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

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

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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This case is part of a brazen strategy by a cohort of large, highly profitable pharmaceutical companies—led by Plaintiff Eli Lilly—unilaterally to upend the decades-old, settled operation of a statutory program that provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients. Nearly thirty years ago Congress struck a bargain with drug companies by creating the "340B Program": Participating manufacturers gain valuable access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs (at or below a statutory ceiling price) to certain safety-net healthcare providers. The providers, in turn, can generate much-needed revenue through sale of those medications (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has served a critical role in facilitating healthcare for vulnerable patients ever since.

But late in 2020 Lilly and its peers, clearly dissatisfied with the scope of the 340B Program, unilaterally imposed onerous and non-statutory restrictions on providers' access to 340B discounted drugs. Specifically, the manufacturers announced that no longer will they honor (or honor without significant restrictions) discounted-drug orders placed by eligible healthcare providers but shipped to, and dispensed by, outside pharmacies. These outside-pharmacy arrangements (called "contract pharmacies") have been an integral part of the 340B Program's operation for decades, since the vast majority of 340B-eligible providers do not operate an in-house pharmacy and thus rely on contract pharmacies to serve patients. Lilly and other manufacturers' abruptly announced changes—impacting healthcare entities serving the country's most vulnerable patients, in the midst of a global pandemic—have upended the settled operation of the 340B program and spawned a raft of litigation against the Department of Health and Human Services ("HHS"), the agency to which Congress delegated oversight and implementation of the 340B Program.

Lilly's ultimate goal in this suit is manifestly clear in its complaint: It seeks to have this Court sanction Lilly's rewrite of its statutory obligations in a way that would drastically restrict many providers' access to discounted drugs (and, in so doing, boost Lilly's profits). In this emergency motion, however, Lilly seeks to advance that goal by blocking implementation of a new rulemaking that establishes a straightforward, statutorily mandated administrative dispute-resolution mechanism

Congress devised to resolve disputes over 340B Program violations. In other words, Lilly seeks to head off resolution by HHS of the legality of its recent changes by asking this Court to enjoin the agency's newly available adjudication system—a system established by statute and modeled on numerous other administrative bodies.

There is no cause for this Court to do so. As demonstrated herein, Lilly is unlikely to succeed on the merits of its challenge to the rule: decision-makers are supervised by, and can be removed at will by, the HHS Secretary, and thus constitute inferior officers; Lilly's Article III challenge rests on false premises regarding the ADR Board's powers and the claims it may hear; the rule was issued only after notice-and-comment procedures and fully complies with the APA; and the Secretary fully explained the choices made in designing the new system, thereby satisfying substantive APA requirements. Moreover, Lilly faces no irreparable harm in being "subjected to" the dispute-resolution mechanism Congress envisioned. And the public interest firmly lies in allowing the agency charged with oversight of the 340B Program to resolve, in the first instance, whether the recent manufacturer restrictions are lawful, thereby providing clarity for both covered entities and drug makers.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of Health and Human Services ("HHS"), through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities 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), and also may benefit uninsured and underinsured patients, when covered entities opt to pass along the discounts by helping patients afford costly medications. Congress expressly conditioned drug

makers' access to an incredibly valuable federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). Pharmaceutical companies thus may opt out of providing discounted drugs to safety-net healthcare providers and their low-income patients, but then lose access to "billions of dollars in revenue" annually through drug coverage in federal health-insurance programs. *See* Am. Compl. ("Compl.") at ¶ 157, ECF No. 17.

During the early years of the 340B Program, it became clear that fewer than five percent of the covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies; instead, the vast majority of safety-net providers relied on arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). And because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing." *Id.* at 43,549. Covered entities participating in the 340B Program thus began relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to low-income patients. *Id.*

In 1996 HHS issued non-binding guidance to aid pharmaceutical companies and covered entities in the use of contract pharmacies, explaining that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. Rather than imposing any new requirements, that guidance confirmed the Department's *pre-existing* position "that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," regardless whether the covered entity directs that the drugs be shipped for handling and dispensing to a contract

pharmacy. *Id.* at 43,549. And, the agency continued, restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* at 43,550. Critically, the agency explicitly rejected the argument, suggested in comments to the proposed guidance, that the use of contract pharmacies constitutes an unauthorized expansion of the 340B Program: "The statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549.

