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' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S NEW COUNTS X-XIII; REPLY IN SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT; OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT; AND OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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As explained in HHS's pending dispositive motion, the present dispute arose in mid-2020 when Lilly led a cohort of large, global drug makers in a campaign to abruptly upend the twenty-five year operation of the 340B Program by restricting access to discounted drugs by safety-net healthcare providers that rely on neighborhood pharmacies. Specifically, the manufacturers announced that no longer will they offer (or offer without manufacturer-imposed, unlawful restrictions) access to discounted drugs for certain statutorily defined healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies" located in the neighborhoods where patients live. Lilly's policy is more extreme than that of its peers and results in *the denial of* "purchases by" safety-net providers unless they meet restrictive conditions, with no basis in statute, unilaterally imposed by Lilly. Lilly's policy has increased profits for Lilly while dramatically curtailing much-needed funding for safety-net providers and forcing patients to pay more for medications or adjust their medication regimen.

After a thorough, months-long review of Lilly's newly imposed contract-pharmacy restrictions, including assessment of thousands of pages of complaints from safety-net providers, detailed analysis of real-world changes to Lilly's discounted-sales volumes, review of correspondence from Lilly and other manufacturers setting forth the purported basis for their abrupt changes, and meetings with numerous stakeholders, the Health Resources and Services Administration (HRSA) has determined that Lilly is flouting its obligation under Section 340B by overcharging covered entities for its drugs and conditioning access to 340B discounts on demands which have no basis in the statute. As shown herein, that conclusion is based on sound statutory interpretation and voluminous evidence; this Court should reject Lilly's challenge to HRSA's violation finding and allow HRSA's enforcement of the statute to proceed. This Court should also deny Lilly's request for a preliminary injunction and grant summary judgment to HHS on Lilly's challenge to the new ADR Rule.

BACKGROUND

A comprehensive explanation of the 340B Program's statutory and regulatory background, and the concerted actions by six pharmaceutical manufacturers that led to the current litigation, are set forth in HHS's Motion to Dismiss or, in the Alternative, for Summary Judgment at 3-12 ("HHS

Mot."), ECF No. 88. Included herein is information relevant to the new agency action, HRSA's May 17, 2021 violation letter issued to Lilly and challenged in Lilly's second amended complaint (hereinafter "Compl."), ECF No. 103.

Four months before the Advisory Opinion ("AO") initially challenged in this action (and since withdrawn, *see* ECF No. 119) was issued, and shortly after Lilly and its peers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put Lilly on notice that the agency was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *See* Violation Letter Administrative Record ("VLTR") at 7627, Adm. Pedley Letter to Eli Lilly, Aug. 26, 2020; *see also e.g.*, *id.* 7658. HRSA expressly disavowed Lilly's assertion that its "plan did not give rise to an enforceable violation of the 340B statute," and warned that the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* HRSA transparently explained that it "continues to examine whether Lilly's actions amount to attempts to circumvent th[e] statutory requirement by inappropriately restricting access to 340B drugs." *Id.* Unfazed by the warning and concerns expressed by its regulator, Lilly proceeded to implement its new contract-pharmacy restrictions.

HRSA's comprehensive review of Lilly's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. *See* VLTR_3, D. Espinosa Letter to Lilly USA, LLC ("Violation Letter"). That letter informed Lilly that HRSA "has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* It relies on statutory text to determine that the requirement that Lilly honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA directs Lilly to "immediately begin offering

its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that civil monetary penalties (CMPs) may be imposed. *Id.* 4. Although the letter instructs Lilly to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS thus has not made any determination as to whether sanctions are warranted at all but, should Lilly continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the Violation Letter does not rest upon—or even reference—the General Counsel's now-withdrawn December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, VLTR_8048). Instead, the Violation Letter culminates the evaluative process Lilly was apprised of in August 2020, months before the AO was issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. Alongside the statute and its legislative history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other stakeholders, HRSA also gathered proof of the real-world implications of Lilly's changes and the substantial harm to covered entities its restrictions have wrought.

The record contains *over six thousand pages* of complaints from covered entities. VLTR_110-6,806. Although that multitudinous evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's Violation Letter. Beverly Hospital's complaint alerted HRSA to the fact that "manufacturer(s) [are] deliberately refusing [the] 340B Price" and explained that the restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] contract pharmacy" orders—the highest

commercial rate. *Id.* 1460-61. That complaint included a spreadsheet showing specific transactions where the 340B ceiling price[1] was denied and the hospital instead was subject to wholesale acquisition cost on Lilly's medications of up to $3,683 per unit; that hospital's orders from October 2020 alone totaled $126,508 in lost 340B savings. *Id.* 1463. Beverly Hospital again alerted HRSA in writing in December 2020 that Lilly was "deliberately withholding 340B pricing," again including a spreadsheet showing numerous Lilly medications where the hospital was overcharged in amounts exceeding $3,000 per unit—*far* above the ceiling price—and documenting that the safety-net hospital lost more than $70,000 in 340B savings that month alone. *Id.* 1464-68.

The University of Utah Health, a covered entity, wrote to HRSA complaining that it "has been unable to purchase Eli Lilly products at the 340B ceiling price for delivery to its contract pharmacy," which, the university explained, "is contrary to the 340B statute … and the Pharmaceutical Pricing Agreement (PPA) Lilly has entered with HRSA." VLTR_5831. That complaint included explicit examples of Lilly's overcharges: "Eli Lilly has removed the 340B pricing … [s]o when a [covered entity] replenishes a drug on the 340B account for a contract pharmacy, they are actually charged the WAC price. We were charged $3597.83 for a package when the 340B ceiling price is" many orders of magnitude below that inflated price. *Id.* 5834. Not long thereafter, the same covered entity filed another complaint explaining it "purchased 2 packages of NDC 00002840001 on 9/17/2020 [and was] charged $3597.83 per package when the ceiling price is" far lower. *Id.* 5844. Lilly overcharged the same covered entity again on September 25, 2020. *Id.* 5852.

St. Joseph Medical Center attached an actual invoice showing that it was forced to pay "WAC pricing charges" for 340B-covered drugs after the "manufacturer ceased to provide 340B pricing suddenly." VLTR_1837, 1842. The invoice shows that the drugs were ordered *and paid for* by St. Joseph but *shipped to* Franciscan Pharmacy Tacoma and that Lilly charged St. Joseph's $326 for one of its drugs and $274 for another—far above the statutory ceiling price. *Id.* 1842.

[1] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record, along with other figures that would allow a reader easily to calculate the ceiling price for any particular drug. Lilly cannot dispute, however, that the ceiling price for medications referenced in this discussion are only a tiny fraction of the WAC price.

A hospital in South Dakota complained to HRSA that Lilly was unlawfully overcharging it for covered outpatient drugs, explaining that, when it tried to purchase drugs through its existing wholesaler, "[s]ome accounts had the NDC [drug identifier] taken off the catalog," meaning that the drug no longer was available for purchase by the covered entity, while "some accounts had a WAC[] price listed." VLTR_1373. That complaint confirmed that "[t]he purchases that were made were done on the 340b account in what we feel was WAC[] pricing," and that the hospital *did*, in fact, place orders and pay the inflated wholesale acquisition cost. *Id.*

Another covered entity included a screenshot from its ordering system showing that all formulations of Humalog, a Lilly insulin product, were marked as "Ineligible" for purchase on its 340B account. *Id.* 1590. That community health center told HRSA that it "is forced to pay WAC for these products if purchased for a contract pharmacy" to handle dispensing to patients, and included another screenshot showing the commercial rates it was forced to pay for Lilly products, including up to $763 per unit for Lilly insulin—a product that Lilly admits in its complaint should be provided to covered entities at "one-penny-per-milliliter prices," Compl. ¶ 82. VLTR_1593, 1597.

A critical-access hospital in Nebraska documented numerous instances where Lilly overcharged by forcing it to pay prices far above the 340B ceiling price. *Id.* 3110 (spreadsheet of Lilly products where 340B pricing was denied); 3116-17 (hospital paid $326 for Lilly insulin); 3119-20 (hospital paid $339 for Lilly insulin); 3122-23 (hospital paid $797 for Lilly insulin); 3125-26 (hospital paid $551 for Lilly insulin). That hospital explained that, "[a]s far as [it was] aware," those prices reflect "the WAC price," despite the fact that the orders were placed and paid for on its 340B account and the sales "counted as a 340B transaction as [they] met all criteria to be 340B." *Id.* 3154.

An Iowa Health Center confirmed to HRSA that Lilly's restrictions are directly harming low-income patients who previously had received the full benefit of the safety-net provider's discounts: "The people most affected by Lilly's actions are those patients helped by our 340B-direct-pricing program. These patients are now left with few options for obtaining life-saving medicines." *Id.* 3070.

Blue Ridge Medical Center complained specifically that "Eli Lilly is blocking 340B prices for their drugs ordered by [the medical center] that are shipped to my contract pharmacies. *I am forced to*

pay WAC [wholesale acquisition cost] for these products for my contract pharmacies." *Id.* 1607 (emphasis added). A family clinic included an email from its wholesaler confirming that, under the new policy, a "covered entity pays WAC if the pharmacy" where its purchases are shipped "is not the Eli Lilly approved pharmacy." *Id.* 3300. Lancaster Health Center notified the agency that Lilly is "refusing to fulfill orders (for any of their manufactured products) placed by [the] covered entity and shipped to my contract pharmacies at 340B prices. *I am forced to pay WAC* for these products." *Id.* 3303 (emphasis added). Lancaster specified seven separate drug formulations it had tried to order at 340B prices, but found that Lilly was "refusing to ship my orders to my contract pharmacies." *Id.* 3314-15. The Chief Executive Officer of Windrose Health Network reported to HRSA in March 2021 that "Eli Lilly is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. *I am forced to pay WAC* for these products." *Id.* 6645-46 (emphasis added). That covered entity also included the drug formulations for which Lilly had overcharged it by charging full price. *Id.* Countless complaints echo these concerns. *E.g.*, *id.* 130-35; 154-55; 278-79; 297-98; 312-17; 389-96 (attaching lengthy list of Lilly drugs hospital was blocked from purchasing at 340B rate); 428-35 (same); 488-95 (same); 833-40 (same); 1659-60 (confirming covered entity "forced to pay WAC" for Lilly's products to have drugs shipped to contract pharmacies); 1678-79 (same); 3239-40 (same).

HRSA also relied on evidence regarding the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents a sizeable, rural area and a "medically underserved population," submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. VLTR_7255-56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "generate additional

revenue" through the spread between the 340B-discount price and the price paid by or on behalf of some patients, as Congress intended,[2] and that it "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[3] *Id.* Despite the critical importance of its contract-pharmacy network to both the provider and its patients, the covered entity documented that it "currently has no access to Eli Lilly … medications at 340B pricing to be dispensed through its contract pharmacies." *Id.* 7257.

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. VLTR_7260-61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to" its pharmacy partners, under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible … patients." *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261-62. The covered entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that Lilly and its peers' restrictions have caused. *Id.* 7262-63. The

[2] As explained in HHS's opening brief (3), Congress designed the program to allow covered entities to generate revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report). Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. As explained herein, this enables covered entities to reinvest in patient care and services.

[3] This covered entity also thoroughly rebutted manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest, predetermined fee to the pharmacy for its services, it "does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270-75; 7277-83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295-98 (safety-net provider with high-poverty population expects to lose $6 million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300-06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309-14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"; further documenting significant harm to patients, *id.* 7312); 7316-20; 7323-25 (explaining that patients are heavily reliant on access to discounted drugs through network of neighborhood and mail-order pharmacies and that covered entity "is responsible for and ensures program compliance in part through daily self-audits of prescription claims and drug purchasing records"); 7331-33; 7347-50.

During its evaluation HRSA also gathered relevant evidence through meetings with stakeholders impacted by Lilly and its cohort's restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. VLTR_7891-92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* The very next day, HRSA officials learned in another meeting that one pharmacy in West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. In another listening session

that same month, HRSA gathered evidence from tribal leaders in multiple states detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[p]atients are having to choose between buying food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894-97. Another tribe reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898. Yet another tribal leader implored HRSA "to take immediate action," pointing out that drug makers are "experiencing record-breaking profit" so it was "unacceptable for them to gauge [sic] small entities." *Id.*

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. VLTR_7957-63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided detailed information on how they use 340B savings to provide more-comprehensive services for medically underserved and low-income patients, such as addiction treatment, oncology treatment, medication management, and outpatient behavioral health for children. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully one-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural hospitals are at even greater risk, since fully three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960-61. Of particular note, survey respondents expressly tied financial concerns to six manufacturers' (including Lilly's) contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most of which expect to lose *more than fifteen percent* of their annual 340B savings as a result of contract-pharmacy

restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

The administrative record contains evidence that Lilly and its peers' restrictions have been particularly devastating for diabetic patients. Although thus far only six manufacturers have restricted access to 340B-discounted drugs for covered entities (the rest of the pharmaceutical industry continues to comply with its statutory obligation, regardless of dispensing mechanism), Lilly, Sanofi, and Novo—three of the six manufacturers currently subject to HRSA enforcement—"make the top 12 insulin products" used by covered-entity patients, which together "represent **99%** of 340B insulin volume." *Id.* 7922. And while the 340B ceiling price is not publicly available for all of these medications, the record demonstrates that two of Lilly's insulin products, Humalog and Humalin, "are penny-priced" under 340B,[4] and alone account for 21% of 340B insulin volume. The record demonstrates one anecdote exemplifying the impact of these changes: UnityPoint Health Methodist in Peoria serves 5,000 patients, who drive up to two hours to receive diabetes care, and now are being denied access to discounted insulin "at the contract pharmacy located on UnityPoint's campus." *Id.* Prior to Lilly's restrictions, *patients themselves* saved more than $1 million annually at that location. *Id.* Since Lilly began overcharging UnityPoint for insulin dispensed to patients at its on-campus (but not entity-owned) pharmacy, clinic staff report significant adverse impacts on patients who "have had to switch from long-acting insulins to insulins that do not work as well for them, are of lesser quality, require more injections per day, or are more difficult to take (i.e., require a vial and syringe to inject)." *Id.* This concretely impacts patient health and "could result in health complications including kidney failure." *Id.* A retired Illinois police officer reports that "lack of access to 340B pricing on the cost of his insulin threatens to push him into poverty." *Id.*

Lilly's overcharges are also reflected in aggregate statistics compiled at HRSA's request in an "attempt[] to quantify the loss of units sold and savings." VLTR_7936-47. That analysis showed a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only

[4] These are two of the same medications for which covered entities documented paying many hundreds of dollars per unit, *supra*.

