UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, Indiana 46225

and

LILLY USA, LLC
1500 South Harding Street
Indianapolis, Indiana 46221,

Plaintiffs,

v.

NORRIS COCHRAN, in his official capacity as Acting Secretary of HHS
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of HHS
Office of the General Counsel
200 Independence Avenue, SW
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington D.C. 20201,

DIANA ESPINOSA, in her official capacity as Acting Administrator of HRSA
5600 Fishers Lane
Rockville, Maryland 20852,

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

Document Electronically Filed

PLAINTIFFS' CONDITIONAL OPPOSITION TO
MOTION FOR INTERVENTION

The American Hospital Association and a number of other trade groups (collectively, "Proposed Intervenors") move this Court for an order allowing them to intervene as defendants. Proposed Intervenors have represented that their "interest in this lawsuit relates only to Lilly's claims regarding the Advisory Opinion" issued by the U.S. Department of Health and Human Services ("HHS") Office of General Counsel ("OGC"). Dkt. 40 at 5; *see* HHS OGC, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program* (Dec. 30, 2020) ("December 30 Decision"). If Proposed Intervenors represent members that have contractual relationships with contract pharmacies under which the latter truly "act[] as agents of" the former, *see* December 30 Decision at 1, then they may well have sufficient interest to satisfy the associational standing requirement and justify their participation in the case as intervenors. At this juncture, however, it is unclear whether or to what extent they do.

Absent such contractual relationships, Proposed Intervenors cannot claim to be affected—much less uniquely harmed—by Lilly's challenge to the December 30 Decision. For if Proposed Intervenors' members do not have agreements with contract pharmacies that satisfy the criteria set forth in the December 30 Decision, then by definition there would be no "discounts to which [Proposed Intervenors' members] are entitled" pursuant to the December 30 Decision. Dkt. 40 at 3. Simply put, if Proposed Intervenors' members do not have contract-pharmacy relationships of the sort described in the December 30 Decision, then it is unclear how their interest could be different from that of the general public—or, for that matter, the United States government, which is defending against Lilly's claims. Additional facts are required to determine whether Proposed Intervenors in fact have sufficient interest to justify their intervention.

Proposed Intervenors contend their "member hospitals use the benefit from 340B discounts for 340B drugs dispensed through contract pharmacies"—*i.e.*, the price-differential between the

high retail price contract pharmacies charge vulnerable patients and the low ceiling price manufacturers may charge covered entities—"to support programs and services." Dkt. 40 at 8. Proposed Intervenors support that assertion with only the Declaration of Maureen Testoni, which in turn cites two surveys conducted by 340B Health, one of the Proposed Intervenors. Dkt. 39-1 at ¶¶ 3-10. Yet Proposed Intervenors do not attach the survey responses on which they rely. More important, Proposed Intervenors do not submit any of the actual contracts that underlie the survey responses. Without those contracts, there is no way for the Court to know whether or to what extent Proposed Intervenors' members in fact have contractual relationships of the sort the December 30 Decision describes and which they require for a sufficient cognizable interest to intervene to defend against Lilly's claims challenging the December 30 Decision (*i.e.*, the only claims on which Proposed Intervenors seek to intervene).

Lilly does not seek the contracts that underlie all of those survey responses, but instead respectfully requests that Proposed Intervenors be required to disclose a representative sample of contracts between covered entities and contract pharmacies. Specifically, Lilly requests that Proposed Intervenors produce all current contracts between (a) a representative sample of survey respondents (no less than 5) that are members of one or more of the Proposed Intervenors and (b) CVS, Walgreens, Walmart, Rite-Aid, and Kroger, which the U.S. Government Accountability Office (GAO) identified as "[t]he five biggest retail chains … represent[ing] 60% of 340B contract pharmacies" ("but only 35% of pharmacies nationwide"). Dkt. 17 at ¶ 55 (citing U.S. Gov't Accountability Office, *Discount Drug Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 20-21 (June 2018), https://bit.ly/3kJ7eGa). These 25 (or more) representative contracts will aid this Court's determination of Proposed Intervenors' interest in support of their intervention request.

Beyond that required additional information, Lilly responds to two points in Proposed Intervenors' memorandum. First is Proposed Intervenors' assertion that ruling for Lilly "would impair Proposed Intervenors' members' interests … in receiving the discounts to which they are entitled." Dkt. 40 at 3. That is simply not true. As Lilly has explained at length, its current (lawful) distribution policy ensures that each and every covered entity receives each and every discount the statute requires. At ceiling prices or lower, Lilly will sell directly to a covered entity as much as a covered entity seeks to provide for the needs of its patients, regardless what the covered entity does with the discounts it receives. Invalidating the December 30 Decision and affirming the validity of Lilly's current (lawful) distribution policy would not change that in any way. All it would do (besides vindicate the text and structure of the 340B statute) is return the 340B program to the way it worked for more than two decades; in other words, it would ensure (1) that covered entities receive all the discounts to which the statute entitles them, but (2) that contract pharmacies and other for-profit entities not included in the statute cannot force manufacturers to give discounts that they then ***pocket for themselves***.

Second is Proposed Intervenors' assertion that ruling for Lilly "would significantly, adversely impact the services all 340B covered entities provide." *Id.* at 9. Again, that is simply not so. Covered entities can either (a) buy directly from Lilly or (b) use a single designated contract pharmacy, as Lilly's policy permits, and still obtain the full discount amount (or at least the same as they could working with pharmacies); there is no basis to say they would lose the ability to provide any services. By buying directly from Lilly, covered entities can decide what to do with ***all*** of the excess profit, not some fraction of it. In all events, covered entities—and certainly contract pharmacies—should not be profiting from pharmacies' demands for 340B discounts for

numerous patients who are ***not*** patients of the covered entity, or from transactions that are not otherwise 340B eligible.

With those clarifications, and on the understanding that Proposed Intervenors' participation will be limited to post-preliminary-injunction proceedings and will relate only to Claims 1-4 in the Amended Complaint, Lilly conditionally opposes Proposed Intervenors' motion to intervene, subject to the terms described above.

Dated: March 5, 2021

Respectfully submitted,

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on **March 5, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ *John C. O'Quinn*
John C. O'Quinn, P.C.