Consistent with HHS's interpretation of the 340B statute and its early guidance implementing its terms, covered entities have for decades relied on contracts with outside pharmacies to serve their patients and access the discounts Congress provided. Indeed, these arrangements proved so pivotal to covered entities' and their patients' access to drug discounts that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance"). The agency agreed with commenters that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more-flexible use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* at 10,273. No pharmaceutical manufacturer, trade association, or the like filed suit to challenge the substance of the 2010 guidance. For more than a decade, manufacturers have complied with the guidance, and many covered entities have relied on the ability to contract with multiple pharmacies to best serve their patients and maintain flexibility in accessing 340B discounts.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *See Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121-22 (2011). Specifically, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to "Improve[] … program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted

authority to issue new regulations imposing civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

A neighboring provision also instructed the Secretary to establish a 340B Program administrative dispute-resolution process ("ADR process") for covered entities and manufacturers:

> [T]he Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers … of violations [of provisions prohibiting diversion of drugs and duplicate discounts], including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described [herein].

42 U.S.C. § 256b(d)(3)(A). Congress included several directives regarding the new dispute-resolution mechanism, but largely granted the Secretary discretion to devise a workable system. The Secretary is granted authority to "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices" above the statutory ceiling price, as well as "claims by manufacturers that violations" of prohibitions on duplicate discounts or improper drug diversion have occurred. *Id.* § 256b(d)(3)(B)(i). The Secretary may "establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously," and may "establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim." *Id.* § 256b(d)(3)(B)(ii),(iii). Congress mandated a restriction on claims by manufacturers against covered entities, however; such claims require, "as a prerequisite to initiating" proceedings, that a drug maker first audit a covered entity. *Id.* § 256b(d)(3)(B)(iv). Finally, the statute confirms that ADR decisions "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

The Secretary began work to establish that process several months later by issuing an advanced notice of proposed rulemaking to request comments on the development of an ADR process. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sep. 20, 2010). The agency received only about a dozen comments in response. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,382 (Aug. 12, 2016). A Notice of Proposed Rulemaking ("NPRM") then followed, which included proposed ADR regulations establishing a panel within the agency to adjudicate disputes between drug manufacturers and covered entities. *Id.* at 53,381-82. The agency received 31 public comments on that proposal. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10). HHS finalized the 340B ADR Rule late last year. In drafting the final Rule, it considered the comments received on the 2016 NPRM and adjusted its proposal in response to several comments. The final ADR Rule was published in the Federal Register on December 14, 2020, and became effective on January 13, 2021. *See* 85 Fed. Reg. 80,632.

Both covered entities and drug manufacturers now have a mechanism to resolve before the agency disputes arising under the 340B Program. *See* 85 Fed. Reg. at 80,644. The Rule created "a decision-making body within the Department that, acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision for a claim brought under the ADR Process." *Id.*, codified at 42 C.F.R. § 10.3. The Secretary selects at least six members to serve on an ADR Board, consisting of individuals selected in equal numbers from the Health Resources and Service Administration ("HRSA", an HHS component to which implementation of the 340B Program has been delegated), the Centers for Medicare and Medicaid Services, and HHS's Office of General Counsel (plus a non-voting member from the Office of Pharmacy Affairs). 85 Fed. Reg. 80,644. When a particular claim is presented, the HRSA Administrator then selects three members from the Board to serve on a 340B ADR Panel and, "pursuant to authority expressly delegated through this rule by the Secretary, [] to make precedential and binding final agency decisions." *Id.* The diversity of experience among the members of each panel ensures "relevant expertise and experience in drug pricing or drug distribution" and "in handling complex litigation."

Importantly, the Rule places no restrictions whatsoever on the Secretary's authority to remove a Board member. Nor does it purport to grant any defined term to any Board member. The HRSA Administrator, however, has authority to remove a particular employee from a particular panel for cause, where necessary, and to substitute that panel member for another member of the Board. *Id.*

ADR proceedings are governed by the Federal Rules of Civil Procedure, including the procedural mechanisms established therein. *Id.* at 80,644-45, 42 C.F.R. § 10.23(b). ADR Panels are granted considerable discretion during the pendency of a claim to "permit a covered entity limited discovery," to "[r]eview and evaluate documents and other information" as needed to evaluate a claim, and to "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," including through conducting an evidentiary hearing. *Id.* at 80,644-45, 42 C.F.R. §§ 10.20(c)(1), 10.22(a), 10.23(a).