2.9 million in January 2021. *Id.* 7936 (Figure 1). "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* The statistics include graphs showing the stark, immediate impacts of Lilly and its peers' refusal to honor 340B pricing. Figure one shows that, from August to October 2020, when Lilly and three other manufacturers put in place their changes, 340B units sold took a nosedive from 9.6 million units to 5.1 million units sold monthly; WAC-priced units consequently rose sharply, from a negligible volume to 1 million units monthly.[5] *Id.* Figure two shows that covered entities' monthly 340B savings fell from $357 million in July 2020, just before restrictions were put in place, to $92 million in January 2021—representing annualized lost savings of $3.2 billion. *Id.* Figure three shows that, in January 2021, covered entities lost an estimated $234 million in that month *alone* and had lost an estimated $665 million in roughly four months of restrictions. *Id.* That analysis also shows the impact of Lilly's specific changes, separated from other manufacturers; its severe restrictions caused 340B sales to plummet *in one month* from roughly 1.5 million units to only .31 million units—that same month, WAC-priced units sold by Lilly skyrocketed from negligible to .35 million units. *Id.* 7937. Stated plainly, not only were millions of units of Lilly's drugs sold at above-ceiling prices to covered entities—the analysis even demonstrates that Lilly sold *more* WAC-priced units to covered entities than 340B-discounted units in the months following its restrictions. The analysis also quantifies the fiscal impact of Lilly's changes. Monthly savings to covered entities dropped from $67.5 million just before it began overcharging safety-net providers to only about $3.8 million within two months. *Id.* 7939. By January 2021, Lilly's restrictions represented an average lost savings to covered entities of $62.3 million monthly. *Id.* 7940.

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Lilly's neighborhood-pharmacy restrictions and their real-world impact on the 340B Program. After evaluating this evidence, alongside Lilly's

[5] As the analysis explains, VLTR_7936, WAC-priced units do not fully reflect the loss of 340B-priced sales and thus underrepresent the impact of manufacturers' changes. This is because some sales will be lost entirely and because covered entities' third-party administrators will shift 340B-priced sales to other purchasing accounts rather than pay the highly marked-up WAC price. For this reason, lost 340B sales is a better indicator of impact than increased WAC sales.

communications to covered entities and to the agency explaining its policy, *see* VLTR_7576; 7591; 7594; 7624; 7632, HRSA concluded that Lilly is violating the 340B statute and issued its May 17, 2021 letter to that effect.

ARGUMENT

HRSA's 340B-violation letter is a new agency action that must be challenged and considered independently from previous agency decisions. Although Lilly amended its complaint to challenge the Violation Letter after this Court ordered it to do so, ECF No. 103, it continues inaccurately to allege that the Violation Letter "enforces the final agency determination … announced in the December 30 opinion." Compl. ¶ 164. Not so: HRSA's Violation Letter is the culmination of a separate process begun *months* before the AO was issued and based directly on the statute itself—not the General Counsel's legal advice—along with copious evidence gathered through HRSA's investigative process. It also embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Lilly is overcharging covered entities and may face sanctions or expulsion from government-insurance programs. And whereas the AO opined generally and consistently with previous agency guidances on what the 340B statute requires, without purporting to analyze the legality of Lilly's restrictions, HRSA's Violation Letter concludes directly and for the first time that Lilly is overcharging covered entities. Besides, the Advisory Opinion now has been withdrawn by HHS's General Counsel, *see* ECF No. 119, yet HRSA's enforcement against Lilly proceeds unaffected. The actual dispute between the parties—whether Lilly is, in fact, in violation of its statutory obligation—now is squarely presented in the 340B Violation Letter, and must (notwithstanding Lilly's inapposite framing) be decided on the basis of HRSA's reasoning in the Violation Letter and the administrative record supporting it.

Nonetheless Lilly continues to seek declaratory relief that so fundamentally misportrays the agency's interpretation that granting it would have no bearing on HRSA's ongoing enforcement. Lilly asks this Court to declare that the statute does not "require Lilly to *offer or give 340B discounts to* contract pharmacies or on *purchases made by* contract pharmacies." Compl., Prayer for Relief ¶ b (emphasis added). As explained in HHS's opening brief and discussed extensively at this Court's hearing on

Lilly's motion for a temporary restraining order, HRSA has *never* interpreted the statute to allow contract pharmacies to purchase 340B-discounted drugs, receive 340B discounts, or otherwise participate in the program (as opposed to covered entities), so Lilly's requested declaration is meaningless. *See* HHS Mot. 13-14 (explaining that Lilly relies on artful drafting to misframe the obligation imposed upon it). Neither HHS nor HRSA require Lilly to sell any drugs to any pharmacies at any price.

But in its Violation Letter HRSA made the specific determination that Lilly's policy violates the 340B statute, 42 U.S.C. § 256b(a)(1), and may warrant sanctions, including expulsion from Medicaid and Medicare Part B, because Lilly is overcharging and refusing statutorily mandated discounts *to covered entities* using outside-dispensing channels. As demonstrated below, that conclusion is based on voluminous evidence and a correct interpretation of the statute. This Court should grant summary judgment in favor of the agency on Lilly's challenge to the Violation Letter and allow HRSA's enforcement action to proceed. The Court should also grant summary judgment for HHS on Lilly's numerous (but meritless) challenges to the ADR Rule.

I. THE COURT SHOULD ALLOW HRSA'S ENFORCEMENT OF THE 340B STATUTE TO PROCEED AGAINST LILLY

A. HRSA Correctly Found That Lilly Is Violating Its Statutory Obligation

The question before this Court is not, as Lilly would prefer, whether "the 340B statute require[s] manufacturers to deliver discounted drugs to contract pharmacies." Lilly Mot. 1. The 340B statute is (unsurprisingly) silent as to delivery location because Congress's intent was to provide access to discounted medications for safety-net providers—not to detail the minutiae of how such transactions are effectuated. Properly framed, the question before this Court is whether HRSA correctly found that Lilly's contract-pharmacy restrictions violate the statutory prohibition on overcharging covered entities. As shown herein, HRSA correctly found that Lilly cannot evade its statutory obligation by erecting hurdles around covered entities' access to discounted medications.

HRSA's 340B Violation Letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of Lilly's policy that places restrictions on 340B

pricing to covered entities," including "an analysis of the complaints HRSA has received from covered entities." Violation Letter 1. The determination "that Lilly's actions have resulted in overcharges and are in direct violation of the statute," *id.*, is not only consistent with HRSA's interpretation since 1996, *see* HHS Mot. 3-10, 17-22, but also relies directly on statutory text. *See* Violation Letter 1 (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Lilly's adherence to the 340B statutory scheme that Lilly opted into by executing a Pharmaceutical Pricing Agreement ("PPA"), that requires manufacturers to ensure that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1). It also specifies that "[e]ach such agreement shall require … that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As HRSA explained, that straightforward obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. HRSA also reminded Lilly that compliance with its PPA requires Lilly to "ensure that the 340B ceiling price is available to all covered entities." *Id.*

HRSA further explained that Lilly's restrictions run afoul of its obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because Lilly's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." *Id.* (citing 42 C.F.R. § 10.11(b)(2)). In short, HRSA's analysis rests on the statute itself and duly promulgated regulations issued through an express grant of rulemaking

authority. It does *not* rest on the HHS General Counsel's now-withdrawn Advisory Opinion, *contra* Lilly Mot. 12.

And HRSA plainly is correct in its statutory interpretation. In urging this Court to find that it can somehow fulfill its duty to honor "purchases by" covered entities while admitting that it now *denies* those very purchases (forcing covered entities instead to pay wholesale acquisition cost) based solely on delivery location or dispensing mechanism, Lilly rips particular words from statutory context and asks the Court to consider them in a vacuum. The statute does not, as Lilly portrays, only require it to *offer* drugs for purchase by covered entities, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access. And HRSA certainly has not "command[ed] manufacturers to sell outpatient drugs at 340B discounts *to contract pharmacies*," Lilly Mot. 12 (emphasis added).

Since 1992 the statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). And as discussed in detail in the government's opening brief, 19-21, HRSA's 1996 and 2010 guidances were unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense those drugs (importantly, both guidances were issued *before* Congress amended the statute to include the "offer" language on which Lilly hangs its hat). *E.g.,* ADVOP_370 (interpreting statute to *prohibit* manufacturers from denying purchases where the covered entity "directs the drug shipment to its contract pharmacy"). Read "as a whole," *United States v. Atlantic Research Corporation*, 551 U.S. 128, 135 (2007), as this Court must, 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to *sell* discounted drugs *to covered entities*.

The "offer" language in § 256b(a)(1) on which Lilly relies, added in 2010, codified an *additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases. *See* ADVOP_394, Clarification of Non-Discrimination Policy, May 23, 2012. That amendment in no way changed the substance of Lilly's preexisting obligation. Were the requirement to "offer each covered entity" discounted drugs the sum total of manufacturers'

obligation, as Lilly portrays, Mot. 3, 14-16, the inescapable conclusion would be that, from 1992 until 2010, the pharmaceutical industry sold deeply discounted drugs to covered entities on a purely voluntary basis (since the "offer" language did not yet exist). But of course that is not the case: From the statute's enactment, drug companies wishing to receive coverage for their products through certain government health-insurance programs have been required by both the statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment. Moreover, Lilly fails to grapple with the fact that its restrictions *do* violate the "offer" provision's non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases, as evidenced by the fact that Lilly places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases.

In addition to the 1996 and 2010 guidances discussed in HHS's opening brief, additional historic evidence demonstrates that HRSA always has understood the statute (and, as evidenced by their past conduct, so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. Nearly thirty years ago HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. 25,110-01, 25,112-14 (1994). In 1994 HRSA demonstrated the distinction between manufacturer requirements that *facilitate* access versus those that *restrict* access, explaining that manufacturers could "require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers." *Id.* But—although the ministerial task of collecting "standard information" such as that needed "to set up … an account" is permissible—HRSA made clear that manufacturers could not deny 340B purchases by covered entities unless non-statutory demands are met. "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations

on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and drug companies are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* 25,113-14. HRSA may not yet have conceived in 1994 of the *precise* restrictions Lilly now seeks to impose, whereby it denies sales based on the delivery mechanism and commonplace dispensing mechanism employed by the covered entity, but the agency made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill 340B orders.

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. Contrary to Lilly's insistence that its obligation to offer discounted drugs first was imposed through the 2010 amendments, *in 1994* HRSA interpreted the statute to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue."[6] *Id.* at 25,113. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to

[6] Lilly insists throughout its brief that its obligation to "offer" discounted drugs to covered entities did not arise until the 2010 amendments. *E.g.*, Lilly Mot. 15 (claiming it "literally cannot be true" that the requirement HRSA now seeks to enforce "has been clear from its guidance documents issued in 1996 and 2010"). But HRSA informed manufacturers through guidance published *in 1994* that "manufacturers must offer covered outpatient drugs" to covered entities, including when they "use purchasing agents or contract pharmacies." 59 Fed. Reg. 25,111-13. The 2010 amendments speak to a *different* obligation that manufacturers must not discriminate against 340B purchases relative to commercial sales—an obligation Lilly also is violating.

their patients through outside pharmacies, so too are 340B purchasers. *Id.* It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

Legislative history forecloses Lilly's reading of its statutory obligation, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Lilly's interpretation of the program's proper operation. The draft of what would become § 256b(a)(1) that first was considered by the Senate proposed to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity). *See* S. Rep. No. 102-259, at 1-2 (1992) (emphasis added). In other words, the bill as originally drafted would have restricted covered entities' purchases of 340B drugs to only those dispensed *directly by* the covered entity or *on-site* at the same location. But rather than codify that plain restriction on covered entities' choice of dispensing mechanism—indeed, precisely the constraint Lilly urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity. Congress legislates against the backdrop of real-world facts and surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy, and reliance on outside pharmacies was commonplace. 61 Fed. Reg. 43,550. It defies reason to suggest that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. The fact that Congress specifically chose to *remove* any restriction on how covered entities dispense medications forecloses Lilly's attempt to read those restrictions back into the statutory scheme.[7]

[7] Lilly tells this Court that "In 1992, 2010, and today, the point of the 340B program has always been to "create[] a low-cost source of pharmaceutical medication *for the indigent patients themselves*." Lilly Mot. 3. But for that proposition Lilly cites a law review article, not statutory text, and elsewhere Lilly is forced to admit that "the 340B statute does not provide for discounts to be given to the *patients* themselves, only to the covered entities." *Id.* 25. Contrary to Lilly's portrayal, the best reading of the

Lilly's interpretation is equally incompatible with the Supreme Court's depiction of the pharmaceutical pricing agreements manufacturers sign as "uniform agreements that recite the responsibilities § 340B imposes," including "impos[ing] ceilings on prices drug manufacturers *may charge for medications sold to specified health-care facilities*." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (emphasis added); *id.* at 115 ("manufacturers agree to charge covered entities no more than predetermined ceiling prices"). That straightforward reading of § 256b(a)(1) mirrors HRSA's interpretation and forecloses Lilly's policy—under which, as evidenced in the record, a covered entity is denied 340B discounts (and must pay full price) anytime the covered entity directs discounted drugs be *shipped to* outside dispensers.

Lilly's repeated claim that covered entities' decades-old, commonplace reliance on outside pharmacies to dispense the drugs they purchase "allow[s] diversion—[] conduct specifically proscribed by the statute," Lilly Mot. 32, is meritless. As explained in HHS's opening brief, 27-28, the statute states that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), which quite plainly means that covered entities may not provide discounted drugs for use by non-patients or non-covered healthcare providers for prescribing to their own patients. That straightforward prohibition on use of 340B drugs by non-eligible patients or providers cannot be stretched into an implicit prohibition on patients physically attaining those drugs at neighborhood pharmacies—*i.e.*, the locations where most Americans receive prescription drugs. Pharmacies store and handle the medications on behalf of eligible patients of eligible covered entities.

