STATEMENT OF ALLIANCE FOR PHARMACY COMPOUNDING
CEO SCOTT BRUNNER, CAE

• Submission of APC Comment Letter in Response to Eli Lilly Nomination of Tirzepatide to FDA's Demonstrably Difficult to Compound List

• Response to Comments by Novo Nordisk's CEO on Purported Adverse Events Related to Compounded Semaglutide

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Lawyer for APC Submits Comment Letter to FDA in Response to Eli Lilly's Nomination of Tirzepatide to FDA's Demonstrably Difficult to Compound List
On August 28, Eli Lilly submitted a comment letter to FDA urging the agency to take emergency action to add tirzepatide to the 'Demonstrably Difficult to Compound" list, thereby permanently prohibiting compounding with it.

This week APC responded with a comment letter from its attorney asking the agency to deny Lilly's self-serving request. In it, we note that it sure seemed to take the drugmaker a long time to muster enough concern about patients' safety to write such a letter — a full two years into the shortage, with millions of compounded doses already dispensed. (It's enough to make one question the drugmaker's motive, isn't it?)

Our letter pokes holes in Lilly's flimsy claims that tirzepatide is difficult to compound and that compounded versions put patients at risk. It's not and it doesn't.

FDA-approved drugs are first-line therapies in our healthcare system. If a prescriber judges an FDA-approved drug is appropriate for and accessible to a patient, that's what should be prescribed and dispensed. But for two years we've been in a period when Lilly has been unable to meet the demand for its drug. As allowed in FDA guidance, compounding pharmacies have been preparing copies of tirzepatide injection and dispensing them to individual patients based on a prescription from a provider who has determined that the compounded version of the drug is appropriate for the patient. Compounding pharmacies have been and are providing patients access to a life-enhancing drug at a time when the drugmakers cannot.

Indeed, Lilly's letter should be read as saying to patients, in effect, "Tirzepatide is ours, and until we get our act together and make enough of it, you can't have any."

Response to Comments by Novo Nordisk's CEO on Purported Adverse Events Related to Compounded Semaglutide

Any serious adverse event, whether from a compounded or FDA-approved drug, is concerning. But context matters, and there's plenty Mr. Jorgensen left unsaid in his comments about compounded semaglutide this week to CNN – including mentioning his own FDA-approved drug products' adverse events records. He's plucked the alarming number of deaths he says have resulted from compounded semaglutide from FDA's FAERS dashboard. Yet a disclaimer on the FAERS database itself specifically reminds that a report in the database does *not* mean that the drug *caused* the adverse event. Moreover, as compounded drugs go, there's often no indication in the FAERS database who prepared the substance in question – was it a legitimate state-licensed compounding pharmacy or a bogus entity claiming to be a pharmacy? That distinction matters, especially if the aim is to prevent more such adverse events. But if the aim is to spin a headline-grabbing narrative that casts pharmacy compounding in a bad light, maybe not.

Mr. Jorgensen says he's concerned about "patients who believe that they're getting access to a safe product, and they believe they're getting semaglutide … I know for a fact that they are not getting semaglutide, because there's only one semaglutide, and that's produced by Novo Nordisk, and we don't sell that to others."

There's a lot to parse in that comment. For two years now his company in its public statements has consistently conflated drugs prepared in a legitimate state-licensed pharmacy with counterfeit and other illicit substances, continually referring to both as "compounded" drugs. Novo has claimed to have found potency discrepancies and impurities in "compounded" drugs it has tested, but when asked to disclose how and from what source it acquired those patient-specific drugs to test – was it a legitimate state-licensed compounding pharmacy or an illicit non-pharmacy entity – the company has declined to comment. So when Novo's CEO speaks of "compounded" drugs, one needs to ask what he means since the company can't seem to differentiate between legitimate compounding and counterfeiting.

The suggestion that there's only one semaglutide and it's only available from Novo Nordisk is flatly, demonstrably false. It's a statement easily debunked by a quick look at the FDA website, where dozens of FDA-registered manufacturers are listed. Perhaps he meant to say there's only one FDA-approved Ozempic or Wegovy – a true statement. But that's not what he said.

Compounded drugs are legitimate therapies created from pure bulk ingredients by state-licensed pharmacies that adhere to the rigorous compounding standards of the US Pharmacopeia, are licensed and regularly inspected by state boards of pharmacy, and that adhere to FDA guidance and regulation as well.

While adverse events do sometimes occur, as they do with FDA-approved drugs as well, legitimate compounding pharmacies operate in a compliance framework in which

ensuring patient safety is both paramount and essential to the pharmacy's ability to continue to serve its patients. Mr. Jorgensen's comments this week do a disservice to the pharmacists and technicians who prepare compounded drugs that serve as a lifeline to millions of patients.

The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers. Learn more at compounding.com or a4pc.org.