Critically, the Rule does *not* render decisions of a Panel self-executing. *Id.* at 80,646. On the contrary, while claims may be brought "for monetary damages or equitable relief [above a $25,000 threshold] against a manufacturer or covered entity," *id.* at 80,644, the Panels are instructed to "submit the final agency decision to all parties, *and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.*" *Id.* at 80,646 (emphasis added), 42 C.F.R. § 10.24(e). In other words, the Secretary has delegated to ADR Panels authority to issue binding decisions, while retaining authority within HRSA to execute those decisions. Any dissatisfied party may seek judicial review under the APA. *Id.* at 80,641, 42 C.F.R. § 10.24(d).

II. PHARMACEUTICAL COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS FOR SAFETY-NET PROVIDERS

During the latter half of 2020 several drug makers, led by Plaintiff Eli Lilly ("Lilly"), took unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Lilly that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for only one of its drugs—Cialis, a drug used to treat erectile dysfunction.

Compl. ¶ 78. But only one month later, Lilly extended its new contract-pharmacy restrictions to *all* its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact Lilly to designate a single contract pharmacy). *See* Compl. Exh. G (notifying covered entities they "will not be eligible to purchase [Lilly] products at the 340B ceiling price *for shipment to a contract pharmacy*") (emphasis added). Lilly's changes purported to contain an exception for insulin—but conditioned it on novel, onerous restrictions found nowhere in the 340B statute, including that insurance not be billed for insulin, no markup or dispensing fee be charged to the patient, and that the covered entity provide Lilly detailed information demonstrating compliance with Lilly's conditions. *Id.* Nowhere does Lilly allege that, since September 2020, it has reversed course, and so continues unilaterally to restrict access to 340B discounts through contract-pharmacy arrangements. Lilly also continues to impose its own restrictions on insulin purchases (although it is not restricting insulin to only a single contract pharmacy). Lilly's campaign also included a request that HHS rescind its 2010 Guidance on use of contract pharmacies to dispense drugs purchased by 340B covered entities, *see* Compl. Ex. E, Hakim Letter, despite the fact that Lilly had not previously challenged that guidance and had complied with its substance for more than a decade.

Although HRSA published on its official 340B website Lilly's original notice restricting access to Cialis, HRSA declined to post Lilly's later notice expanding the 340B restrictions, and told an industry reporter that the agency "is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply," including, "but not limited to, civil monetary penalties."[1] HRSA further warned that "manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies"; the agency thus "continues to strongly encourage all manufacturers to sell 340B priced drugs … directly and through contract pharmacy arrangements."

[1] *See* BREAKING: HRSA Is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute, 340B Report (Sept. 2, 2020), *available at* https://340breport.substack.com/p/breaking-hrsa-is-investigating-whether.

Lilly's restrictions were soon emulated, with certain modifications, by other large, global pharmaceutical companies. For instance, Sanofi-Aventis soon announced it would no longer honor 340B prices for covered entities requesting delivery of drugs to contract pharmacies unless the covered entity complies with demands, found nowhere in the statute, to provide Sanofi detailed claims data; AstraZeneca imposed the same restrictions as Lilly had mandated; and Novartis and Novo Nordisk imposed their own, separate restrictions soon thereafter. *See Sanofi-Aventis v. HHS*, No. 21-cv-634, ECF No. 17, Am. Compl., Exh. 1 (D. N.J.); *AstraZeneca Pharmaceuticals v. Azar*, No. 21-cv-27-LPS, ECF No. 13, Am. Compl. Exhs. A, C (D. Del.); Novartis 340B Policy Changes, https://www.novartis.us/news/statements/new-policy-related-340b-program; *Novo Nordisk v. Azar*, No. 21-cv-806-FLW-LHG, ECF No. 1, Compl. ¶¶ 56-58 (D.N.J.).

The pharmaceutical manufacturers' abruptly announced, unilateral restrictions on 340B access caused upheaval due to covered entities' longstanding reliance on contract-pharmacy arrangements, prompting various safety-net providers to urge HHS to take action by filing emergency motions *against the agency* seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO and Prelim. Inj., *Ryan White Health Clinics for 340B Access v. Azar*, No. 20-cv-2906-KBJ (D.D.C. Nov. 23, 2020)), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020), ECF No. 7. HHS has moved to dismiss those suits for lack of jurisdiction while confirming that its investigation of the manufacturers' actions is ongoing.

