IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, and LILLY USA, LLC Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 1:21-cv-81-SEB-MJD

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL AUTHORITY

Defendants respectfully submit this filing in opposition to Plaintiffs' (collectively "Lilly") Motion for Leave to File Notice of Supplemental Authority ("Supplement" or "Supp."), ECF No. 56.

Lilly's Supplement inaccurately asserts that guidance issued by the Department of Health and Human Services ("HHS") in 1996 provides an adequate, alternative dispute-resolution method for covered entities to bring claims arising from the harms inflicted by Lilly's recent 340B restrictions. *See* Supp. at 2, Ex. A. In reality, that guidance does not provide any available method to resolve the legality of Lilly's non-statutory restrictions on access to its medications and lacks relevance to the preliminary-injunction motion now pending. It thus should receive no consideration by the Court.

The dispute-resolution process discussed in the 1996 guidance "is … a voluntary process"—meaning that "[c]overed entities or manufacturers are not required to enter this informal process for resolution of disputes regarding section 340B." Supp. Ex. A at 12. In other words, the process is entirely toothless because manufacturers, like Lilly, have no obligation to participate. Moreover, there

is strong reason to believe that Lilly would *not* participate in the voluntary dispute-resolution process, since Lilly already has sought emergency relief in this Court to *avoid* participating in the formal dispute-resolution process mandated by Congress, while simultaneously refusing to engage with covered entities and other stakeholders that have reached out to Lilly in an attempt to resolve the contract-pharmacy dispute without litigation. Indeed, Lilly appended to its preliminary-injunction motion communications Lilly received from covered entities conveying "the negative impact [Lilly's] policy is having on [hospitals] and their patients," "ask[ing] that [Lilly] revoke [its] policy effective immediately," and "reverse any transactions where [Lilly] charged [hospitals] above the applicable ceiling price." *See* Mot. for Prelim. Inj. Ex. G, Asay Decl., Ex. 5, ECF 19-8; *see also* Ex. G, Ex. 6 (communication from Jamestown S'Klallam Tribe conveying harm to Indian health system caused by Lilly's policy and requesting "that Eli Lilly immediately resume providing 340B access to all of the Tribe's contract pharmacies"). In light of Lilly's demonstrated refusal to engage with covered entities to resolve the contract-pharmacy dispute—in addition to its aggressive litigation position seeking to enjoin the dispute-resolution process Congress designed for 340B violations—Lilly's suggestion that a *voluntary*, informal mechanism provides covered entities an adequate alternative process is meritless.

Moreover, *even if* Lilly were willing to engage in good faith in a voluntary dispute-resolution process, the process set forth in the 1996 guidance still would not suffice to resolve the legality of Lilly and other manufacturers' recent restrictions. Most importantly, Congress already deemed the informal process insufficient. As the Supreme Court explained when it confirmed that covered entities may not bring claims for 340B violations in federal court (because the statutory scheme requires resolution of disputes *before the agency*), "in the [Affordable Care Act], Congress directed [HHS] to create a formal dispute resolution procedure … Congress thus opted to strengthen and formalize [HHS's] enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements.'"

Astra USA, Inc. v. Santa Clara Cty., 563 U.S. 110, 121-22 (2011) (citing 42 U.S.C. § 256b(d)(1)(A)). The pre-existing dispute-resolution process is a wholly inadequate substitute for the formal process because Congress deemed it so—and mandated resolution of claims for 340B program violations in the formal process Lilly seeks to enjoin. And Congress's judgment rested on sound reasoning, considering that the informal, voluntary process envisioned by the 1996 guidance *never*, in a twenty-year span, resulted in any claim being resolved to the point of enforcement. *See* Notice of Proposed Rulemaking, Alternative Dispute Resolution Mechanism, 81 Fed. Reg. 53,381, 53, 386 (Aug. 12, 2016) (noting that there had been only *four* requests for informal dispute resolution in twenty years, none of which had reached resolution on the merits). Should this Court enjoin the ADR Final Rule, not only will covered entities be denied access to the process specified by Congress, but they also will lack any effective mechanism to bring the contract-pharmacy dispute before the agency, where it must be decided. For these reasons, the 1996 guidance submitted by Lilly should not be considered by the Court in resolving Lilly's emergency motion.

Dated: March 5, 2021

Respectfully submitted,

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