Compounding must not become a drug-approval shortcut for Big Wellness

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Patients deserve innovation, but they also deserve evidence. FDA should not allow pharmacy compounding to become a shortcut around safety and efficacy standards that protect the public. If compounding becomes an entry point for every substance that attracts an online following, the distinction between individualized patient care and mass production of unapproved, untested drugs begins to disappear.

The outcome of the FDA's recent Pharmacy Compounding Advisory Committee (PCAC) meeting is about far more than a handful of peptides. It is about whether the country still has a functioning line between regulated medicine and unaccountable experimentation. At stake is whether pharmacy compounding will be reined back in as the narrow pathway for individual patient care it was designed to be — or whether the mass compounding of GLP-1s becomes the template, with peptides opening the next front in a scalable commercial pathway for selling experimental drugs that have never demonstrated they are safe or effective.

The gray market is already moving faster than the science. Peptides promising faster recovery, weight loss, better sleep, improved endurance and even slower aging are promoted widely across social media, podcasts, telehealth platforms, and wellness clinics. As The Atlantic recently reported, thousands of Americans are using BPC-157 and other peptides despite limited human-safety data and no FDA approval. Vendors sell untested peptides labeled "for research use only" — which, it must be mentioned, are not manufactured to be safe for human use — while influencers and clinics tout their supposed benefits.

This is not a fringe trend. It is part of the rise of "Big Wellness," a commercial ecosystem connecting influencers, clinics, telehealth companies, compounders, investors and overseas suppliers. According to the Global Wellness Institute, the U.S. wellness economy reached $2.1 trillion in 2024 and the global market reached $6.8 trillion. This scale creates enormous incentive to turn each viral health claim into a product and each experimental compound into a recurring revenue stream, regardless of merit. With PCAC recommending that the compounding of certain peptides be permitted, the peptide marketplace could have a powerful new distribution channel. The result could be a peptide gold rush in which commercial demand, not reliable clinical evidence, determines which experimental treatments reach patients.

That distinction matters because compounded products are not FDA approved, which means that FDA does not evaluate their safety, effectiveness, or quality before they are given to patients. Traditional compounding pharmacies are not required to comply with current good manufacturing practice requirements or report adverse events. Compounding simply does not provide the same safeguards as the drug-approval process, which is why FDA warns that compounded products "can be risky for patients."

None of this diminishes the value of traditional pharmacy compounding, which has long served an important and respected role in patient care by preparing individualized medications when a patient's medical needs cannot be met by an FDA-approved product or when shortages arise. But that respect is undermined if compounding becomes merely a way to commercially distribute unapproved and experimental drugs without FDA oversight.

Supporters argue that patients already buy these substances online and that compounding would offer a safer alternative. The concern about the underground market is legitimate—but a compounding pharmacy does not establish that a substance works, identify a safe dose, or resolve unknown long-term risks any more than this emerging unsafe pathway does.

Worse, it may lend a false veneer of legitimacy to these experimental products: patients understandably assume a prescription filled by a licensed pharmacy has been FDA-reviewed, even when it hasn't.

We've learned this lesson before. Thalidomide was marketed in Europe in the late 1950s and 1960s before its catastrophic effects on fetal development were understood — a catastrophe the U.S. largely avoided only because FDA withheld approval pending stronger evidence. The episode led Congress to require proof of both safety and efficacy before any drug reaches the market. In 2012, the New England Compounding Center shipped contaminated steroid injections across the country, causing more than 750 infections and more than 60 deaths in 20 states. This tragedy prompted Congress to pass the Drug Quality and Security Act, strengthening federal oversight and drawing a clearer line between small-scale pharmacy compounding and large-scale drug manufacturing conducted under the guise of compounding.

Thalidomide and NECC point to the same underlying lesson: individualized, evidence-based medicine breaks down when either approval standards or manufacturing oversight are skipped in the name of speed or access. In the specific case of compounding, the risk changes dramatically when a narrow pharmacy practice becomes mass compounding at a national scale. Today's combination of direct-to-consumer advertising and social-media promotion, rapid telehealth prescribing, centralized fulfillment and foreign-sourced ingredients lets mass compounding scale a product far faster than the compounding market of 2012. The regulatory framework must account for that reality.

Research into peptides should continue, and some may prove valuable. But scientific promise is not clinical proof, and popularity is not evidence. The proper response to a promising experimental treatment is rigorous research — not broad commercial distribution before the necessary trials are complete.

FDA's decision will therefore reach beyond any specific peptide recommended by the PCAC. If compounding becomes an entry point for every substance that attracts an online following, the agency will lose any meaningful distinction between individualized patient care and mass production of unapproved and untested drugs. That distinction is what separates safe medicine from guesswork, and patients pay the price when it disappears.

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