The public outcry to the drug companies' changes was swift, and HHS's General Counsel issued an Advisory Opinion on December 30, 2020, confirming his view—in accord with the agency's longstanding guidance—"that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("AO") at 1.[2] The AO explained that the 340B statute requires manufacturers, in exchange

[2] AO 20-06, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

for access to Medicaid and Medicare Part B, to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the distribution or dispensing arrangements selected by the covered entity. *Id.* at 2. And contract-pharmacy arrangements unequivocally involve purchase by a covered entity, the General Counsel explained, regardless whether "[t]he situs of delivery[] be [] the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Id.* at 3. Moreover, the opinion continues, covered entities have relied on contract pharmacies for decades—and that system is wholly compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," *i.e.*, "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. A restriction limiting 340B discounts in the manner now imposed by drug makers would produce "a bizarre result," "inconsistent with the purpose of the Program and common sense." *Id.* The General Counsel confirmed that this interpretation is compelled by the statute itself; no rulemaking is required, and no expansion of the 340B Program has been effectuated, because Congress did not permit drug makers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. AO at 2-4.

III. PHARMACEUTICAL COMPANIES SUE TO PREVENT HHS's ENFORCEMENT OF THE 340B STATUTE

The pharmaceutical companies' concerted actions to upend the 340B status quo have continued in litigation. Three drug makers, including Lilly, filed suit on the same day challenging the General Counsel's Advisory Opinion. *Lilly*, No. 1:21-cv-81-SEB-MJD (Jan. 12, 2021), ECF No. 1; *Sanofi-Aventis*, No. 3:21-cv-634 (D.N.J. Jan. 12, 2021), ECF No. 1; *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1. Motions for extraordinary injunctive relief are now pending in all three actions. *Lilly*, ECF No. 18; *Sanofi-Aventis*, ECF No. 19; *AstraZeneca*, ECF No 14. Two additional, similar suits were filed shortly thereafter. *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

As for this action, notwithstanding the advisory nature of the General Counsel's opinion and the fact that it reiterated guidance the agency long ago had issued (and with which Lilly had complied,

without challenge, for ten years), Lilly now asks this Court to declare the advice unlawful and to bless Lilly's intention "*not to offer 340B price discounts to contract pharmacies*." Compl., Prayer for Relief a, b, ECF No. 1 (emphasis added). In other words, Lilly asks this Court to sanction a substantially more-sweeping change to the 340B Program than the disruptive restrictions Lilly already has imposed.

Two weeks after filing this suit, Lilly amended its complaint to add new claims related to the ADR Rule issued last December. *See* Am. Compl., ECF No. 17. That same day, Lilly filed an omnibus motion for extraordinary injunctive relief, challenging the Rule on nearly every conceivable ground: Lilly contends that the ADR Board violates the Constitution's Appointments Clause; that it unlawfully impinges on the province of Article III courts; that HHS failed to comply with the APA's notice-and-comment requirements; and that the Rule is substantively arbitrary and capricious and exceeds the statutory authority granted by Congress. *See* Mot. for Prelim. Inj. ("Mot.") 15-30, ECF No. 19.

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary and drastic remedy." *Munaf v. Geren*, 553 U.S. 674, 689 (2008) (citation omitted). It is "never awarded as of right," *id.* at 690, and "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion," *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted). To obtain a preliminary injunction, "a plaintiff must establish that [he] has some likelihood of success on the merits; that [he] has no adequate remedy at law; that without relief [he] will suffer irreparable harm." *GEFT Outdoors, LLC v. City of Westfield*, 922 F.3d 357, 364 (7th Cir. 2019), *cert. denied*, 140 S. Ct. 268 (2019) (citation and quotation marks omitted). "If the plaintiff fails to meet any of these threshold requirements, the court must deny the injunction." *Id.* (citation and quotation marks omitted). Only after a plaintiff passes this threshold must a court "weigh the harm that the plaintiff will suffer absent an injunction against the harm to the defendant from an injunction, and consider whether an injunction is in the public interest." *Id.* (citation and quotation marks omitted).

The Seventh Circuit "'employs a sliding scale approach' for this balancing: if a plaintiff is more likely to win, the balance of harms can weigh less heavily in its favor, but the less likely a plaintiff is to

win the more that balance would need to weigh in its favor." *Id.* (citation and quotation marks omitted). If a plaintiff cannot show a likelihood of success, "there [is] no need for the district court to conduct further analysis of the 'threshold phase' for preliminary injunctive relief, or to move to the 'balancing phase.'" *Id.* at 367-68 (citation omitted). And a plaintiff "seeking preliminary relief [must] demonstrate that irreparable injury is *likely*," not merely possible, "in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008).

