STATEMENT BY ALLIANCE FOR PHARMACY COMPOUNDING CEO SCOTT BRUNNER ON ELI LILLY'S INTERVENTION IN THE OFA/FARMAKEIO LAWSUIT AGAINST FDA

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As a legal strategy, Eli Lilly's intervention last week in the OFA lawsuit against FDA makes sense: It preserves the drugmaker's ability to defend against claims made by OFA even if incoming Trump-appointed leaders at FDA choose to reverse the agency's tirzepatide injection shortage resolution. Plus, the drugmaker's lawyers are respected conservatives who are likely to have high credibility with this particular court.

What's concerning is claims in Lilly's intervention brief that mischaracterize Section 503A of the Food, Drug & Cosmetic Act and which, if those claims prevail, would undermine FDA's authority to stipulate conditions under which pharmacies may prepare copies of FDA-approved drugs. A careful reading of the statute contradicts what Lilly is asserting, but that doesn't mean the court won't take the claims seriously. If the court agrees, the implications extend well beyond GLP1 drugs. Accepting Lilly's argument would eviscerate a critical drug-supply policy that empowers pharmacies to prepare copies of FDA-approved drugs to fill supply gaps and meet patient need when the drugs are listed on the FDA Shortage List.

Lilly's brief asserts that "compounding pharmacies under 503A are only permitted to make 'essentially a copy' of an FDA-approved medicine in certain limited circumstances" and "That drug product appearing on FDA's drug shortage list is *not one of them*." But that statement fails to note that the FD&C Act clearly delegates to the HHS Secretary authority to determine circumstances under which pharmacies may prepare copies of FDA-approved drugs "regularly or in inordinate amounts." Within HHS, the FDA has done so via a Guidance for Industry that states that a drug appearing as "currently in shortage" on the FDA Drug Shortage List is such a circumstance.

No doubt Lilly's attorneys are betting that in a world in which courts' deference to agency interpretation of statute has been weakened by the U.S. Supreme Court (*Loper v. Raimondo, 2024*), a conservative court may not look friendly upon an agency defining via guidance the circumstances under which pharmacies can make copies of FDA-approved drugs. But on this particular issue, the statute is clear in its delegation of authority to the agency to determine those circumstances. One hopes the court would agree with that clarity, but that's far from certain.

There's well more at risk in Lilly's attempt here than simply ending the compounding of GLP1 copies. Pursuant to a prescription, pharmacies routinely prepare copies of a wide range of

drugs that appear as “currently in shortage” on the FDA Drug Shortage List. Their authorization to do so is intentional policy designed to assure continuity of patient care even when drugmakers can’t provide the needed medication. Without that explicit authority, a patient taking a drug that goes into shortage will be out of luck, at least initially, until a 503B outsourcing facility can ramp-up production of the shortage drug – a process that can take from three to nine months depending on the drug, and that’s presuming the 503B determines there’s a viable economic model for undertaking that ramp-up and production at all. Often there is not such a model, and thus prescribers and their patients may be left with few options.

Case in point: Think back to Fall 2023 and Winter 2024 when millions of children were taken ill and amoxicillin suspension was in severe shortage. Even some suitable alternative medications went into shortage as a result of demand. With parents frantic and prescribers frustrated that they could not treat the children, it was compounding pharmacies that stepped up to meet that critical need, preparing copies of the FDA-approved pediatric suspension until production resumed and the drug was no longer in shortage.

That’s but one recent example of the need for such a policy. Should Lilly’s argument prevail, perhaps millions of patients taking a medication that goes into shortage will need to be shifted by their prescriber to alternative drugs – if indeed there is an alternative (and often there is not). And even that transition process will take time, meaning that for some patients, medically consequential interruptions of therapy could occur.

Lilly seems heedless of such concerns. As its legal brief makes clear, it’s much more interested in protecting its financial interests, even as pharmacies continue to report difficulty in sourcing Lilly’s tirzepatide injectables in quantities sufficient to meet patient demand. Lilly’s commercials for Zepbound and Mounjaro are again blaring from TVs across America. Some might call it false advertising: Marketing a drug that there’s not yet enough of.

And that’s our other concern. Certainly, we expect that tirzepatide injection will eventually – even soon – be available in sufficient quantities to meet demand. But evidence suggests we’re not there yet, and the info FDA relied on in resolving the shortage was incomplete at best.

Nevertheless, Lilly says that 100% of orders for Mounjaro and Zepbound are being filled. But that fails to note that backorders by pharmacies aren’t allowed or counted, so it appears is if there aren’t any backorders, no unmet demand. There’s no reporting mechanism for the number of units the pharmacies may need (in order to transfer patients taking the compounded version over to the Lilly version) but can’t get.

Compounding pharmacists recognize and respect the role of FDA-approved medications in our drug supply chain. But as the record numbers of recent drug shortages presages, a system without compounding to support continued medication access will fail millions of patients. That’s why Congress via the FD&C Act and FDA via agency guidance not only allows for compounding copies of FDA-approved drugs to meet a critical need in shortages but also

stipulates a rigorous safety framework in which those drugs must be prepared. Lilly's claims in its *OFA v Califf* intervention brief put that essential policy at risk.

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.

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