The covered entity is not "simply lend[ing] its name to the prescription—nothing more," as Lilly charges (Mot. 28); Lilly simply misreads the statutory prohibition on transfer of discounted drugs. Its proper understanding has been clear since 1994, when HRSA issued "guidelines regarding drug diversion," explaining that "[c]overed entities are required not to resell or otherwise transfer outpatient

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statute (and one that comports with legislative history) is that Congress designed the program to provide much-needed funding *to safety-net providers* to allow for expanded access to care for underserved communities. And as evidenced in the administrative record and discussed in the background to this brief, 340B savings are fulfilling that vital role.

drugs purchased at the statutory discount to an individual who is not a patient of the entity" and that "[t]here are several common situations in which this might occur." 59 Fed. Reg. 25,112-13. That guidance went on to explain that covered entities must "develop and institute adequate safeguards" to ensure that discounted drugs are dispensed only to eligible patients, that covered entities must use 340B drugs only in outpatient settings (not for inpatient services), and that a larger provider which contains both a covered entity and non-eligible entity must "maintain separate dispensing records for the eligible entity." *Id.* These situations have in common that they all would involve dispensing and use of 340B-discounted drugs for either ineligible patients, services, or settings—but they certainly would not, as Lilly posits, encompass instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity. As HRSA has confirmed for decades, "the use of contract services is only providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." 61 Fed. Reg. 43,550. There is no unlawful transfer of discounted drugs when a covered entity purchases drugs for dispensing at outside pharmacies, because pharmacies only are facilitating the exchange of tightly controlled *prescription drugs* on behalf of admittedly eligible patients of admittedly eligible prescribers.

Lilly continues to counterfactually insist that this dispute concerns "transactions in which covered entities do not themselves 'purchase' covered outpatient drugs," Compl. ¶ 281, and that HRSA is forcing "manufacturers *to sell* outpatient drugs at 340B discounts *to contract pharmacies*," Lilly Mot. 12. Those claims are flatly disproven by record evidence documenting Lilly's overcharges to covered entities (and the harms to patients now being denied access to discounted medications).[8] Not only is Lilly's portrayal of the system ungrounded in evidence, it expressly relies on extra-record materials that this Court should not credit. "[T]he focal point for judicial review should be the

[8] Lilly's claim that the statute leaves it to drug makers to "lawfully opt [whether] to deliver discounted product to a dispensing pharmacy of the covered entity's choosing," Lilly Mot. 5, would mean that Congress enacted a novel social-safety-net program creating a new statutory right that, *at time of passage*, could not be accessed by 95% of intended beneficiaries. That interpretation renders the statutory obligation toothless and cannot have been Congress's intent.

administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (*per curiam*). Lilly points to a "study" performed by Aaron Vandervelde, a self-styled "nationally recognized expert on the 340B program" who has filed a purported *amicus curiae* brief before this Court. *See* ECF No. 92-1 at 1 (Vandervelde materials relied upon by Lilly at Compl. p. 3, ¶¶ 49, 51, 53, 59). These materials are not only inappropriate extra-record material, they also come from a biased source[9] and are used by Lilly to present a misleading view of the so-called "replenishment model" on which some covered entities rely. *E.g.*, Compl. ¶ 58 (claiming "contract pharmacies therefore may purchase prescription drugs at these same steep discounts … but then turn around and sell them for the full list price); *id.* ¶ 56 ("Like covered entities, contract pharmacies pay significantly discounted prices, known as ceiling prices … ."). In truth, even under this model manufacturers are still selling drugs to covered entities, not pharmacies, and thus must do so at the discounted 340B price. *See* Decl. of Krista M. Pedley ("Pedley Decl.") ¶ 10, attached here as Exhibit 2 (explaining that, under the replenishment model, "the covered entity is the legal purchaser and authorizes the order").[10]

Generally speaking, under the replenishment model, a covered-entity patient who is 340B eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the

[9] Mr. Vandervelde acquired his purported "expertise" by serving as an industry consultant for PhRMA, the predominant pharmaceutical-manufacturer trade organization, and producing materials for PhRMA that undermine the 340B Program. Vandervelde *curriculum vitae*, *available at* https://media.thinkbrg.com/wpcontent/uploads/2020/06/27145336/Vandervelde_Aaron_CV.pdf (last visited June 15, 2021). Mr. Vandervelde prepared for PhRMA a lengthy publication on "abuse" of 340B by contract pharmacies, Aaron Vandervelde, et al., *For-Profit Pharmacy Participation in the 340B Program* (October 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf, cited in Lilly's complaint, and has even developed and sold the very software platform that some manufacturers now are using to impose contract-pharmacy restrictions. *See* Email from J. Garner to K. Talmor (May 7, 2021 12:07:47 PM), attached here as Exhibit 1. Aside from constituting impermissible extra-record evidence, Mr. Vandervelde has a *financial* stake in manufacturers' ability to continue their contract-pharmacy restrictions (and a client relationship with PhRMA), thus rendering his views a particularly inappropriate basis for Lilly's allegations.

[10] While Lilly's challenge to HRSA's letter should be decided on the basis of the administrative record, RADM Pedley submits her declaration in response to the extra-record Vandervelde materials relied upon heavily in Lilly's complaint. Pedley Decl. ¶ 2.

prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. *Id.* ¶ 3; *see also e.g.*, VLTR_7323; *id.* 7257. The model works in three main steps. First, a contract pharmacy dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient is eligible for 340B savings. Pedley Decl. ¶¶ 5-6. The software is operated under the oversight of the covered entity, and HRSA audits the process by taking a sample of drugs dispensed and requiring the covered entity to show "each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient." *Id.* ¶ 6. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *Id.* ¶¶ 7-8; *see also e.g.*, VLTR_7317 (covered entity explaining "virtual inventory" system where "each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the covered entity] places an order via our 340B wholesaler to replenish the contract pharmacies' stock"). Importantly, the order is placed on a covered entity's 340B account and the covered entity is billed for that order. Pedley Decl. ¶ 9. If any dispute (including instances of non-payment) about the invoice arises, it is the covered entity that is responsible—not the contract pharmacy—which merely serves as the "ship to" address on the invoice. *Id.* During this process, "the covered entity is the legal purchaser and authorized the order." *Id.* ¶ 10; *see also, e.g.* VLTR_7296 (declaration of covered entity CEO explaining that it purchases "drugs at 340B pricing … and direct[s] those drugs to be shipped to our contract pharmacies on a replenishment basis," during which time the covered entity "maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies"); VLTR_7279 (same). Indeed, the covered entity should be aware of all replenishment orders and "the order is often approved by the covered entity prior to submission to the wholesale/distributor to ensure accuracy." Pedley Decl. ¶ 10. Finally, the drug is shipped to the contract pharmacy, where it becomes neutral inventory "and may be dispensed to any subsequent patient." ¶ 11.

At no point during this process is the pharmacy *purchasing* 340B drugs (nor do they "drive the transactions," *contra* Lilly Mot. 32); the drugs simply are delivered to pharmacies after being purchased by covered entities to replenish the drugs that were distributed to 340B-eligible patients. This model

does not "expand … the list of covered entities eligible to participate in, and receive discounts pursuant to, the 340B program," *id.* 33, because the manufacturer still is charging the covered entity the price of the 340B-eligible drug and those purchases are tracked and tied to dispenses to eligible patients of the covered entity. On the contrary, it is Lilly's policy that violates the will of Congress because, when Lilly refuses to honor purchase requests placed by a covered entity based solely on the "ship to" location specified on an invoice, it forces the covered entity either to pay commercial pricing or forego the needed medication altogether. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25, 110, 25,113 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Lilly most glaringly distorts the agency's interpretation by claiming that HRSA is "allowing for-profit enterprises to milk [340B] for their benefit" through "draconian wealth transfers" "for the benefit of contract pharmacies," Lilly Mot. 2. On the contrary, though Lilly is correct that only the statutorily enumerated covered entities may participate in the program, HHS need not "expand[] the scope of the program," *id.* 5, for covered entities to continue their decades-old reliance on neighborhood pharmacies. Lilly's misframing of the program's current operation serves to obscure the fact that Lilly is *denying* sales to covered entities.

Lilly studiously avoids any discussion of the real-world impact of its new restrictions, claiming that it allows covered entities to use neighborhood pharmacies, "but only so long as the contract pharmacies agree to pass on the entire discount to the patient"—*i.e.*, so long as a business agrees to provide a valuable service for free. Lilly Mot. 41. Aside from being unsupported by statute, Lilly is inaccurately describing its own policy; in actuality, its narrow "exception" applies *only* to insulin products. *See* Compl. ¶ 82. And even if Lilly allowed covered entities' patients to access all its products through neighborhood pharmacies, Lilly's "pass on the entire discount" restriction is not reasonable

or workable in practice. As explained *supra*, Background, pharmacies provide the necessary infrastructure to allow covered entities to access the benefits of the 340B Program, including paying for all of the retail space, licensing, human resources, and other requirements to store and dispense pharmaceuticals. They collect a reasonable, set fee for that service and pass on savings either to indigent patients or to the covered entity. Lilly cannot demand pharmacies perform these services *for free*.

Lilly similarly elides any substantive discussion of how, exactly, its policy can fulfill the statutory duty to charge covered entities no more than the ceiling price while *charging them WAC prices* based solely on delivery location. Instead, Lilly relies on the reductionist observation that "contract pharmacies are not covered entities" and argues that "should be the end of the matter." Lilly Mot. 25. But Lilly ignores the fact—proven now in the administrative record—that its restrictions *have* forced covered entities to pay inflated commercial prices for Lilly's products (because it is not, as Lilly wishes, contract pharmacies that make the purchases). Lilly also ignores the fact that its refusal to deliver its drugs to pharmacies capable of dispensing them on behalf of the covered-entity purchaser renders its "offer" to sell drugs meaningless in practice in many instances. These are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Congress did not need to impose any explicit *delivery* obligation on manufacturers; it is self-evident that prescription drugs *cannot* be delivered to just any location. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, staff pharmacists, appropriate storage space to keep and safeguard medications, software to bill insurers, etc., that would allow it to take delivery of, and dispense, pharmaceuticals. As has been explained in this litigation, the majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are not entitled to handle their own dispensing or even to *take delivery* of Lilly's medications. And even for those that do, as explained *supra*, Background, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or in just one location. *E.g.*, VLTR_7260-61 (explaining that

covered entity "provide[s] primary health care and related services *across a 10,000 square mile service area*" for population that "is significantly underserved, aging, and impoverished" and who rely on "local retail pharmacies" to obtain medications). Were it as simple as Lilly portrays for covered entities to accept its "offer" through direct, in-house dispensing, 340B sales would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra* 9-10.

These practical realities demonstrate that Lilly's purported offer to ship its drugs to each provider's physical location often is meaningless in practice. If Lilly were correct that it only had to *offer* drugs to covered entities, not to also "deliver the product" to a location where the covered entity can accept and use the drugs for its patients, Lilly Mot. 28, then by the same logic it could refuse to deliver drugs at all and force covered entities to physically pick up prescriptions from Lilly's warehouses. Clearly, in mandating that manufacturers provide discounted drugs to covered entities, Congress intended manufacturers to honor real-world, preexisting supply chains (including sales made through wholesale channels for delivery to pharmacies, which Lilly now refuses), not to force safety-net providers to restructure their businesses entirely to allow for in-house drug dispensing *or* to require thousands of patients of the covered entity all to obtain their monthly refills at one designated location. Lilly's restrictions thwart the intent of Congress by erecting barriers to covered entities' ability to access the program in practice. Manufacturers like Lilly have known for thirty years that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program," 59 Fed. Reg. 25,113.

Nor did HRSA previously suggest that it "had no authority to require manufacturers to provide drugs at 340B prices" to covered entities that dispense through contract pharmacies, *contra* Lilly Mot. 6. Lilly rips from context statements in which an individual HRSA official acknowledged that the agency is limited to enforcing requirements that derive *from the statute* because Congress has not granted the agency explicit authority to promulgate rules having the force and effect of law in

some instances. HRSA's statements only confirm (accurately) that *guidance* is unenforceable.[11] But that does not mean HRSA now is relying on the (withdrawn) AO or guidance, rather than the statute and manufacturer PPAs (which are enforceable), to determine that Lilly is out of compliance. On the contrary, the record evidences that Lilly's restrictions have forced some covered entities to pay inflated WAC prices for Lilly's drugs while others are foregoing certain 340B purchases altogether. Both results are unlawful, when caused by Lilly's refusal of discounts based solely on delivery location.

HRSA agrees with Lilly that the statute does not allow contract pharmacies to participate in or become beneficiaries of the 340B Program, and that Lilly has no obligation to sell discounted drugs to *any* pharmacies. But the statute conditions Medicaid and Medicare Part B access on Lilly's agreement to provide its discounted drugs to covered entities, and does not authorize Lilly to place barriers that make those purchases inaccessible in practice. HRSA's review of the evidence has demonstrated that Lilly is denying sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies. Lilly remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to flout its statutory obligation.

B. HRSA'S VIOLATION LETTER IS A REASONABLE INTERPRETATION OF THE 340B STATUTE, AND IS BOTH SUBSTANTIVELY AND PROCEDURALLY COMPLIANT WITH THE APA.

1. HRSA's determination that Lilly is flouting its statutory obligation is neither arbitrary nor capricious.

HRSA reasonably explained its conclusion that Lilly is violating its statutory obligation in the Violation Letter, and properly grounded its determination in the text of Section 340B. Agency action is not arbitrary and capricious under § 706(2)(A) of the APA if the agency "has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Judicial review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut.*

[11] Similarly, although HRSA did "ma[k]e patently clear that such guidance did not create new rights and obligations," Lilly Mot. 6, HRSA also made clear that was because *the statute itself* required manufacturers to honor covered entities' purchases, so no new rulemaking to that effect was required. *See* 61 Fed. Reg. 43,550.