ARGUMENT

Lilly and its peers are engaged in a brazen attempt to effect a unilateral sea change in the settled operation of the 340B Program. Congress devised the program to provide affordable medications and much-needed revenue to vulnerable patients and safety-net healthcare providers, and expressly conditioned a valuable federal benefit, coverage of drug manufacturers' products in the nation's largest health-insurance programs, on the companies' agreement to provide deep discounts on *purchases by* covered entities. Now a cohort of highly profitable, massive pharmaceutical companies seek to litigate out of the obligation to comply with their end of the bargain, by creating from whole cloth novel restrictions on covered entities' access to 340B discounts, including limitations on the delivery site or dispensing mechanism employed by the covered entity, and onerous reporting requirements with no basis in statute or regulation. Lilly's abruptly imposed restrictions have caused upheaval by severely curtailing access to the discounts to which covered entities are entitled. Any doubt as to Lilly's intent is dispelled by the fact that its motion is larded with grievances about covered entities' use of contract-pharmacy arrangements—complaints which ignore the covered entities' twenty-five-year reliance on such agreements *and* fundamentally mischaracterize the transactions at issue by pretending it is the pharmacies, not covered entities, that purchase Lilly's discounted drugs.[3]

Regardless, neither the legality nor the wisdom of contract-pharmacy arrangements is now before the Court. In its motion Lilly instead seeks to block implementation of a straightforward

[3] *See, e.g.*, Mot. 1 (HHS has "permitted big-business 'contract pharmacies' to hijack this carefully circumscribed program and siphon from it hundreds of millions of dollars"); *id.* (ignoring HHS's 1996 and 2010 guidance to suggest HHS "recently concluded that manufacturers must offer 340B discounts … to those for-profit pharmacies"); *id.* at 5-8 (arguing rampant abuse among contract pharmacies).

administrative dispute-resolution mechanism, mandated by Congress and modeled after numerous existing agency systems, that Lilly fears will issue an adverse decision on its unilaterally imposed contract-pharmacy restrictions. There is no cause for this Court to do so. Lilly's constitutional challenges fundamentally misrepresent the Rule and the powers it grants to Board members. The Rule fully complies with both notice-and-comment and substantive APA requirements. Moreover, Lilly faces no irreparable harm in being "subjected to" the dispute-resolution mechanism Congress mandated, and cannot overcome the fact that the public interest firmly lies in allowing HHS to resolve, in the first instance, whether Lilly's contract-pharmacy restrictions are lawful.

I. LILLY CANNOT SUCCEED ON THE MERITS

A. ADR Board Members Are Inferior Officers

Lilly's argument that the ADR Rule creates principal officers in contravention of the Appointments Clause, U.S. Const. art. II, § 2, cl. 2, contorts the Rule's plain language and ignores precedent holding that similar schemes create inferior, not principal, officers. Lilly insists that ADR "decisions are unreviewable by any superior Executive Branch official and [officers] are protected by for-cause removal restrictions to boot," Mot. 16, but neither premise finds support in the plain text of the Rule. Although the Rule does not create an internal agency appeals process, there are no restrictions on the Secretary's oversight and supervision of the Board. The Secretary appoints ADR Board members and delegates to them responsibility for issuing final decisions, and the Secretary retains the ability to revoke that delegation at any time, to issue binding regulations that constrain the Board members, and may remove a Board member at will, at any time. Under established precedent, Board members thus serve as inferior officers who may be appointed by the Secretary.

The Appointments Clause divides officers into two categories: principal and inferior. *See* U.S. Const. art. II, § 2, cl. 2. Although principal officers require appointment by the President with confirmation by the Senate, the Constitution grants flexibility for the appointment of inferior officers; they may be named in the same manner as principal officers, or Congress may vest their appointment "in the President alone, in the Courts of Law, or in the Heads of Departments." *Id.*

