The Daily Dish

No, Mr. Secretary. No.

DOUGLAS HOLTZ-EAKIN | NOVEMBER 13, 2026

AAF's Director of Health Care Policy, Michael Baker, and I penned a missive to Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. in order to:

> *...provide comments on the Department of Health and Human Services' October 30, 2026, notice announcing an interim enforcement discretion policy concerning the compounding of six peptide bulk drug substances under Section 503A of the Federal Food, Drug, and Cosmetic Act. The policy would allow qualifying state-licensed pharmacies, federal facilities, and licensed physicians to compound products using BPC-157, Epitalon, KPV, MOTS-c, Semax, and TB-500 without HHS pursuing certain enforcement actions while the Food and Drug Administration completes its review of the substances for inclusion on the Section 503A bulks list.*

Whew! That hardly rolls off the tongue, especially first thing in the morning. Let's try it in English.

HHS, via the Food and Drug Administration (FDA), has procedures by which new, large-scale, commercial drugs are tested for safety and efficacy against specific ailments, and their manufacturing facilities are inspected and free of contaminants. It also has a set of procedures for small amounts of bespoke drugs to be formulated by compounding pharmacies to fit unique needs of some patients.

HHS is proposing to use "enforcement discretion" – aka looking the other way – to permit compounding pharmacies to produce large amounts of six peptides, without checking those drugs (technically, short chains of amino acids) for safety and efficacy or inspecting the manufacturing facilities. Baker's and my official comment is: No.

The primary concern is that Secretary Kennedy's proposal will result in a *de facto* second

channel for commercial drug sales, and one that lacks sufficient oversight:

> *The distinction between individualized compounding and commercial drug distribution has become increasingly consequential as new business models have expanded access to compounded products. Telehealth platforms, centralized prescribing arrangements, and nationwide pharmacy networks can connect patients with compounded drugs at a scale that was not contemplated when the traditional framework was established.*
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> *The recent experience with glucagon-like peptide-1 (GLP-1) drugs illustrates these challenges. During extended shortages, compounding provided an alternative source of medication for some patients. Yet the growth of the market also demonstrated how rapidly temporary accommodation could support a substantial commercial distribution network. As shortages resolved, federal regulators faced increasingly difficult questions about the appropriate boundaries of compounding and the obligations of firms distributing products outside the conventional approval framework.*
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> *The circumstances involving the six peptides differ in one particularly important respect: There are no FDA-approved versions of these substances. Consequently, the central concern is not that compounded products will displace approved equivalents. It is that compounding could become an enduring pathway through which drugs are broadly marketed without completing the established regulatory process.*

The full letter responds to a range of assertions by advocates for the proposal, but the bottom line is simple. This HHS move is unnecessary and potentially dangerous.