Auto. Ins. Co., 463 U. S. 29, 43 (1983)). And a court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). Here, Lilly makes a number of attempts to pick apart HRSA's reasoning—none of which are persuasive—and the Court should reject Lilly's effort to undermine HRSA's enforcement of the 340B statute.

Lilly argues that HRSA "does not acknowledge" its concerns about the proliferation of contract pharmacy arrangements. Compl. ¶ 300. But HRSA was not required to consider manufacturers' generalized concerns about contract pharmacy arrangements because it was not relevant to the question before it—whether Lilly's specific policy violated the 340B statute. *See U.S. v. An Article of Device . . . Diapulse, etc.*, 768 F.2d 826, 830 (7th Cir. 1985). In any event, HRSA did, in fact, consider Lilly's concerns about contract pharmacy arrangements, including diversion and duplicate discounts. The Violation Letter concluded that the 340B statute "provides a mechanism by which a manufacturer can address these concerns." VLTR_4. "Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in [the statute]." *Id.* Although Lilly suggests that HRSA improperly placed "the burden on manufacturers," Lilly Mot. at 39, it is in fact Congress who required manufacturers both to address diversion and duplicate-discounting concerns in the ADR process and to audit covered entities before availing themselves of the ADR process. 42 U.S.C. § 256b(d)(3)(B)(iv) (requiring "that a manufacturer conduct an audit of a covered entity . . . as a prerequisite to initiating [ADR] proceedings against a covered entity"). It cannot be arbitrary and capricious for the agency to simply require manufacturers to follow the procedures that Congress mandated to address their concerns regarding diversion and duplicate discounting. Indeed, as HRSA acknowledged, the 340B statute does not provide an end run around the ADR process by allowing manufacturers to impose "industry-wide, universal restrictions." VLTR_4.

While Lilly purports to be concerned with "program integrity," the record underlying the Violation Letter tells a different story. Lilly Mot. at 39-40. For example, aggregate statistics contained in the record provide evidence that Lilly's actions have negatively impacted covered entities, in direct

contrast to congressional intent, and in contrast to Lilly's generalized grievances about the 340B program. When Lilly stopped offering 340B pricing on drugs shipped to contract pharmacies, the number of 340B-priced units of Lilly drugs sold through contract pharmacies plummeted from 1.55 million to .31 million and the number of non-discounted units rose from under .01 million to .35 million. *See* VLTR_7937. This constituted $55.9 million in average lost savings by covered entities on Lilly products in September 2020 alone, a trend which continued with more than $60 million in lost savings per month over the next four months. *See* VLTR_7940. These statistics represent thousands of transactions in which Lilly's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices, with direct and substantial impacts on the savings of covered entities. Thus, contrary to Lilly's allegations that HRSA failed to "reconcile its approach" with "abuses" of the 340B program, Lilly Mot. at 40, HRSA relied on clear evidence of the harm to covered entities and their patients in issuing the Violation Letter.

In addition to Lilly's new arguments with respect to the Violation Letter, Lilly also attempts to recast several of its other arguments as reasons to declare the Violation Letter arbitrary and capricious. These attempts are unpersuasive. For example, Lilly attempts to reincorporate its statutory claims into its arbitrary and capricious claim, arguing that HRSA fails to "reconcile" its position "with the text of the statute." Compl. ¶ 300. But, as explained *supra* Sec. I.A., the Violation Letter is consistent with and squarely based on the text of the 340B statute, and Lilly's re-casting of its argument does not undermine this conclusion. Lilly also repeats its oft-stated and incorrect conclusion that HHS has changed its position with respect to manufacturers' obligations under the 340B statute, Compl. ¶¶ 300, 302, an issue which has been exhaustively briefed and corrected by HHS. Finally, Lilly claims that the Violation Letter cannot be reconciled with the "agency theory" supposedly contained in the AO. Compl. ¶ 301. This claim is meritless because, in addition to the inescapable fact that the AO has been withdrawn, the "agency" discussion in that Opinion was limited to creating a helpful analogy to rebut manufacturers' claims of diversion, not a prerequisite to the application of statutory requirements.

HRSA's Violation Letter is both "reasonable and reasonably explained," and the Court should grant HHS's motion for summary judgment on Lilly's claim to the contrary. *Prometheus*, 141 S.Ct. at 1158.

2. The APA's notice-and-comment requirement is inapplicable to HRSA's 340B Violation Letter.

Lilly claims that HRSA's Violation Letter should be set aside for failing to comply with the APA's notice-and-comment procedures set forth in 5 U.S.C. § 553(b)(3)(A). Compl. ¶ 306–10. This procedural objection is built on the same flawed assertion that Lilly leveled at the AO: That HRSA's Violation Letter "creates" or "enshrines" a "new obligation[]" that is "binding" on the drug maker, turning the letter into a legislative rule that can only be issued by notice-and-comment rulemaking. Compl. ¶¶ 306–09; *see also Metropolitan School District of Wayne Township v. Davila* (*Davila*), 969 F.2d 485, 489 (7th Cir. 1992) ("[I]f by its action the agency intends to create new law, rights, or duties, the rule is properly considered to be a legislative rule." (citation omitted)). But as with the AO, *see* HHS Mot. 22–24, HRSA's letter imposes no new obligations on Lilly. The Violation Letter merely enforces a *pre-existing* obligation sounding in the 340B statute itself, *see supra* § I.A, and is thus an interpretive rule exempt from the APA's notice-and-comment requirement. *See Davila*, 969 F.2d at 489 ("An interpretive rule simply states what the administrative agency thinks the underlying statute means, and only reminds affected parties of existing duties"); *see also Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666 (6th Cir. 2005) ("[A] pure legal determination of what the applicable law already is does not require notice and comment under APA § 553(b).").

The Seventh Circuit in *Davila* rejected arguments virtually identical to those asserted by Lilly in support of its procedural challenge. There the court considered whether a letter (issued by a sub-agency of the Department of Education) interpreting Part B of the Individuals with Disabilities Education Act ("IDEA-B") to require that school districts provide educational services to expelled disabled children "or face potential sanctions" was a legislative rule subject to the APA's notice-and-comment requirement. *Davila*, 969 F.2d at 487–89. The court found the letter to be a "paradigmatic case of an interpretive rule," because it "relie[d] upon the language of the statute and its legislative

history" to "simply state[] what" the agency "thinks the IDEA-B requires." *Id.* at 492. In so holding, the court rejected the notion "that a binding rule is necessarily a legislative one" (as Lilly argues here), asking rhetorically: "Could an agency [seriously] announce, 'We think Congress intended this when it enacted this statute, but you don't have to do it.'?" *Id.* at 493. "All rules which interpret the underlying statute must be binding … on the regulated parties," the court reasoned, "in the sense that they set … the legal minima of behavioral standards" in light of "what the agency believes is congressional intent." *Id.* (citation omitted). The court explained similarly that "a rule affecting rights and obligations is not *ipso facto* legislative" either. *Id.* (quoting *Production Tool v. Employment & Training Admin.*, 688 F.2d 1161, 1166 (7th Cir. 1982)). "Penalizing the agency for explaining what was for the plaintiffs bad news about [the meaning of a statute] would be like killing the messenger." *Id.* (citation omitted). Therefore, although the letter before it announced binding obligations that had substantial impacts on the regulated parties, the court found that the letter "simply explained what the statute already requires" and was thus exempt from the APA's notice-and-comment requirement. *Id.* at 493.

So too here. HRSA's Violation Letter simply alerts Lilly that it is acting in contravention of "what the [340B] statute already requires"—namely, that Lilly sell 340B-discounted drugs to covered entities regardless of how those drugs will be dispensed to patients. *See id.*; *accord Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994). By drawing this obligation directly from "the language of … specific statutory provisions" and the 340B statute's legislative history, the letter "merely explicate[s] Congress' desires." *Davila*, 969 F.2d at 490, 492 (alteration adopted and citation omitted); *accord Columbus Regional Hosp. v. Fed. Emergency Mgmt. Admin*, 2012 WL 13027087, at *7 (S.D. Ind. Mar. 29, 2012) (Barker, J.) (applying *Davila* and finding agency decision "based upon" its interpretation of "a specific statutory provision" to be "an interpretive rule exempt from notice and comment"). It is thus *Congress* that has spoken with "the force and effect of law" to "bind[]" Lilly to this statutory requirement, not HHS. *See id.* at 490, 493.

C. HRSA'S VIOLATION LETTER DOES NOT EFFECT A TAKING

Lilly alleges that the Violation Letter contravenes the Takings Clause of the Fifth Amendment on the same grounds that it challenged the Advisory Opinion: (1) the letter effects a "purely private"

regulatory taking of Lilly's property by forcing Lilly to transfer its drugs to contract pharmacies "solely" to serve those entities' private interests, Compl. ¶¶ 289–92; and (2) by requiring Lilly to succumb to a private regulatory taking of property to obtain coverage of its drugs under federal health-insurance programs, the letter imposes an unconstitutional condition on a valuable government benefit, *id.* ¶¶ 293–96. As explained in HHS's dispositive motion, *see* HHS Mot. 29–37, Lilly's takings claims—whether directed at the withdrawn Advisory Opinion or the Violation Letter—are doctrinally barren and do not articulate a viable theory under the Takings Clause.

Lilly argues further that HHS has adopted a constitutionally problematic reading of the 340B statute, such that the Court should apply the canon of constitutional avoidance and reject the agency's statutory interpretation. Lilly Mot. 33. But because the 340B statute offers but "one plausible construction," *see Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018)—that drug makers must sell 340B-discounted drugs to covered entities irrespective of their method of distribution, *see supra* § I.A "the canon of constitutional avoidance has no role to play here," *see Warger v. Shauers*, 574 U.S. 40, 50 (2014). Were the Court to disagree, Lilly's contention would still fail, because it has identified no "serious constitutional problems" with HHS's interpretation. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988); *accord Almendarez-Torres v. United States*, 523 U.S. 224, 238 (1998) ("[To] invoke the doctrine," courts must find "a serious likelihood that the statute will be held unconstitutional.").

1. To begin, Lilly challenges the Violation Letter as effecting a private regulatory taking. Apart from "two relatively narrow categories" of *per se* regulatory takings that are not applicable here, "regulatory takings challenges are governed by the standards set forth in *Penn Central Transportation Co. v. New York City*, 438 U.S. 104 (1978)." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538–40 (2005). But in both opposing HHS's dispositive motion and moving for preliminary relief, Lilly makes no mention of *Penn Central* or the factors it applied to determine whether regulatory action amounts to a taking. By ignoring this governing legal framework "for resolving regulatory takings claims," *id.*, Lilly's private-regulatory-takings claim (as well as its derivative unconstitutional-conditions claim, *see Singer v.*

City of New York, 417 F. Supp. 3d 297, 327 (S.D.N.Y. 2019) ("Absent the pleading of facts sufficient to demonstrate a 'taking,' an unconstitutional conditions doctrine claim fails.")) cannot succeed.

That should resolve Lilly's constitutional complaints. But even assuming that Lilly addressed the *Penn Central* factors and that they weighed in its favor (they do not, *see* HHS Mot. 32 n.6), Lilly cannot demonstrate a taking based on an obligation arising under the 340B Program in which it voluntarily participates. *See Ruckelshaus v. Monsanto Co.* (*Monsanto*), 467 U.S. 986, 1007 (1984); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983); *see also* HHS Mot. 31 (collecting cases from eight other federal courts of appeals). Lilly offers no cogent response to this substantial, unified body of precedent.

Lilly first claims that it "never 'voluntarily' participated" in the 340B Program with the understanding that it was statutorily required to sell discounted drugs to covered entities with contract-pharmacy arrangements. Lilly Mot. 35. But Lilly cannot escape the record. Drug manufacturers participating in the 340B Program have been aware for decades that the 340B "statute directs [a] manufacturer to sell [a covered outpatient] drug at the discounted price" to "a covered entity using contract pharmacy services."[12] 61 Fed. Reg. at 43,549; 75 Fed. Reg. at 10,278; VLTR_7627. Notwithstanding this statutory obligation, Lilly chose to participate in the 340B Program, *see* Compl. at 2 ("[M]anufacturers are not formally required to participate in the Program."), in exchange for the substantial economic benefits available under Medicaid and Medicare Part B. Indeed, Lilly *continues* to participate (and thus *continues* to generate substantial revenue from those federal health insurance programs) even though it is free to walk away from the program at any time and to thus free itself from any regulatory burdens it finds objectionable. An obligation imposed under such a voluntary government program "can hardly be called a taking." *See Monsanto*, 467 U.S. at 1007.

Lilly also seeks to escape *St. Francis Hospital Center*, *see* Lilly Mot. 37, in which the Seventh Circuit rejected a takings challenge to a regulatory condition imposed on voluntary participants in the

[12] Lilly's attempt to distinguish *Monsanto* on the grounds that the regulated entity in that case had been aware of the statutory obligation to relinquish its property in exchange for a valuable government thus provides Lilly no refuge. Lilly Mot. 37.

Medicare program, 714 F.2d at 875–76. Lilly asks the Court to simply ignore this binding Circuit precedent because it was decided "before the Supreme Court's modern takings cases." Lilly Mot. 37. But Lilly points to no "modern" decision of the Supreme Court that unsettles either *St. Francis Hospital Center* or the decidedly "modern" decisions of other federal courts of appeals relying on the same basic takings principle applied therein. *See, e.g., Nat'l Lifeline Ass'n v. FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020); *Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Baker Cty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1278–80 (11th Cir. 2014). Even if there were such a decision, however, it would still not be the prerogative of *this* Court to ignore binding Circuit precedent. *See United States v. Wahi*, 850 F.3d 296, 302–03 (7th Cir. 2017) ("[A] district judge [must] faithfully follow[] existing circuit precedent," even "when an intervening Supreme Court decision unsettles [that] precedent."); *see also Beckem v. Minott*, 2015 WL 3613714, at *1 (S.D. Ind. June 9, 2015) ("[I]t is for the Seventh Circuit, not [a district court], to revisit or clarify [the Circuit's] position on [an] issue should it choose to do so.").