Although the Supreme Court has "not set forth an exclusive criterion for distinguishing between principal and inferior officers," it has explained that, "[g]enerally speaking, the term 'inferior officer' connotes a relationship with some higher ranking officer or officers below the President: Whether one is an 'inferior' officer depends on *whether he has a superior*." *Edmond v. United States*, 520 U.S. 651, 661-62 (1997) (emphasis added). The focus is not merely on whether the officer has some "superior" who "formally maintain[s] a higher rank," but on whether the officer is one "whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.* at 662-63. *Edmond* involved a challenge to military judges of the Coast Guard Court of Criminal Appeals—officers that exercised significant discretion and responsibility, including the authority to resolve constitutional challenges, review death sentences, and independently weigh evidence to determine guilt and sentence. *Id.* at 662. In deeming the judges inferior officers, the Court emphasized that "the line between principal and inferior officers" turns on supervision by a higher authority, not on the "exercise of significant authority," which is the hallmark of *any* officer. *Id.* at 662-66. And because a higher authority could remove a military judge "without cause"—"a powerful tool for control"—and also "exercise[] administrative oversight," including the ability to "prescribe uniform rules of procedure" and "formulate policies and procedure," the judges were subject to sufficient supervision to qualify as inferior officers. *Id.* at 664. This conclusion was not altered by the fact that the supervising principal officer "may not attempt to influence (by threat of removal or otherwise) the outcome of individual proceedings." *Id.*[4]

The Supreme Court again addressed the line between principal and inferior officers in *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 561 U.S. 477 (2010). There, after striking down a statutory removal restriction, thus rendering Board members subject to at-will removal by the Securities and Exchange Commission, the Court had "no hesitation in concluding that under *Edmond* the Board members are inferior officers." *Id.* at 510. "Given that the Commission is properly viewed, under the Constitution, as possessing the power to remove Board members at will," and given the

[4] The *Edmond* Court also noted that certain decisions issued by the judges were subject to limited review in the Court of Appeals for the Armed Forces. 520 U.S. at 664-65. As demonstrated herein, however, numerous persuasive decisions establish that the absence of direct review of an officer's *decisions* does not render that officer a principal.

Commission's general oversight abilities, no constitutional concerns were presented by the absence of Presidential appointment. *Id. Free Enterprise Fund* emphasizes the importance of removal as a relevant and "powerful" form of control for Appointment Clause purposes—regardless of the fact that oversight of the Board was not "plenary." *Id.* at 504, 510. "[T]he Board is empowered to take significant enforcement actions, and does so largely independently of the Commission," which lacks statutory authority "to start, stop, or alter individual Board investigations." *Id.* at 504.

Persuasive appellate authorities applying these principles demonstrate the different ways in which an inferior officer's work may be "directed and supervised at some level" by superior officers. For example, the D.C. Circuit held that the judges of the Copyright Royalty Board are inferior officers, so long as they have no statutory restrictions on removal, even though their decisions are not "directly reversible" by any other Executive Branch officer. *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1338-41 (D.C. Cir. 2012). After severing a statutory removal restriction, the court explained that: "With unfettered removal power, the Librarian [of Congress] will have the direct ability to 'direct,' 'supervise,' and exert some 'control' over the Judges' decisions"—even though individual decisions "will still not be directly reversible" by any higher official. *Id.* at 1341. As with *Edmond*, although the judges exercised "broad discretion" to decide the cases before them, a principal officer provided general supervision through the ability to approve the judges' procedural regulations, issue ethical rules, and "oversee[] various logistical aspects of their duties," including the provision of administrative resources. *Id.* at 1338. Yet even absent any mechanism for the supervising principal officer "to play an influential role in the [judges'] substantive decisions," and that the judges "issue decisions that are final for the executive branch, subject to reversal or change only when challenged in an Article III court," the court of appeals was "confident that … the [judges] will be inferior rather than principal officers" absent any statutory removal restriction. *Id.* at 1338, 1340, 1341.

Indeed, the D.C. Circuit reaffirmed *Intercollegiate Broadcasting* the same day HHS filed this brief, and specifically rejected the argument that "an inferior officer's decisions must be subject to review by a principal officer." *Fleming v. USDA*, No. 17-1246, slip op. at 18-19 (D.C. Cir. Feb. 16, 2021). In light of "substantial oversight by the Secretary," including through promulgation of "procedural and

substantive regulations," the court had "little difficulty classifying the Department[of Agriculture's] ALJs as inferior officers." *Id.*

Likewise, that same court recently concluded that Special Counsel Mueller was an inferior officer, even though Department of Justice regulations "impose various limitations on the Attorney General's ability to exercise effective oversight of the Special Counsel." *In re Grand Jury Invest.*, 916 F.3d 1047, 1052 (D.C. Cir. 2019). That conclusion turned on the Attorney General's "authority to rescind" those regulations "at any time," thereby allowing him to exercise supervisory authority. *Id.* In other words, regulations restricting a principal officer's supervisory authority make no difference from a constitutional perspective, because the agency head retains plenary authority to revise or rescind the regulations. Applying that reasoning, the court of appeals confirmed that the Special Counsel is a validly appointed inferior officer because he "effectively serves at the pleasure of" the Attorney General. *Id.* at 1052-53.

