STATEMENT OF ALLIANCE FOR PHARMACY COMPOUNDING
CEO SCOTT BRUNNER, CAE, in response to Novo Nordisk's October 21 request that FDA take action to place semaglutide off limits to compounding pharmacies
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Let me get this straight: So Novo Nordisk is apparently so deeply concerned about patient safety that it's taken them a whopping two-and-a-half years while their drug has been in shortage to conclude that the semaglutide API is so demonstrably difficult for compounding pharmacies to prepare that FDA now needs to place it off-limits for compounding? To me, this looks more like desperation and an attempt by Novo to protect its revenue stream than a serious scientific argument.

Some observations:

• Novo seems to be confusing the fact that the semaglutide molecule is demonstrably difficult to manufacture – indeed it is – with the relative simplicity of compounding with it.

• Novo asserts that because it uses recombinant active pharmaceutical ingredient in its FDA-approved GLP1s – instead of the synthetic API* that most compounders use – its API is somehow superior. While it is true that synthetic manufacturing of peptide API may result in more impurities in the drug, the testing labs we've talked with all indicate that those impurities are below 1%, well within acceptable industry ranges. And in terms of the clinical efficacy of the FDA-approved versus the compounded versions of semaglutide injection, there's generally not a dime's worth of difference.

This is from FDA on that topic:

> *Given the current state of technology for peptide synthesis and characterization, FDA believes it is now possible for an ANDA (abbreviated new drug application) applicant to demonstrate that the active ingredient in a proposed generic synthetic peptide drug product (proposed generic synthetic peptide) is the "same" as the active ingredient in a previously approved peptide of rDNA origin.*
>
> *From this GFI: https://www.fda.gov/media/107622/download*

So, the FDA says you can demonstrate that they are the "same," and generics don't have to be recombinantly made to *be* the "same."

• In terms of reported adverse events, those reported to FDA's FAERS database by patients taking the compounded version of semaglutide injection are remarkably similar to those reported by patients taking the FDA-approved version. This is further indication that the compounded and FDA-approved versions act in a patient's body in the same way.

Look, when in the judgment of a prescriber an FDA-approved drug is appropriate for a patient and that FDA-approved drug is available for dispensing to a patient, the FDA-approved drug is *always* the one that should be prescribed and dispensed. But we continue to be in a prolonged era in which the finished-form FDA-approved semaglutide injection products are not available. Novo's ridiculous claims to the contrary, compounding pharmacies are dispensing compounded versions of those life-enhancing drugs to hundreds of thousands of patients. I get that Novo doesn't like it, but the answer is not to restrict patient access, as Novo's October 21 letter attempts, it's for it to fix its supply chain.

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***Recombinant peptides** are produced using genetically engineered organisms like bacteria or yeast, which naturally create the peptide inside cells. This method allows for precise control, higher purity, and scalability, while being environmentally friendly. **Synthetic peptides**, on the other hand, are chemically synthesized step-by-step in a lab. This process provides flexibility in producing complex modifications but involves using more solvents and chemicals, often leading to a higher waste output and potential impurities. Interestingly, tirzepatide, the API in Eli Lilly's FDA-approved GLP1 products is a synthetic, not a recombinant, peptide.*