2. Assuming only for argument's sake that the Violation Letter did effect a taking of Lilly's property, such a taking would easily satisfy the Fifth Amendment's exceedingly deferential "public use" requirement because it is "rationally related to a conceivable public purpose." *See Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 241 (1984); *see also Daniels v. Area Plan Comm'n of Allen Cty.*, 306 F.3d 445, 460 (7th Cir. 2002) ("[T]he burden on the [government] is remarkably light … [and] the scope of judicial scrutiny is narrow[.]"). As already explained, *see* HHS Mot. 33–34, Congress created the 340B Program to help both uninsured and under-insured patients "afford costly medications" and covered entities serving those patients to "use the discounts [on drugs] to stretch scarce federal resources and serve a greater number of uninsured and under-insured patients." *See Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *1 (N.D. Cal. Feb. 17, 2021); *see also* H.R. Rep. No. 102-384, pt. 2, at 12. And Congress sought to achieve these public benefits by requiring drug manufacturers, in exchange for the benefits available under Medicaid and Medicare Part B, to sell discounted drugs to covered entities, regardless of how those drugs are dispensed to patients. That legislative determination cannot be said to be "palpably without reasonable foundation," *Daniels*, 306 F.3d at 460 (quoting *Midkiff*, 467 U.S. at 241), particularly in light of evidence that this statutory requirement is achieving its objectives, *see, e.g.*,

VLTR_1571, 7257, 7262; *but see Nat'l R.R. Passenger Corp. v. Bos. & Me. Corp.*, 503 U.S. 407, 422–23 (1992) (a taking need not "accomplish its objectives" to satisfy the public-use requirement). It is thus "not for [this Court] to reappraise" Congress's decision, *Berman*, 348 U.S. at 33, *even if* the Court finds that it was not the "perfect" plan, "or the best possible scheme, or even likely to achieve its intended goal," *Keystone Bituminous Coal Ass'n v. Duncan*, 771 F.2d 707, 719 (3d Cir. 1985).

Lilly offers no arguments addressing the standard (outlined above) by which public-purpose determinations are properly evaluated under the Fifth Amendment, choosing instead to craft new, alternative standards that have no doctrinal basis in the Public Use Clause.

Lilly first contends that HHS has effected a "*purely* private taking" of the drug manufacturer's property because selling 340B drugs to covered entities with contract-pharmacy arrangements benefits private parties—*i.e.*, contract pharmacies.[13] Lilly Mot. 33–34 (emphasis added and citation omitted). But "the fact that a taking creates incidental benefits for individual private parties 'does not condemn that taking as having *only* a private purpose.'" *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 309 (3d Cir. 2008) (emphasis added) (quoting *Midkiff*, 467 U.S. at 243–44); *accord Daniels*, 306 F.3d at 461–62. In fact, the Supreme Court has "foreclose[d] this objection" for the "simpl[e]" reason that "government's pursuit of a public purpose will often benefit individual private parties," *Kelo v. City of New London*, 545 U.S. 469, 485 (2005), and "[a]ny number of cases illustrate that the achievement of a public good often coincides with the immediate benefitting of private parties," *id.* at 485 n.14; *see, e.g.*, *Berman v. Parker*, 348 U.S. 26, 32–34 (1954) (affirming the public purpose underlying a taking of private property that would be transferred to private parties whose private interests would directly benefit from the taking); *accord Midkiff*, 467 U.S. at 243–45; *Monsanto*, 467 U.S. at 1014–16.[14]

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[13] Lilly takes its allegations a step further by asserting, without any support, that "[t]he government explicitly admits that its expansion of the statute seeks to benefit … contract pharmacies." Lilly Mot. 34. This remark warrants no response, as it so fundamentally mischaracterizes HHS's arguments and ignores the public benefits Congress sought to achieve (and *has* achieved) by requiring drug manufacturers to sell 340B drugs to covered entities irrespective of whether they depend on contract pharmacies to dispense drugs to needy patients.

[14] Lilly thus misapprehends Supreme Court precedent by suggesting that the Court would not uphold a taking were it to "*benefit*[]'a particular class of identifiable individuals.'" Lilly Mot. 34 (emphasis added)

Lilly also maintains that the challenged "taking" cannot satisfy the public-use requirement because it does not "abate some public nuisance." Lilly Mot. 34. But no public nuisance was abated by the alleged taking of trade secrets in *Monsanto*, 467 U.S. at 1014–16 (finding that the elimination of time-consuming registration processes would promote competition in the pesticide market, which was a sufficient public purpose to satisfy the Fifth Amendment); nor by the taking of IOLTA funds in *Brown v. Legal Foundation of Washington*, 538 U.S. 216, 231–33 (2003) (finding the provision of legal services to individuals in need qualifies "as a 'public use' within the meaning of the Fifth Amendment"); nor by the taking of rail track in *National Railroad Passenger Corp.*, 503 U.S. at 422 (finding the facilitation of Amtrak's rail service "suffices to satisfy the Constitution")—and the list could continue, *see Kelo*, 545 U.S. at 486 n.16 (citing prior precedent to reject the "novel theory that the government may only take property and transfer it to private parties when the initial taking eliminates some 'harmful property use'" (*e.g.*, a public nuisance)). Yet, in each case, the Supreme Court found that the purported taking of property was justified by an underlying public purpose.

3. In challenging the Violation Letter under the unconstitutional-conditions doctrine, Lilly relies on the Supreme Court's decisions in *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), *Dolan v. City of Tigard*, 512 U.S. 374 (1994), and *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013), *see* Compl. ¶¶ 294–96; *see also* Lilly Mot. 35–36, without acknowledging that the Supreme Court has doctrinally delimited the applicability of these three decisions to "the special context of exactions" in land-use permitting decisions, *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702–03 (1999); *accord Koontz*, 570 U.S. at 604 ("*Nollan* and *Dolan* 'involve a special application' of [the unconstitutional-conditions] doctrine . . . for property the government takes when owners apply for land-use permits." (quoting *Lingle*, 544 U.S. at 546–47)); *id.* at 604–05 (explaining that the "nexus" and "rough proportionality" requirements of *Nollan* and *Dolan* were developed to accommodate realities

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(quoting *Kelo*, 545 U.S. at 478). Lilly's view of *Kelo* (and thus *Midkiff*) misses the point the Court actually made in those cases—that is, that the Public Use Clause forbids the government from taking property "when executed *for no reason other than* to confer private benefit on a particular private party … or a particular class of identifiable individuals." *Midkiff*, 467 U.S. at 245; *accord Kelo*, 545 U.S. at 477–78. No such argument can be made here.

unique to the adjudicative land-use permitting process). But even assuming this idiosyncratic line of cases could be generalized to apply beyond the land-use permitting context, Lilly fails to mention, let alone apply, the nexus-and-rough-proportionality test the Supreme Court has distilled from *Nollan* and *Dolan* to evaluate the constitutional propriety of a an exaction conditioning the provision of a land-use permit. *See Koontz*, 570 U.S. at 604–05. In fact, Lilly seems to suggest that *all* conditions on government benefits that affect constitutionally protected interests are *per se* invalid, a position rejected by the very authorities on which Lilly relies, *see, e.g.*, *id.*, and others, *see Burgess v. Lowery*, 201 F.3d 942, 947 (7th Cir. 2000); *Hall v. Sweet*, 666 F. App'x 469, 476 (6th Cir. 2016) (unpublished).

Relying on *National Federation of Independent Businesses v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), Lilly also suggests that the Constitution forbids the government from using "financial inducements" to encourage private parties to relinquish their property in exchange for a valuable government benefit. Lilly Mot. 36 (quoting *NFIB*, 567 U.S. at 577). But Lilly's reliance on *NFIB* is misplaced, as that case concerned the alleged coercion of state governments to implement a federal program, which is not at issue here. Nor can Lilly square its argument with the Supreme Court's decision in *Monsanto*, which rejected an unconstitutional-conditions challenge to a condition on a valuable government benefit (*i.e.*, a license to sell a product) *for the very reason* that the plaintiff received "the economic advantages of" the license "in exchange" for relinquishing its property. 467 U.S. at 1007. And the Seventh Circuit and a number of lower courts are in accord with *Monsanto*, finding regulatory conditions affecting property constitutionally permissible under the Takings Clause "[d]espite the strong financial inducement" the government used to encourage compliance. *See, e.g.*, *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *accord St. Francis Hosp. Ctr.*, 714 F.2d at 875–76; *see also* HHS Mot. 35–36 (collecting cases).

D. THE *ASTRA* DECISION DOES NOT COMPEL A DIFFERENT RESULT

The district court's recent decision in *AstraZeneca Pharmaceuticals LP v. Becerra* does not answer the statutory question before this Court—whether HRSA correctly found that Lilly is overcharging covered entities—indeed, the Violation Letter was not even before that Court. No. 21-27-LPS, ECF No. 78 (June 16, 2021) (*Astra* op.). On the contrary, the *Astra* court made plain that its "role" in that

opinion was "to decide only the narrow question[]" whether "the position outlined in the [AO] [is] compelled by the unambiguous text of the 340B statute." *Id.* at 1. Answering that question, the court found the AO to be "legally flawed" because its "analysis is not the sole reasonable interpretation of the statute." *Id.* at 17, 2. Far from setting forth a position *contrary* to law, however, the court confirmed that "HHS's current interpretation of the statute is permissible." *Id.* at 19. Thus not only did the *Astra* court have neither any claims regarding HRSA's Violation Letter nor the administrative record before it, the Court expressly found that the General Counsel's view regarding manufacturers' obligations represents a permissible reading, albeit not an unambiguous one.[15]

Although HHS disagrees that there is ambiguity regarding whether manufacturers can deny 340B-priced drugs to covered entities based on the dispensing mechanism or delivery location chosen by the purchaser, even if this Court agrees that the statute is ambiguous, HRSA's letter is based on the

[15] HRSA respectfully contends that the relevant inquiry is not whether "the Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies," *Astra* op. 12. HRSA had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities' sales based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020 manufacturers universally complied). Plus, HRSA's stance is not that drug makers must "provide" drugs to contract pharmacies, but that they must honor the ceiling price when selling to covered entities, regardless of the "ship to" location on the *covered entities'* invoice. Moreover, the briefing before the *Astra* court did not include the *1994 guidance*, *supra* 19-20, which interpreted the statute to require that "manufacturers *must offer* covered outpatient drugs at or below the section 340B discount prices" while confirming that use of contract pharmacies is a customary, common business practice, and that manufacturers are prohibited from placing limitations on such transactions. 59 Fed. Reg. 25,113. Regardless whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these historic guidances consistently explained that, *e.g.*, "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. Stated differently, the agency had no cause to opine in the *Astra* court's precise formulation because the broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit requirement. HRSA respectfully contends that, properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, its "interpretation of manufacturers' obligations" does not "shift[] every time that HHS changes its guidance with respect to covered entities' rights." *Astra* op. 14. But even if this Court disagreed that the position has been consistent, HRSA's interpretation of the statute still would be the best interpretation for all the reasons set forth *supra* § I.A.

best reading of the statute and its decades of expertise administering the statute and thus is entitled to deference. Moreover, the HRSA letter does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity), so HRSA's rationale would not suffer from the same "flaw" identified by the *Astra* court. As demonstrated *supra* § I.A, HRSA's conclusion that Lilly is overcharging covered entities by refusing discounted-drug orders and imposing unlawful, extra-statutory conditions is well-grounded on statutory text, historic evidence of the agency's interpretation, and material in the administrative record, even if this Court agrees with the *Astra* opinion's finding of ambiguity.

To the extent this Court finds ambiguity in the 340B statute, it should afford deference to HRSA's interpretation of the statute under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Under *Skidmore* informal interpretations such as this one "are entitled to respect to the extent they have the power to persuade." *Am. Federation of Gov't Empls. v. Rumsfeld*, 262 F.3d 649, 656 (7th Cir. 2001) (internal quotation omitted). Because HRSA's statutory interpretation is based on its "specialized experience" and "the broader information available to [it]," *id.*, evidenced "thorough" consideration by the agency, contained "valid[]" reasoning, was consistent with "earlier and later pronouncements," the interpretation has the "power to persuade," and should be accorded deference. *Costello v. Grundon*, 651 F.3d 614, 632 (7th Cir. 2011).

The *Astra* court's other observations do not undermine HRSA's conclusions in the Violation Letter. True, as the court found, 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Astra* op. 18. But as explained above, that that overlooked the fact that Congress considered *and explicitly removed* a provision from the statute that would have limited 340B purchases to drugs dispensed in-house or on-site at a covered entity;[16]

[16] The *Astra* court wrote that Congress considered including this restriction when it "added the 'must offer' requirement to the statute in 2010." *See Astra* op. 21. In actuality, Congress considered restricting covered entities to in-house or on-site dispensing *when the statute was enacted in 1992*. Rather than "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies," *id.*, Congress's *removal* nearly three decades ago of any

this, coupled with the fact that 95% of covered entities at the time of enactment did not have an in-house pharmacy, makes it unlikely that Congress created a novel social-safety-net program that the majority of beneficiaries had no means to access in practice.[17] Similarly, the fact that § 256b(a)(1) is directed to the Secretary of HHS, requiring him to enter agreements obligating manufacturers to honor covered-entity purchases, *discussed Astra* op. 18, does not displace HRSA's finding because HRSA is acting (through delegation from the Secretary) to enforce against Lilly the requirement in the statute and its PPA to provide discounts to safety-net providers. In other words, the Violation Letter is HRSA's effort to effectuate the command to the Secretary in § 256b(a)(1), and there is no question that the statute instructs the Secretary to ensure that covered entities are not charged more than the 340B ceiling price.

Because the *Astra* Opinion was limited to the narrow ground of finding the AO erred in concluding its interpretation was compelled by unambiguous statutory text, and the court explicitly found that "HHS's current interpretation of the statute is permissible," id. 22, *Astra* does not undermine HRSA's determination that Lilly is violating the statute.

