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Whopper of the Week: RFK Jr's Peptide Vibes Influence FDA Policies

IN SUMMARY

Recently, the Secretary of Health and Human Services (HHS) has been hyping peptides and promising changes to FDA rules that would make some unapproved peptides legally available. In February, Secretary Kennedy told Joe Rogan that he was "a big fan of peptides" and has used them" with really good effect with a couple of injuries." He also claimed that under the Biden administration the Food and Drug Administration (FDA) had "illegally" changed regulations for compounding pharmacies, and pushed nineteen peptides into the black market, just like during the Prohibition era. Kennedy used his interview on Rogan, to signal that, under his watch, the FDA will soon allow compounding pharmacies to make certain peptides despite concerns about their safety.

WHY IS THIS A WHOPPER?

Kennedy's claim that the FDA does not have the authority to restrict the use of peptides is a whopper. Peptides are chemicals which if used as drugs fall squarely under FDA oversight. In addition, in 2013, Congress required the FDA, with the help of an advisory committee, publish a list of ingredients that can be safely used by compounding pharmacies. The FDA has spent the past decade doing a substance-by-substance review for the official "bulk ingredients" list; it has permitted the use of some ingredients and prohibited others. In 2023, according to ProPublica, the FDA placed 19 peptides in the category of "substances the agency considered to be dangerous." The FDA's concerns, which were echoed by the advisory committee, focused on the immune responses to the synthetic peptides, the purity of the products, and the limited available human safety data. The FDA acted, as Congress intended, to protect patients from risky and unproven products.

There are multiple ways people get access to peptides. Some peptides are sold as FDA approved pharmaceuticals. There are 130 such peptides on the market, including insulin and oxytocin. The most well-known is the blockbuster anti-diabetic and obesity medicine Ozempic (also known as semaglutide). Ozempic, like all pharmaceuticals, was tested in human clinical trials and passed rigorous safety and efficacy reviews before it was FDA approved. Compounding pharmacies can also prepare peptide drugs, but only in limited situations—such as when they're customizing an approved medication, when there's a drug shortage, or when the ingredient is specifically allowed by the FDA. For example, pharmacies produced semaglutide injection products, at lower costs than Ozempic, when there was a shortage between 2022 and 2025. Finally, there is a black market of unregulated peptides that are sold as "research-grade" products directly to consumers. The FDA claims that many such unregulated peptides made for injection are really unapproved new drugs that are advertised

and marketed illegally. These products are hip and edgy, but they are not tested on humans in clinical trials, not quality controlled, not approved by the FDA, and not for human consumption.

The peptides that Kennedy wants to legalize are popular in the wellness industry for their alleged anti-inflammatory, muscle-enhancing, and neurological properties. On his blog, Dr. Eric Topol described how little is known about them: "There is no evidence from randomized trials in humans that any of these peptides provide the benefits that are advocated." The FDA has flagged these products as potentially dangerous, and Topol also raised concerns about possible cancer risk, immune disruption, and hormonal imbalances. He warns that "there are very limited ongoing clinical trials to illuminate the real efficacy and safety of these peptides." But Scott Brunner, CEO of the Alliance for Pharmacy Compounding, thinks personal testimonials should be enough. "Where we don't have research, clinical trials, what we've got a ton of, is, shall we say, testimonials, patient affidavits, attesting to the wonders of the drug," he said. "And RFK Jr. is one of those testifiers."

WHY IT MATTERS

Kennedy is trying to influence policies at the Food and Drug Administration. As Secretary of Health, he could replace members of the FDA's Pharmaceutical Compounding Advisory Committee (PCAC) with "experts" more aligned with the wellness industry. He could override the advice of PCAC and put some popular peptides on the allowed bulk ingredient list. Or he could have the FDA issue an "enforcement discretion" statement indicating that there will be no consequences if compounding pharmacies violate the law on peptide compounding.

This month the FDA issued a draft guidance which requires companies that market compounded drugs to "clearly and prominently" disclose that the FDA hasn't approved or evaluated the products for safety, effectiveness, or quality. It also forbids them from making misleading comparisons to any FDA-approved drug or from pointing to data based from clinical trials of authorized medicines. The FDA may yet find a middle road, by reclassifying some peptides as legal to compound but requiring pharmacies to issue a public disclaimer and forbidding advertisement.

Secretary Kennedy went on Rogan to say he personally believes peptides are safe and useful even though his own agency and its scientific advisors classified them as potentially dangerous. His anecdotes are propaganda for the "influencer" industry. The peptide debate shows Kennedy is willing to risk public safety in order to serve as the "Secretary of Wellness."

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