Alliance for Pharmacy Compounding
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Peptides: A regulated pathway is better than an illicit marketplace

Some peptides patients are seeking today cannot legally be compounded by pharmacies. Yet demand has not disappeared. Consumers can readily obtain "research use only" or improperly sourced products outside the regulated healthcare system. APC believes FDA should consider a carefully controlled pathway for appropriate peptides that brings patients and ingredients into a regulated healthcare framework.

THE ISSUE

Patient interest in peptides has grown rapidly, including products promoted for recovery, metabolism, anti-aging, weight management and other uses.

At the same time, an online market offers substances labeled "research use only" or "not for human use" – and ingredients from sources that may not meet federal requirements for human drug compounding – while plainly promoting their use in humans.

That is a genuine public-health concern.

For several peptides patients are seeking, there is currently no lawful pathway for a state-licensed pharmacy to compound them from bulk substance. Yet consumers can readily obtain those same substances from research-chemical sellers, overseas sources and others operating outside normal pharmacy and drug-supply-chain safeguards.

Simply saying "no" to pharmacy compounding does not make that market disappear.

APC is not advocating unrestricted peptide compounding. We have proposed to FDA a narrow, controlled interim pathway for selected peptides, with specific conditions designed to protect patients and move sourcing into a legitimate drug-supply chain.

THE DETAILS

Under APC's proposed framework, FDA would determine substance by substance which peptide APIs, if any, qualify for the pathway. Participating pharmacies would then operate under specific conditions:

API purchased only through a validated, FDA-registered intermediary.
A pharmacy could obtain the designated peptide API only through an FDA-registered repackager, relabeler or reseller that has performed and documented appropriate vendor validation of the API manufacturer and validation of the manufacturer's Certificate of Analysis. Direct pharmacy purchases from the API manufacturer or purchases through unvalidated channels would not qualify.

Lot-specific provenance and documentation.
The intermediary would provide the pharmacy documentation establishing the source of the API, the specific lot, the validated Certificate of Analysis and information sufficient to establish provenance and traceability. Research-grade or laboratory-use-only material would not qualify.

Patient-specific prescribing.
Compounding would remain within Section 503A's patient-specific prescription framework, subject to otherwise applicable anticipatory-compounding provisions. This is not a pathway for mass production or general office stock.

Clear patient disclosure.
Patients would receive a standardized disclosure explaining that the preparation is compounded and not FDA-approved, that FDA has not reviewed the finished preparation for safety, effectiveness or quality, and – where applicable – that FDA has not determined the API to be safe and effective for the intended use.

Serious adverse-event reporting.
Participating pharmacies would report serious adverse events through FDA's MedWatch system so FDA can identify emerging safety signals.

Limited real-world utilization reporting.
APC has proposed pairing adverse-event information with limited aggregate dispensing data so FDA can understand the denominator behind reported events. The data would be analyzed through an independent academic partner and would not provide FDA raw patient-level information or competitively sensitive pharmacy data.

Existing applicable USP standards, state pharmacy laws and board-of-pharmacy oversight would continue to apply. The proposed pathway does not replace those requirements; it adds sourcing, transparency and surveillance safeguards for this limited category of peptide APIs.

THE ASK

APC is not asking Congress to authorize specific peptides for compounding. Those scientific determinations belong with FDA.

We are asking policymakers to recognize the public-health reality: the choice is not between pharmacy compounding and no peptide use. An illicit marketplace already exists.

APC's proposed pathway would give FDA a controlled option between an unrestricted market and a prohibition that leaves patients seeking these substances outside the regulated healthcare system.

The question is whether appropriate patients who seek these substances can be served within a framework of legitimate sourcing, prescriber oversight, pharmacy standards and regulatory visibility – or whether demand will continue to be pushed into the illicit marketplace.

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