II. THE ADMINISTRATIVE-DISPUTE RESOLUTION MECHANISM MANDATED BY CONGRESS WAS LAWFULLY ESTABLISHED

A. *ARTHREX* CONFIRMS THAT ADR BOARD MEMBERS ARE LAWFULLY APPOINTED INFERIOR OFFICERS

restriction on delivery site or dispensing mechanism can best be interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme.

[17] HRSA respectfully disagrees with the *Astra* court's statement that "[t]he statute's total omission of contract pharmacies renders it ambiguous *with respect to the central issue in this case*," op. 19. The central issue in that case (and this one) is not the role of contract pharmacies under 340B, but the obligation of manufacturers to honor purchases by covered entities. Similarly, that court's statement that "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication," *id.* 20, is inapposite to HRSA's conclusion. HRSA is not including contract pharmacies as a "type of covered entity" nor allowing pharmacies to participate in 340B. Congressional silence strongly supports HRSA's conclusion: At time of enactment (and now) the overwhelming majority of healthcare providers relied on outside pharmacies to serve their patients. Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medications in-house) surely it would have said so explicitly. Finally, Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers—who plainly *are* permitted to serve patients through outside dispensers.

This past week the Supreme Court issued additional guidance on the appointment of adjudicatory officers, holding that administrative judges operating under statutory restrictions on *both* review of their decisions *and* removal from their office exceeded the power that properly may be vested in inferior officers. *United States v. Arthrex, Inc.*, 594 U.S. __ , slip op. 19-1434 (June 21, 2021). *Arthrex* concerned Administrative Patent Judges (APJs) appointed by the Secretary of Commerce and empowered, when assigned to three-judge panels, to hear challenges to previously issued patents in an adversarial proceeding "which resembles civil litigation in many respects." *Id.* 1, 3-4. Although a dissatisfied litigant could request rehearing by a panel, under the statutory scheme "[n]either the Secretary nor Director," the supervising principal officer, "had the authority to review [APJs'] decisions or to remove them at will"; the APJs' decisions were final for the Executive Branch and could be appealed only to the Court of Appeals for the Federal Circuit. *Id.* at 4-6. The Court determined that this novel structure, where "Congress has assigned APJs 'significant authority' in adjudicating the public rights of private parties[] while also insulating their decisions from review and their offices from removal," was inconsistent with the Appointments Clause. *Id.* at 19.

As a remedy, the Court concluded that the will of Congress could best be effectuated in that particular scheme by severing the statutory restriction on review of APJs' decisions by the Director, rather than the statutory restriction on removal from office at will. "In every respect save the insulation of their decisions from review within the Executive Branch, APJs appear to be inferior officers—an understanding consistent with their appointment" by a Head of Department, the Court concluded, so the most-sound result was to render the statute "unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the [APJs] on his own." *Id.* at 21-22. It mattered not that no formal mechanism for appeal to the Director would then exist, because vesting the Director with the discretionary power to review APJs' decisions "would follow the almost-universal model of adjudication in the Executive Branch." *Id.* "To be clear, the Director need not review every decision," because "[w]hat matters is that the Director *have the discretion to review* decisions rendered by APJs." *Id.* at 23 (emphasis added).

Arthrex confirms that the ADR Rule challenged here is consistent with the Appointments Clause. The statutory scheme at issue here contains no restraint on the Secretary's ability to direct and supervise the ADR Board through review of panel decisions or removal from office at will. To be sure, the statute directs the Secretary to "establish a decision-making official or decision-making body … to be responsible for reviewing and finally resolving claims." 42 U.S.C. § 256b(d)(3)(B)(i). But that language instructs the Secretary *to delegate* authority to issue final agency actions reviewable in district court; it does not resemble the language at issue in *Arthrex*, where "Congress unambiguously specified" in *prohibitory* terms that the Director could not alter a decision. *See* slip op. at 10; *see also* 35 U.S.C. § 6(c) (specifying that "[o]nly the … Board may grant rehearings"); *Arthrex* at 12 (confirming § 6(c) represents "a statutory prohibition on review"). Here, the absence of any statutory constraint on discretionary review by the Secretary of final decisions of his subordinates makes the ADR Rule analogous to the *Arthrex* Court's statutory *fix*—not the initial constitutional *violation*.[18]

Lilly points to a separate provision confirming the "finality of administrative resolution" and argues that it confirms "ADR panels' … decisions cannot be modified or undone by any superior officer within the Executive Branch—not even by the Secretary." Lilly Mot. 46. Not so. The finality provision confirms only that the ADR process will result in final agency actions reviewable in district court under the APA (as is common practice for agency adjudications): "The administrative resolution of a claim or claims under the regulations promulgated" under § 340B "shall be a final agency decision and shall be binding on the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C). Unlike the language at issue in *Arthrex*, which expressly *prohibited* review by the Director, by specifying that "*[o]nly* the [APJs] may grant rehearings," 35 U.S.C. § 6 (emphasis added), § 256b(d)(3)(C) contains no express restriction on the Secretary's ability to reverse an ADR decision as part of the "administrative resolution of a claim." Stated differently, the cited provision provides for review by a court after conclusion of the administrative process—it is

[18] Even if this Court concluded that the statute was unclear as to whether it preserves the Secretary's authority to review Board decisions, principles of constitutional avoidance counsel in favor of construing the statute to allow for such review.

not, as Lilly posits, a statutory constraint on the Secretary's ability to control that process by reviewing decisions. *Arthrex*, slip op. at 15 (confirming "authority to review" "decisions of [] subordinates despite congressional silence on the matter").[19]

Under both the ADR Rule and the statute, the Secretary freely may exercise discretionary review of panel decisions; it matters not that no formal mechanism for appeal to the Secretary is set forth in the regulation. Indeed, the *Arthrex* Court confirmed that an express grant of power to direct and review the decisions of subordinates is unnecessary, so long as no express *restriction* on that power is found in the statutory scheme. Notably for the present case, not only was there no need for express statutory authorization for the Director's review of APJs' decisions, the Court also made clear that the Director need not promulgate regulations establishing a formal mechanism to facilitate his review. Simply severing the statutory prohibition on review of APJs' decisions "does not result in an incomplete or unworkable statutory scheme," since "[w]hat matters is that the Director have the discretion to review decisions rendered by APJs." *Arthrex*, slip op. at 21, 23; *see also id.* at 15 ("For the most part, Congress left the structure of administrative adjudication up to agency heads, who prescribed internal procedures (and thus exercised direction and control) as they saw fit."). This principle was well established even before *Arthrex*; "[a]s a general proposition of administrative law, the head of an administrative agency has the power to review and revise the acts of subordinates where … the powers in question are vested in the subordinate under the supervision and direction of the superior." *Morrow v. Clayton*, 326 F.2d 36, 45-46 (10th Cir. 1963). *Accord Chevron Oil Co. v. Andrus*, 588 F.2d 1383, 1387-88 (5th Cir. 1979) (confirming officer who delegates authority does not divest himself of the power to exercise that authority to review and overrule subordinate absent express restriction

[19] Even were there ambiguity on whether the statute itself constrains the Secretary's review of ADR decisions, Lilly would not be entitled to relief on the theory that *the statute itself*, as opposed to the Rule, violates the Constitution. That is because Lilly has not pleaded any claim that the scheme devised by Congress violates Article II and has not asked this Court for any relief as to the statute. Compl., Prayer for Relief (pleading ADR Rule violates the APA by exceeding statutory authority and violating the Constitution). And *even if* Lilly repleaded to mount a facial challenge to the 340B statute *and* prevailed, *Arthrex* teaches that the proper remedy would be merely to render unenforceable any constraint on the Secretary's review—not to strike down the entire adjudicatory process.

in delegation). Because Congress has placed no restrictions on the Secretary's authority to review and revise ADR panel decisions, ADR Board members serve as properly appointed inferior officers. Lilly's argument that ADR panel decisions bind even the Secretary himself, Lilly Mot. 46, fails as a matter of law because neither the statute nor the Rule prohibit the Secretary from overturning a panel decision with which he disagrees.

Rather than engage HHS's points regarding the Secretary's ability to review decisions under the scheme that now exists, Lilly mischaracterizes the government's opening brief as having "insist[ed] that any defect in the ADR Rule is illusory because the Secretary can always just 'rescind' the ADR Rule's delegation" and "solve the constitutional problem by" personally adjudicating disputes. Lilly Mot. 46. On the contrary, there is no constitutional defect for the Secretary to fix because he *already has* authority to reverse the decisions of his subordinates. And HHS certainly did not, as Lilly accuses, "all but concede[] … that the Rule can be upheld ***not*** on its own terms," but because the Secretary can modify it. *Id.* 47. As the government explained, HHS Mot. 43, the Secretary's (fully intact) authority to modify or rescind the regulation is relevant because it shows that the Secretary would not manufacture a constitutional violation *even if* he had promulgated a Rule purporting to constrain his review authority (because he always would retain the power to rescind that regulatory constraint). There is no need for the Secretary to revise the Rule that exists, because it contains no constitutional defect.[20]

But there is more: Not only may the Secretary review ADR decisions, he also may freely remove ADR Board members at will. In arguing otherwise, Lilly does not (and cannot) point to any constraint on the Secretary's ability to remove *Board* members and instead focuses myopically on the *panels* to which members are assigned. Lilly Mot. 47-49 (focusing exclusively on the officer status of

[20] Lilly's argument that the Secretary cannot overturn decisions with which he disagrees because "the Secretary is not a panelist" and "neither is any other principal officer appointed by the President," Lilly Mot. 46, is meritless. A principal officer need not *sit on* the adjudicatory body s/he supervises to exercise effective control, as the Supreme Court confirmed. "What matters is that the [Secretary] have the discretion to review decisions rendered by [panelists]," *Arthrex* at 23, a discretion that the head of an agency possesses even in the absence of an express delegation or procedural mechanism to facilitate review.

ADR *panelists*). That shift in focus is unavailing; the Appointments Clause, U.S. Constitution art. II, § 2, cl. 2, concerns the *appointment* of federal officers—not the interim *assignments* on which those officers are tasked to work. Just as Article III is concerned with the manner in which federal judges are appointed and removed (through Senate confirmation and impeachment)—not their selection or deselection from particular cases or appellate panels during their judicial tenure—so, too, the Article II analysis turns on the manner in which ADR *Board* members, as officers, are appointed and can be removed—not the individual panel assignments for which they later are selected.

This principle was on display in *Arthrex*, where the Supreme Court confirmed that the Director's ability to "reassign[] an APJ to a different task going forward" was not the relevant consideration since, according to the statute, the APJs could only be "remov[ed] from federal service entirely" for cause. Slip op. at 12. In other words, it is removal from one's office—not reassignment from the task at hand—that has constitutional significance. Under the ADR Rule, a federal employee becomes an officer when s/he receives an *appointment* by the Secretary to the ADR Board, not when s/he is selected from that Board by the HRSA Administrator to hear any particular petition.

Lilly's removal arguments fail even as applied correctly to the ADR Board. Neither the Rule nor the statute contain any restraint on the Secretary's ability to remove ADR Board members, thus demonstrating that this "powerful tool for control," *Edmond v. United States*, 520 U.S. 651, 664 (1997), remains fully with the Secretary. The Secretary's partial delegation of authority to the HRSA Administrator to share in this task, by re-assigning a panel member when cause is shown, is a sensible delegation without constitutional significance.[21]

In arguing otherwise, Lilly contends that plenary removal power "belies everything the government says to justify its decision to eschew independent, impartial ALJs" because HHS "cannot … assure the Court that ADR panelists will be objective and impartial adjudicators while simultaneously touting" the Secretary's removal power. Lilly Mot. 48. This convoluted claim gets Lilly

[21] Even if the Court considered the circumstances for re-assignment of panel members, rather than removal from the Board (an approach not supported by caselaw), the Rule contains *no* constraint on the Secretary's ability to re-assign panels. On the contrary, the Rule merely authorizes the HRSA Administrator to re-assign panelists in more-limited circumstances where cause is shown.

nowhere. No authority supports the idea that the existence (or lack) of impartiality has any bearing on whether officers receive a proper appointment. The question whether ALJs or Board members are better equipped to render impartial decisions simply has no bearing on whether the Rule creates principal officers. Lilly's argument serves (ineffectually) to obscure the fact that neither the statute nor Rule restrict the removal of Board members.

Because there are no "statutory restrictions on the [Secretary] that insulate the decisions of [ADR Board members] from his direction and supervision," *Arthrex*, slip op. at 23, Board members receive a proper appointment under the ADR Rule. Board members also may be removed *from their appointment* at-will by the Secretary at any time, further demonstrating their status as inferior officers. Lilly's Article II challenge fails.

B. CONGRESS PROPERLY VESTED ADJUDICATION OF STATUTORILY CREATED 340B CLAIMS BEFORE THE AGENCY

Lilly's Article III challenge is equally wrong on the law. Lilly spills significant ink insisting that the alleged remedial powers granted to the Board render it unconstitutional, Lilly Mot. 68-72, while ignoring the caselaw and examples set forth in the government's brief demonstrating that, far from an infringement on the judiciary, the powers granted to the ADR Board are commonplace features of modern administrative law. HHS Mot. 43-45. HHS disagrees with Lilly regarding the scope of the Board's remedial powers, but even if Lilly is correct that panels may purport to issue injunctive relief (which, as explained in the government's opening brief, would resemble a cease-and-desist demand to comply with statutory requirements, not a judicial-style order backed by contempt power) or a damages calculation, that *still* would pose no Article III problem. *See id.* 43 (explaining that many agencies have the power to order equitable relief and damages, including findings of violation, restitution, and fines, subject to judicial review under the APA, just like ADR panel rulings). The remedial powers Lilly contends are vested in the Board are not only constitutional, they're not unusual.

