DECLARATION OF KRISTA M. PEDLEY

I, Krista M. Pedley, declare as follows pursuant to 28 U.S.C. § 1746:

1. I currently serve as Director of the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), United States Department of Health and Human Services (HHS). OPA is the component within HRSA with primary responsibility for the day-to-day administration of the 340B Program. I have worked at OPA since 2007 and served as Director since 2010. In my role at OPA, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies.

2. I submit this Declaration to respond to certain factual representations that I understand have been made by drug manufacturers and a consultant for the pharmaceutical industry, Aaron Vandervelde, in litigation involving the issue of contract-pharmacy use. Specifically, Mr. Vandervelde has submitted amicus briefs in various cases that describes the "replenishment model" used in some contract-pharmacy arrangements. *See* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind. May 12, 2021), Dkt. 92-1 at 13-14; *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del. Apr. 16, 2021), Dkt. 46; *Sanofi-Aventis U.S., LLC v. HHS et al.*, 21-cv-634 (D.N.J. May 13, 2021), Dkt. 71-2. The drug manufacturers, in reliance on Mr. Vandervelde's brief, have also made assertions about how contract-pharmacy arrangements work. *See* Tr. of May 27, 2021 Hrg., *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del.), 10:6-14:6; Tr. of May 27, 2021 Hrg., *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind.), 20:9-15, 22:21-25, 67:8-14.

3. The following paragraphs describe my understanding of how, in general, contract-pharmacy arrangements work under the replenishment model. Of course, contract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy. But at its most basic level, under the replenishment model, to the extent that

an individual is determined to have been a 340B patient of the covered entity, the contract pharmacy's drug inventory is "replenished" with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed.

4. As an initial matter, for all contract-pharmacy arrangements (replenishment or otherwise), a covered entity may establish a relationship directly with a pharmacy, or it may elect to employ a third-party vendor or administrator (TPA) to facilitate data-capture and reporting in the administration of a covered entity's contract-pharmacy program. In the former situation, the covered entity sends data feeds about its patients' 340B eligibility directly to the contract pharmacy; in the latter, it sends that data to the TPA.

5. The replenishment model proceeds in three steps. First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from "e-prescribing," whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy's own inventory.

6. Various 340B-tailored software programs exist to evaluate each dispense. That software compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product. The software operates under the oversight of the covered entity, in that each 340B-eligible dispense is recorded and reported to the covered entity. And HRSA audits this process: we obtain a random sample of the drugs dispensed, and the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient. Each year, HRSA audits approximately 200 covered entities, along with any of the covered entities' contract-pharmacy arrangements.

7. Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity's 340B account with the relevant wholesaler. The replenishment order has to be an exact 11-digit match under the National Drug Code (NDC) system for the product that was identified by the software. (The NDC for a product identifies (1) the product's labeler, *i.e.* manufacturer or distributor; (2) the identity of the product, *i.e.* strength, dosage form, and formulation of the drug; and (3) the product's package size and type.)

8. The trigger for a replacement order will not usually be a single dispense. Rather, the TPA and/or contract pharmacy will "accumulate" 340B-eligible dispenses of a specific 11-digit NDC product towards a pre-set package size. So, for example, a package may be 270 tablets of Amoxicillin, which means that it would take 3 dispenses of the 90-tablet bottles to accumulate one package and lead to submission of a replenishment order. Covered entities are provided accumulation reports where they can track each accumulation to a specific patient/dispense.

9. As noted, the replenishment order will be placed on a covered entity's 340B account with the relevant wholesaler. The 340B account is in the covered entity's name and reflects its financial payment information. That 340B account reflects a "bill to" address and "ship to" address. The covered entity is reflected as the "bill to" party; the contract pharmacy (or sometimes, its warehouse) is reflected as the "ship to" address. The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. And so, the covered entity pays for and purchases the drug at the 340B discount price from the wholesaler. If the wholesaler's invoice is not paid, it will seek to collect payment from the covered entity directly—not the contract pharmacy.

10. While it is true that the logistics of placing the replenishment order can vary—for example, sometimes the covered entity places the order, sometimes the contract pharmacy orders it as a purchasing agent of the covered entity, sometimes the order is submitted by the TPA—HRSA

understands that the covered entity is the legal purchaser and authorizes the order. If the replenishment order is sent on behalf of the covered entity, the entity should be aware of the replenishment order; indeed, the order is often approved by the covered entity prior to submission to the wholesaler/distributor to ensure accuracy.

11. Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes "neutral inventory," and may be dispensed to any subsequent patient.

12. When utilizing a replenishment model, covered entities must ensure that appropriate safeguards are in place at the contract pharmacy to ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients. The covered entity must have systems in place to be able to demonstrate that the covered entity is properly accounting for 340B purchases in a replenishment system. HRSA ensures that is the case through the audits mentioned above (¶ 6).

13. OPA maintains the 340B Office of Pharmacy Affairs Information System (OPAIS), a database that assists in the functioning of the 340B Program. When registering on OPAIS, a covered entity must list its contract pharmacy(ies), and that listing must reflect a bill-to/ship-to arrangement. Thus, OPAIS clearly shows that the covered entity, as the bill-to party, is the party that purchases the 340B drugs.

Executed on June 16, 2021, in Frederick, MD.

Krista M. Pedley -S

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