There is no question that the ADR Rule creates inferior officers that may validly be appointed by the Secretary and remain subject to his supervision. Through the Rule, the Secretary has delegated to Board members the authority to act as adjudicators under the APA and the 340B statute, 42 U.S.C. § 256b(d)(3)(A). *See* 42 C.F.R. § 10.3 (creating "a decision-making body within the Department that, acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision for a claim"). The Secretary retains the ability to revoke this delegation and could, if he so chose, adjudicate these matters personally; nothing in the statute places any restriction on the "decision-making official or decision-making body" selected by the Secretary to resolve 340B disputes. 42 U.S.C. § 256b(d)(3)(B). Moreover, Board members are bound by the Secretary's regulations, including those governing adjudicatory procedures, and substantive regulations relating to the 340B Program. Perhaps most importantly, Board members serve at the pleasure of the Secretary and can be removed at any time. Neither the statute nor the regulations contain any restrictions on the Secretary's removal power (and *even if* the Rule itself contained a removal restriction, it would make no difference because the Secretary could rescind that restriction at any time, *In re Grand Jury Invest.*, 916 F.3d at 1052-53).

Lilly's arguments to the contrary misconstrue the Rule and misapply both the supervision and removal prongs of the Appointments Clause analysis. As to supervision, Lilly insists that, because "[t]he Supreme Court has never concluded that an agency adjudicative officer was an inferior officer when—as here—no superior officer could review her decisions," the absence of an internal appeals process "standing alone[] suffices to demonstrate ADR panelists' status as principal officers." Mot. 17-18. That assertion lacks merit for numerous reasons: the weight of Appointments Clause authority does not involve *adjudicative* officers; the Supreme Court has never held that an inferior adjudicative officer's decisions *must* be reviewed, individually, by a principal officer; and the Court's reasoning in *Edmond* and *Free Enterprise Fund* emphasizes other means of "supervision" than direct review of an officer's decisions. Moreover, the lack of direct, intra-agency review was true of the judges in *Intercollegiate Broadcasting* too, yet the court of appeals was "confident" in deeming them inferior officers. 684 F.3d at 1341. At bottom, the absence of an internal review mechanism does not prevent the Secretary from supervising Board members—nor does it render them principal officers.[5]

Lilly's argument as to the removal prong rests on a flatly false premise. Lilly admits, as it must, that "the Rule sets out no method of removal," Mot. 18, yet argues that this silence somehow constrains the Secretary's removal authority. But the statute contains no restriction on the Secretary's removal of Board members, 42 U.S.C. § 256b(d)(3)(A)-(B), and the regulation likewise does not purport to prevent members' removal at will (and a regulatory for-cause provision would *have no impact* on the Secretary's power regardless, *In re Grand Jury*, *supra*). Lilly's argument contravenes "[t]he general and long-standing rule [] that, in the face of statutory silence, the power of removal presumptively is incident to the power of appointment." *Kalaris v. Donovan*, 697 F.2d 376, 389 (1983); *see also Free*

[5] Lilly's reliance on *Association of American Railroads v. U.S. Department of Transportation* is misplaced. 821 F.3d 19 (D.C. Cir. 2016). The arbitrators in question there were not deemed principal officers solely because their decisions lacked secondary review before constituting final agency action. Rather, "[n]owhere d[id] [the statute] suggest the arbitrator 'is directed and supervised at some level by others'"; indeed, the arbitrators lacked *any* supervision, whatsoever, by any official. *Id.* at 39 (citation omitted). That level of independence is fundamentally different from the ADR Rule, which leaves Board members subject to supervision by the Secretary in numerous ways, discussed above. Moreover, it is telling that Lilly places heavy reliance on the D.C. Circuit's opinion in *Association of American Railroads* while wholly ignoring that circuit's holding in *Intercollegiate Broadcasting* that an agency adjudicator's decisions *need not* be subject to internal review to establish the "supervision" required of inferior officers.

Enterprise Fund, 561 U.S. at 509 ("Under the traditional default rule, removal is incident to the power of appointment.").