Lilly's private-rights argument rests on inapposite caselaw and ineffective attempts to distinguish relevant authorities. Article III challenges arise in two distinct settings: challenges arising in *bankruptcy courts* typically concern the ability of those Article I bodies, serving as adjuncts of district

courts, to adjudicate common-law counterclaims and similar matters that arise with some relationship to the bankrupt estate. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 56 (1989) ("fraudulent conveyance actions by bankruptcy trustees … are quintessentially suits at common law that … resemble state-law contract claims" and "therefore appear matters of private rather than public right"); *Stern v. Marshall*, 564 U.S. 462, 487 (2011) ("No 'public right' exception" permitted bankruptcy court to adjudicate "state common law counterclaim" for tortious interference); *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 71 (1982) (adjudication of "the right to recover contract damages" under state law "obviously is not" a public right and thus belongs in Article III court). In other words, Article III challenges to the jurisdiction of bankruptcy courts involve private rights because traditional, common-law *claims* (or those closely resembling them, and created by statute) are at stake. By contrast, Article III challenges arising before *administrative agencies* often involve the adjudication of entirely *new* rights, created by Congress through statute as part of a comprehensive regulatory scheme. *See Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 593-94 (1985). In such cases, Congress need not even create a remedy in the courts at all, so it "may set the terms of adjudicating" that right, including by assigning adjudication in another branch of government. *Stern*, 564 U.S. at 489 (citation omitted). And it matters not that the dispute may arise between private parties, or affect some interest in money or property. It is *the nature of the claim asserted* that renders it capable of non-judicial adjudication. *See* HHS Mot. 45-50 (providing thorough analysis of public-rights caselaw and demonstrating that ADR Board adjudicates only statutory rights created by Congress).

Lilly ignores the proper test for determining when *statutory* rights may be adjudicated outside Article III. Lilly Mot. 54-56. For example, Lilly emphasizes that the claims at issue in *Granfinanciera* "are entirely statutory," and asserts that they could not be resolved outside Article III because "resolving them would require the adjudicator to decide how much money one private party owed another." *Id.* 55. Not so: *Granfinanciera* involved a private right (necessitating Article III resolution) because the statutory cause of action effectively supplanted and resembled a pre-existing common-law action. 492 U.S. at 53-56 (analogizing statutory claim to state-law contract dispute). And the *Granfinanciera* Court emphasized that "[t]he crucial question" in determining whether public rights are

at issue is whether it "involv[es] statutory rights that are *integral parts of a public regulatory scheme* and whose adjudication Congress has assigned to an administrative agency or specialized court of equity." *Id.* at 54, 55 n.10 (emphasis added). That precisely describes the comprehensive 340B drug-discount program, and the novel claims for "overcharging," "diversion," and "duplicate discounting" that arise under it. *See also Stern*, 564 U.S. at 490-91 (public rights are "cases in which the *claim at issue* derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority") (emphasis added).

Lilly's reliance on *CFTC v. Schor*, 478 U.S. 833, 851 (1986), is equally misplaced. In that case the Supreme Court neither "made crystal clear that the suite of powers exercised by an administrative tribunal is directly relevant to the degree of infringement on the judicial power," nor did it "deem[] constitutionally suspect administrative schemes that allow federal-court review of agency decisions only under the deferential APA standard." Lilly Mot. 53-54. *CFTC* involved a Congressional grant of jurisdiction for an agency to hear a *common law counterclaim* and thus, like the bankruptcy cases cited above, required the Court to consider whether adjudication of *private rights* infringed the power of the judiciary. 478 U.S. at 853 ("The counterclaim asserted in this litigation is a 'private' right for which state law provides the rule of decision."); *see also id.* 853-54 (explaining that "where private, common law rights are at stake, our examination of the congressional attempt to control the manner … [of] adjudicat[ion] has been searching" *in contrast to* scenarios where "Congress selects a quasi-judicial method of resolving matters that could be conclusively determined by the Executive and Legislative Branches," *i.e.*, new claims created by statute). The "suite of powers" exercised by a tribunal comes into play when Congress has withdrawn a traditional suit from judicial cognizance, *id.* at 854, not when Congress has created new rights.[22]

[22] Lilly's repeated complaints that the ADR process relies on "the official rules that govern federal-court proceedings," Lilly Mot. 51, gets it nowhere. There is nothing proprietary about the Federal Rules of Civil Procedure or Evidence, and nothing unconstitutional about an administrative agency choosing to apply them. Equally unhelpful is Lilly's continued insistence that the ADR Rule should have (or could have) authorized federal courts to exercise *de novo* review (rather than APA review) of panel rulings. Lilly Mot. 54. As noted in HHS's opening brief, 49 n.12, administrative agencies cannot "authorize" federal courts to do anything—only Congress has power over the Third Branch.

Similarly, Lilly's dismissal of *Union Carbide*, 473 U.S. at 584, ignores the Supreme Court's discussion and approval of *various* agency adjudicative schemes which "determine liabilities of individuals" to one another yet are able, consistent with constitutional constraints, to adjudicate "claims between individuals." 473 U.S. at 587, 589. It is not the government, as Lilly contends, that "misread[s] the Supreme Court's decision" in *Union Carbide*, *contra* Lilly Mot. 54-55, because that decision does not stand for the proposition that any pre-existing property rights must be extinguished by a statute before claims may fall within the public-rights exception.

Lilly's continued insistence that the claims heard by ADR panels—that a manufacturer has charged a covered entity more than the ceiling price for pharmaceuticals, or that a covered entity unlawfully has diverted or claimed duplicate discounts for 340B drugs—would have been "tried by the courts at Westminster in 1789," is absurd, as there clearly is no historic precedent for these disputes. Lilly Mot. 50 (quoting *Stern*, 564 U.S. at 484). Lilly asserts that covered entities' claims belong in federal court because the 340B statute "only impaired a pre-existing, independent common-law right by essentially placing *restrictions* on making sales." Lilly Mot. 56. Lilly is wrong. As evidenced in the government's opening brief, the private/public rights inquiry focuses on the *claim* being adjudicated and whether it is "an integral part of a public regulatory scheme, assigned to an administrative agency," *Beard v. Braunstein*, 914 F.2d 434, 441 (3rd Cir. 1990), not whether property changes hands through the disposition.

ADR panels simply do not, as Lilly claims, determine "Lilly's right to sell its property at its chosen price," Lilly Mot. 55. Lilly has opted into the 340B Program and *given up* its right to set the price for products sold to covered entities. ADR panels can decide only whether Lilly is overcharging those entities. Congress created these rights from whole cloth, so it is no infringement on the traditional power of the judiciary for initial adjudication to be placed outside the Third Branch. Besides, Lilly absolutely has the voluntary choice to opt out of participation in Medicaid and Medicare

Part B and charge whatever it wants to whomever it wants for its drugs.[23] But it may not continue to profit from these lucrative government programs while shirking its complementary statutory obligations.

Were Lilly correct that the claims brought by covered entities against it are "the subject of a suit at the common law" that even *could* be heard, in the first instance, by Article III courts, *id.* 54 (citing *Den. ex dem. Murray v. Hoboken Land & Improvement Co.,* 59 U.S. (18 How.) 272, 284 (1855)), then the Supreme Court wrongly decided *Astra v. Santa Clara County*, 563 U.S. at 121-22 (holding covered entities may not litigate 340B claims for overcharging in federal court). It matters not that "*Astra* did not discuss Article III at all," Lilly Mot. 56, because the Supreme Court *did* decide that covered entities *may not bring* claims for 340B overcharging in federal court. *Astra*, 563 U.S. at 118 (rejecting attempt by covered entities to sue to enforce manufacturers' obligations because it would "render[] meaningless" "[t]he absence of a private right [of action] to enforce the statutory ceiling-price obligations"). Stated differently, were Lilly correct that covered entities' claims of overcharging cannot be adjudicated before the agency, the result—in light of the Supreme Court's holding that those same claims cannot be heard in federal court—would be that claims for 340B violations cannot be heard in *any* forum, thus negating the will of Congress to create a remedy for claims of "overcharging." That untenable result should be rejected.

C. HHS Fully Complied With Notice And Comment In Promulgating The ADR Rule

All parties agree that "[t]he [APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures." *See, e.g.*, *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978). Here, to follow the APA's procedures, the agency need only have published a notice of proposed rulemaking that included "either the terms or substance of the proposed rule or a description of the subjects and issues

[23] Lilly's proclamations that it did not "consent" to the ADR process is irrelevant; consent to a forum matters only where the adjudicatory scheme is "otherwise-unconstitutional," Lilly Mot. 57, and, as shown herein, the scheme Congress created under 340B mirrors other modern administrative adjudications of statutorily created rights.

involved," 5 U.S.C. § 553(b)(3), and then "give[n] interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). HHS has complied with these requirements. Yet, while contending that HHS has "impos[ed] a new procedural requirement on agencies not found in the APA," Lilly Mot. 42, Lilly endorses this Court's opinion that does just that. In its decision on Lilly's motion for preliminary injunction in this case, the Court's opinion imposed a new (and highly subjective) procedural requirement on agencies not found in the APA—that agencies must publish a new NPRM and re-do the notice and comment process if the totality of the circumstances would lead a reasonable observer to view the original NPRM as withdrawn. In addition to creating a new rule that improperly inhibits an agency's statutorily delegated rulemaking authority, this "totality-of-the-circumstances" test, created in the first instance by this Court, is incompatible with existing law setting forth the procedures for review of agency action under the APA.

As explained in HHS's opening brief, courts review the decision to terminate rulemaking as final agency action under the APA. *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 846 (D.C. Cir. 1983); *see also* HHS Mot. 50-51. Accordingly, the APA requires the agency to provide "an explanation [for terminating a rulemaking] that will enable the court to evaluate its rationale at the time of the decision." *Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 44 (D.C. Cir. 2004). Because the need for a statement explaining the reasons for withdrawal stems from the APA itself, *see Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990) (characterizing 5 U.S.C. § 706(2)(A) as imposing "a general 'procedural' requirement of sorts by mandating that an agency take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision"), HHS's position does indeed have basis in the APA, contrary to Lilly's position, *see* Lilly Mot. 42. Thus, it is no surprise that not only have other courts reviewed the termination of rulemaking on the basis of a withdrawal notice published in the Federal Register, *see Int'l Union, United Mine Workers*, 358 F.3d at 42 (acknowledging withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety*, 710 F.2d at 844 (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same), but HHS's usual practice is to

publish a notice of withdrawal in the Federal Register. *See, e.g.*, 78 Fed. Reg. 12,702-01 (Feb. 25, 2013); 79 Fed. Reg. 19,848-01 (Apr. 10, 2014); 83 Fed. Reg. 60,804-01 (Nov. 27, 2018); 84 Fed. Reg. 37,821-01 (Aug. 2, 2019).

But even under this Court's approach, HHS respectfully maintains that the facts on which Lilly relies, Lilly Mot. 43-44, would not have led a reasonable observer to believe the ADR Rule had been withdrawn. For one, HHS was acting pursuant to the Regulatory Freeze Memorandum, HHS Mot. 53. Though Lilly claims that the ADR Rule was exempt, HHS clearly understood the Rule to be impacted "at the time," Lilly Mot. 43, because it froze the ADR rulemaking at the first available opportunity in the next issuance of the Unified Agenda. Moreover, while Lilly claims that the Rule's "completed" status on the Unified Agenda signals an end to the rulemaking, Lilly fails to acknowledge the limitations of the Unified Agenda. Indeed, listing a rulemaking on the Unified Agenda does not satisfy statutory requirements to provide notice of rulemaking, 5 U.S.C. § 553(b), or establish presumptive notice of regulation required for enforcement, *cf.* 44 U.S.C. § 1507, so it would be untenable to conclude that de-listing a rulemaking from the regulatory agenda is sufficient to withdraw that rulemaking for the purposes of the APA. Lilly similarly fails to explain the legal significance of the Regulatory Identification Number (RIN) or a HRSA representative's statement to the media, indicating that these facts are not actually relevant to the legal question before the Court.

In a final attempt to invalidate the procedurally proper ADR Rule, Lilly argues that the ADR Rule is not a logical outgrowth of the 2016 NPRM. HHS addressed this claim at length in its motion, HHS Mot. 54-56, and Lilly does not meaningfully engage with the argument therein. Even when a final rule "work[s] a substantial change to the NPR[M]," the standards of the APA may be satisfied. *Am. Med. Ass'n v. United States*, 887 F.2d 760, 767 (7th Cir. 1989). An NPRM need only "apprise[] interested parties of the issues to be addressed in the rule-making proceeding with sufficient clarity and specificity to allow them to participate in the rulemaking in a meaningful and informed manner." *Id.* At bottom, the NPRM gave Lilly adequate notice of the topics covered by the ADR Rule, regardless of whether those topics were addressed in precisely the same manner and language as in the final rule, and thus, Lilly's logical outgrowth claim fails.

For all of these reasons, the Court should reject Lilly's claims challenging the procedures by which HHS issued the ADR Rule.

D. THE ADR RULE IS NOT ARBITRARY, CAPRICIOUS, OR CONTRARY TO LAW

In challenging the substantive validity of the ADR Rule under the APA, Lilly's opening brief largely recites the same arguments contained in its operative complaint and fully addressed by HHS's dispositive motion. And for the reasons explained therein, Lilly identifies no sound basis on which to set aside the ADR Rule under 5 U.S.C. § 706(2). Although Lilly offers little by way of opposition to HHS's contentions, what it does offer does not change that conclusion.[24]

First, by failing to raise its constitutional challenges to the ADR Rule during the NPRM's comment period, Lilly has no basis to indict HHS for failing to consider its constitutional theories. Although Lilly points out that it *did* raise concerns regarding the "impartiality and accountability" of ADR panelists, nowhere did it ground these concerns in the Appointments Clause. Indeed, Lilly's comments take no issue with the Secretary's appointment authority under the ADR Rule. Lilly also concedes that it raised no Article III objections during the comment period, Lilly Mot. 58. But even setting aside Lilly's failure to timely raise its constitutional contentions in comments on the NPRM, they warranted no response from HHS because the ADR Rule fully comports with Articles II and III.

