellers or protect patients.

The policy also raises concerns about the integrity of the medication supply chain.

Compounded products do not undergo FDA premarket review for safety, effectiveness, or quality. In fact, FDA has documented serious deficiencies in manufacturing conditions at a Chinese peptide active pharmaceutical ingredient (API) manufacturer, raising concerns about contamination before ingredients reach a compounding pharmacy. A licensed pharmacy cannot undo contamination introduced during ingredient manufacturing, repackaging, or distribution. In 2019, FDA investigated adverse events in seven patients who received compounded glutathione injections and found excessive bacterial endotoxins in ingredient samples. A separate patient who received an injection made with the implicated ingredient was hospitalized for a possible bloodstream infection.

The draft's conditions for sourcing, testing, supplier verification, and adverse-event reporting are a starting point for addressing quality concerns, but significant questions about compliance and enforcement remain, and their ability to protect patients should not be overstated. But these safeguards cannot establish whether a peptide works, which patients should receive it, or what dose offers an acceptable balance of benefit and harm. Patient safety advocates have called for stronger enforcement against illegal producers and distributors. Allowing these products to be compounded without closing enforcement gaps risks adding another layer of uncertainty to an already fractured oversight framework. Enforcement discretion is not FDA approval, yet patients may interpret availability through a licensed pharmacy as federal assurance of safety and effectiveness.

When complications occur, patients and the broader health care system bear the consequences.

Suspected infections, overdoses, and unexpected reactions may require emergency evaluation, hospitalization, specialist consultation, and continuing care—sometimes without reliable information about what the patient injected. Already, America's Poison Centers reports a nearly 1,500% increase in calls related to overdose or side effects of injectable weight-loss drugs since 2019. Families face illness, lost work, and medical bills, while clinicians must absorb additional demands on limited resources. The Health Resources and Services Administration's December 2025 report identified 92 million people living in designated primary care shortage areas and documented substantial clinician burnout. In addition to peptide safety and efficacy, HHS should assess the potential burden of avoidable peptide-related complications before encouraging broader use.

We support legitimate patient-specific compounding when an FDA-approved medicine cannot meet a patient's medical needs, as well as rigorous clinical research into promising peptide therapies. However, making inadequately studied injectable products widely available is not an evidence-based solution to illicit online sales and risks exposing more patients to preventable harm.

We strongly urge HHS not to finalize this policy.

Patients deserve treatments grounded in reliable evidence, a medication supply chain they can trust, and protection from preventable harm.

Respectfully,

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