Second, Lilly again misapprehends the ADR Rule's "for cause" partial delegation of authority to the HRSA Administrator to remove panelists—a provision HRSA included in the Rule to provide an effective safeguard "to ensure fairness and objectiveness" in the ADR process. *See* 85 Fed. Reg. 80,634–35. Lilly suggests that, if the Secretary is unfettered by the for-cause removal provision and has the authority to remove ADR board members "at will" (as is the case), then the for-cause removal provision would fail to serve its only purpose of "insulat[ing]" ADR panelists from a Secretary's policy

[24] HHS moved for summary judgment on Lilly's claims that the agency acted arbitrarily and capriciously by (i) not considering PhRMA's petition for proposed rulemaking, and (ii) not holding drug manufacturers immune for violating the 340B statute in the three-year period preceding the ADR Rule's promulgation. *See* HHS Mot. 59–60. Lilly offers no response or argument on these claims, and thus has abandoned them. *See, e.g.*, *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 n.2 (7th Cir. 1996); *Eglen v. Am. Oneline, Inc.*, No. TH00-0135-C-M/H, 2001 WL 1028851, at *3 (S.D. Ind. June 19, 2001).

preferences. *See* Lilly Mot. 59. This heads-I-win-tails-you-lose argument fails. Under Lilly's logic, the Appointments Clause is violated if the Secretary *cannot* remove Board members and the APA is violated if the Secretary *can* (due to, according to Lilly, a lack of "impartiality"). No authority supports imposing this Hobson's choice upon the agency. The Secretary's ability to remove Board members from their appointment does not create bias—and the HRSA Administrator's authority (under a partial delegation) to remove an ADR panelist "for cause" allows the Administrator to help ensure panels operate without conflicts of interest. *See* 42 C.F.R. § 10.20(a)(ii). As already explained, *see* HHS Mot. 57, HHS considered and addressed comments raising concerns that panelists may hold biases and that, as Lilly suggests, ALJs would be preferable to ADR panelists. Contrary to what Lilly posits, HHS was under no obligation to *agree* with these concerns or suggestions or otherwise to "insulate" members from Secretarial control.

III. THE COURT SHOULD NOT PRELIMINARILY ENJOIN HRSA'S ENFORCEMENT OF THE 340B STATUTE

A. LILLY HAS NOT ESTABLISHED IRREPARABLE HARM

Setting the merits aside, Lilly is not entitled to preliminary relief because it has failed to show that it is likely to suffer irreparable harm "in the interim period prior to final resolution of its claims" in the absence of a preliminary injunction. *See Valencia v. City of Springfield*, 883 F.3d 959, 965 (7th Cir. 2018); *see also GEFT Outdoors, LLC v. City of Westfield*, 922 F.3d 357, 364 (7th Cir. 2019) ("[T]he court must deny [a preliminary] injunction" if a plaintiff fails to establish the "threshold requirement" that it is likely to suffer irreparable harm.). To establish irreparable harm sufficient to support a preliminary injunction, Lilly must show more than a "theoretical or speculative" threat of harm, *Timberlake v. Buss*, 2007 WL 1280664, at *9 (S.D. Ind. May 1, 2007); *accord E. St. Louis Laborers' Local 100 v. Bellon Wrecking & Salvage Co.*, 414 F.3d 700, 704 (7th Cir. 2005); it must provide evidence of "[a] presently existing actual threat" of irreparable injury, *Michigan*, 667 F.3d at 788 (citation omitted). This it has not done.

Lilly begins by claiming that "every dollar [it] is forced to refund" or "every discount" it is "forced to give"[25] as a result of HRSA's 340B-violation determination "will be irreparable injury by definition," because this financial loss will be unrecoverable due to the government's sovereign immunity. PI 25–26. As an initial matter, enjoining HRSA's enforcement efforts during the pendency of this litigation will have no practical impact on this purported threat of monetary harm. Should HHS prevail on the merits of Lilly's challenge to the Violation Letter, a preliminary injunction will not prevent HHS from either ordering refunds or imposing CMPs based on Lilly's actions during "the interim period prior to final resolution of its claims." *See Valencia*, 883 F.3d at 965. And on the other hand, in the unlikely event that Lilly prevails on the statutory-interpretation question, it would not be ordered to refund overcharges and there would be no grounds for HHS to impose CMPs whether the Court issued a preliminary injunction or not. Thus, preliminary relief would be meaningless in practice because any alleged threats of economic harm to Lilly will not abate in the interim as long as Lilly continues to charge covered entities inflated WAC prices or deny covered-entity sales altogether. *Id.* at 25.

Furthermore, Lilly's bare allegations that it will lose "unrecoverable money" because of HRSA'S 340B-violation determination is far "too vague and speculative to support a finding of irreparable harm." *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 213 (D.D.C. 2012). Contrary to Lilly's argument, the mere "'fact that economic losses may be unrecoverable does not, in and of itself, compel a finding of irreparable harm,' for the harm must also be *great*, *certain* and *imminent*." *Id.* at 211; *see also Otsuka Pharm. Co. v. Burwell*, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) ("That [the plaintiff] is unable to recover monetary damages from [the government] does not … automatically make [its] harm irreparable."); *In re N.A. Refractories Co.*, 542 B.R. 350, 362 (W.D. Penn. 2015) (finding unrecoverable losses in revenue "to be *de minimus*" and thus insufficient to "constitute irreparable harm"); *Cal. Pharmacists Ass'n v. Maxwell-Jolly*, 596 F.3d 1098, 1113–14 (9th Cir. 2010) (requiring the

[25] Lilly repeats that it will be "forced to give [discounts] to *contract pharmacies* going forward." PI at 25 (emphasis added). Again, Lilly can point to no instance where HHS asked it to provide 340B discounts to contract pharmacies.

showing of "*considerable* revenue" loss that the plaintiff "will be unable to recover due to … sovereign immunity" to demonstrate irreparable harm) (emphasis added), *vacated and remanded sub nom.*, *Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606 (2012); *Ariz. Hosp. & Healthcare Ass'n v. Betlach*, 865 F. Supp. 2d 984, 999 (D. Ariz. 2012). But Lilly fails to explain how it will face any concrete financial impact in light of its refusal to reverse course and comply with HRSA's interpretation of the statute; instead, Lilly rests on unsupported assertions of an indeterminate sum of monetary harm. Indeed, Lilly does not even venture a *guess* as to the amount of loss it may incur as a result of enforcement actions taken *during the pendency of this litigation*. But even if Lilly had offered the Court more than bare allegations on this score, the "unrecoverable money," PI at 25, Lilly would lose would have to rise to a sufficient degree of "magnitude," *Cardinal Health Inc.*, 846 F. Supp. 2d at 211, to irreparably harm "one of the leading pharmaceutical manufacturers in the world," Pusey Decl. ¶ 1, ECF No. 95-5. Showing a loss representing only "a minuscule portion of the company's worldwide revenues" would not suffice. *LG Electronics U.S.A., Inc. v. Dep't of Energy*, 679 F. Supp. 2d 18, 36 (D.D.C. 2010).

Lilly also claims that it will "suffer serious reputational injury" resulting from HRSA's "pronouncement that Lilly is acting in violation of its legal obligations." PI at 28. First off, any harm to Lilly's reputation "in the community," "marketplace," and among "health-care partners," Pusey Decl. ¶ 29, is a self-inflicted injury caused by Lilly's decision to deny safety-net healthcare providers the ability to purchase 340B-eligible drugs and dispense them to patients at their neighborhood pharmacies. But at any rate, HRSA has *already made* its "pronouncement" regarding Lilly's unlawful restrictions, and preliminary relief cannot retroactively retract it or nullify its alleged reputational consequences.

And similar to its claims of economic injury, Lilly's claims of reputational injury rest on bare and conclusory allegations, "grounded in platitudes rather than evidence." *See Herb Reed Enterprises, LLC v. Fla. Entertainment Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013). But "[a]s with all other forms of irreparable harm, the showing of reputational harm must be concrete and corroborated, not merely speculative." *Trudeau v. Fed. Trade Comm'n*, 384 F.Supp.2d 281, 297 (D.D.C. 2005), *aff'd*, 456 F.3d 178 (D.C.Cir.2006). Lilly offers no concrete signs of damage to its reputation, let alone damage that would

be prevented by a preliminary injunction. Instead, it points only to a few news articles covering HRSA's 340B-violation determination, PI 28, and to a declaration stating in conclusory fashion that this determination "would plainly be injurious to Lilly's hard-earned reputation and corporate goodwill" and "is already damaging Lilly's reputation in the community," "marketplace," and among "health-care partners," Pusey Decl. ¶ 29. "In failing to supply [actual] evidence of the loss of reputation or good will beyond [its] own conclusory averments, [Lilly] has not made a sufficient showing that irreparable harm is likely at this point in this action." *See Rush v. Hillside Buffalo, LLC*, 314 F. Supp. 3d 477, 486 (W.D.N.Y. 2018); *see also Cardinal Health, Inc.*, 846 F. Supp. 2d at 213 ("[The plaintiff] has made no concrete showing of reputational harm."); *Hunter v. FERC*, 527 F. Supp. 2d 9, 16 (D.D.C. 2007) (rejecting allegations of irreparable reputational harm as too speculative).

Nor can Lilly demonstrate irreparable injury based on its constitutional claims. As explained, Lilly's theories of the Takings Clause cannot succeed, *see supra* § I.C (noting, *inter alia*, Lilly's failure to even address the legal standards governing its regulatory-takings claims), and thus it cannot rely on them to show irreparable harm. Lilly removes all doubt in this regard in attempting to explain the constitutional harm it would suffer: "[HHS is] trying to coerce Lilly into giving away its property to other private parties (*i.e.*, contract pharmacies) not for any public purpose, but simply for the private gain of third parties." PI at 26. This allegation is riddled with inaccuracies that are belied by the administrative record. To start, Lilly can point to no instance in which HHS has asked Lilly to "giv[e] away its property" to contract pharmacies. *See id.* And Lilly's bald assertion that its statutory obligation to sell 340B-discounted drugs to covered entities irrespective of their dispensing mechanism (in exchange for the benefits available under Medicaid and Medicare Part B) serves only the "private gain" of contract pharmacies ignores both (i) the *public purposes* Congress sought to achieve through this 340B requirement, *see supra* § I.C, and (ii) the overwhelming record evidence that this statutory requirement is *in fact* achieving those public purposes, *see, e.g.*, VLTR_1571, 7257, 7262. Lilly can also point to no constitutional right that would protect its eligibility for drug coverage under federal health-insurance programs where it has failed to comply with the necessary conditions Congress has legitimately placed on drug manufacturers' access to those programs.

Finally, contrary to Lilly's assertion, it has not "shown a likelihood" that it will be deprived of the "procedural right to advance notice and comment" absent a preliminary injunction. *See* PI at 27 (quoting "ADR PI Op. 24"). Lilly's argument on this score simply quotes the Court's decision granting a preliminary injunction relating to the *ADR Rule*. *See id.* But enjoining HRSA's enforcement efforts would surely have no impact on Lilly's procedural right to notice and comment on that unrelated rulemaking. And Lilly has identified no other "procedural right" that will be harmed in the absence of preliminary relief. HRSA's enforcement efforts are premised on Lilly's violation of a *pre-existing* obligation rooted in the 340B statute itself. *See supra* § I.A. Lilly thus has no right to notice and comment on *any* measure interpreting or enforcing this statutory obligation. *See supra* § I.B.2. But even assuming that Lilly *did* have such a procedural right, "to justify the issuance of a preliminary injunction," it would have to "show that unless the rule is enjoined, [Lilly] is likely to experience not just some injury, but irreparable harm that cannot be cured by ultimate success on the merits in this case." *See N. Marian Islands v. U.S.*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009). Lilly makes no such showing.

B. THE BALANCE OF THE EQUITIES AND PUBLIC INTEREST STRONGLY FAVOR ALLOWING HRSA TO PROCEED WITH ENFORCEMENT AGAINST LILLY

The balance of hardships and the public interest weigh against issuing a preliminary injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). There is an "inherent harm" to HRSA in preventing it from enforcing the laws that Congress charged to it. *See Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *Seaside Civic League, Inc. v. U.S. Dep't of Housing & Urban Dev.*, No. 14-cv-1823, 2014 WL 2192052, at *3 (N.D. Cal. 2014). No authority Lilly provides (and no authority of which undersigned counsel is aware) supports Lilly's attempt to have this Court preemptively enjoin the agency's enforcement process *in totem*. The APA permits this Court only to review agency action—not to forestall enforcement in its infancy.

And because HRSA, in its expert judgment, has determined that Lilly's policy is unlawful, it is in the public's interest that the Court not upset the current proceedings unless and until it has determined the agency's approach to be unlawful, particularly when the dispositive motions will already be fully briefed. Lilly's view fails to consider the public interest altogether. It matters not

whether anything "bad will happen to the government if it is forced to wait … before penalizing manufacturers," *id.*, because—contrary to Lilly's insistence—*covered entities and their patients are harmed every day Lilly denies access to discounted drugs*, ECF No. 75 at 14-22, particularly diabetic patients denied access to discounted insulin. Lilly has known since last August that HRSA was considering whether its new policy constitutes a violation of section 340B and whether sanctions apply, and it should not be permitted to halt that process before the Court determines the merits of HRSA's position.

Moreover, Lilly's request that the agency be enjoined from "taking any adverse action against Lilly related to the 340B program based on Defendants' interpretation of the statute," TRO/PI 3, would violate the specificity requirements of Federal Rule of Civil Procedure 65(d), which requires an injunction to "state its terms specifically" and "describe in reasonable detail . . . the act or acts restrained or required." First of all, the terms "adverse action" and "related to" are "hopelessly vague." *See PMC, Inc. v. Sherwin-Williams, Co.*, 151 F.3d 610, 619 (7th Cir. 1998). Second, it would be impossible for HRSA to determine what such an order restrained, because the requested injunction "fails to detail what the conduct is, *i.e.,* the substance of the [adverse action]" to which the requested relief refers. *See Patriot Homes, Inc. v. Forest River Housing, Inc.*, 512 F.3d 412, 415 (7th Cir. 2008). For example, would internal assessment and consideration of potential CMPs qualify? Or memoranda analyzing the basis for a "knowing" violation? This demonstrates why injunctions of *enforcement proceedings*, as opposed to *agency actions*, are impermissible. This Court should deny Lilly's request for emergency relief.

CONCLUSION

Because each of Lilly's claims is meritless, the Court should dismiss each count or, in the alternative, grant summary judgment for HHS, and also should deny Lilly's request for preliminary injunctive relief.

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Respectfully submitted,

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