Lilly attempts to elide this lack of constraint by pointing to a provision delegating *to the HRSA Administrator* the power to remove a panel member "for cause," including for a conflict of interest. Mot. 18-19; 42 C.F.R. § 10.20(a)(1)(ii), (2). But that delegation of partial authority to take ADR Board members from a particular panel merely allows the HRSA Administrator to share in the supervision of the ADR process; it in no way constrains the Secretary's ability to remove an individual from a panel, or from the Board, at will—with or without a conflict of interest.[6] Put simply, ADR Board members are not "insulate[d] … from HHS control," Mot. 19, because the Secretary may rescind his delegation of authority at any time by removing a Board member for any reason. This "powerful tool for control," *Edmond*, 520 U.S. at 664, demonstrates that members serve as inferior officers.

Contrary to Lilly's view, *Arthrex, Inc. v. Smith & Nephew, Inc.*, bolsters HHS's argument here. 941 F.3d 1320 (Fed. Cir. 2019). The relevant principal officer there *lacked authority* to review patent judges' decisions, whereas here the Secretary could rescind the Rule and reserve to himself the power to decide 340B claims. The *Arthrex* court also found it significant that, like here, the principal "exercise[d] a broad policy-direction and supervisory authority," could "promulgate regulations governing the conduct of" the adjudicatory process, and could "issue policy directives and management supervision of the Office," all of which "weigh in favor of a conclusion that [the judges] are inferior officers." *Id.* 1331-32. Indeed, the court relied on the D.C. Circuit's opinion in *Intercollegiate Broadcasting* to determine that, once a statutory for-cause removal provision was severed, no constitutional problem was presented by the lack of direct internal review. *Id.* at 1335-38.[7]

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[6] Lilly's assertion that the HRSA Administrator may only remove a panel member for conflicts of interest, Mot. 18-19, also is incorrect; the regulation delegates authority to remove members "for cause," without limiting that term. 42 C.F.R. § 10.20(a)(1)(ii). Lilly's inaccuracy is irrelevant, however, since it is the Secretary's power—not that of the HRSA Administrator, acting through delegation—that matters for constitutional purposes.

[7] This Court should reject Lilly's invitation to infer that the Supreme Court's grant of certiorari in *Arthrex* suggests that, absent a statutory removal restriction, the Appointments Clause is violated by an inferior officer's ability "to have the last word on an issue." Mot. 20. The Court granted the government's certiorari petition challenging the Federal Circuit's conclusion that the statutes governing administrative patent judges contained any Appointments Clause violation, and thus may not need to address the cross-petition's remedial question at all.

Lilly's challenge fails because Board members are inferior officers whose work is "directed and supervised at some level" by the Secretary, a principal officer appointed by the President with Senate confirmation. *Edmond*, 520 U.S. at 663. Like the officers in *Intercollegiate Broadcasting*, 684 F.3d at 1341, and *Free Enterprise Fund*, 561 U.S. at 510, Board members are freely removable at will. Like the Special Counsel in *In re Grand Jury Investigation*, 916 F.3d at 1052-53, the Secretary could revoke or modify the ADR Rule—and thus the members' authorizing regulations—at any time. And like the inferior officers in *Edmond*, 520 U.S. at 664, Board members must follow their superior's rules of procedure and substantive policy, and members may be removed from any particular assignment. The Secretary retains plenary authority to revise the Rule and, in so doing, modify the workings of the Board. Board members thus have received a proper appointment as inferior officers from the Secretary of HHS as the Head of a Department.

B. THE ADR PROCESS DOES NOT INFRINGE THE POWER OF THE JUDICIARY

As with its Article II challenge, Lilly's Article III argument rests on a wildly inaccurate portrayal of the Board's remedial powers and of the claims it is empowered to hear. Far from "unlawfully usurp[ing] the powers Article III assigns exclusively to a judiciary comprised of life-tenured judges," Mot. 20, the ADR Rule creates a straightforward mechanism for the agency to determine compliance with a statutory scheme Congress entrusted to HHS—precisely the type of administrative adjudication that courts have blessed for much of the past century. The Rule creates no Article III concerns.

As an initial matter, Lilly falsely claims that the Board is empowered to "issu[e] injunctions commanding one private party to convey its property to another without full payment." Mot. 21. This assertion is nonsensical because, under the 340B statute, a sale of Lilly's medications to a covered entity at the statutory ceiling price *is full payment*, and Lilly must comply with its obligation to fulfill orders *placed by covered entities* at no more than the ceiling price if it wishes to retain access to Medicaid and Medicare Part B. The Board determines compliance by both covered entities and manufacturers with statutory requirements—it does not set prices or command the conveyance of private property.

Moreover, the ADR Rule facially disproves Lilly's argument as to the Board's powers. Although ADR Panels are empowered to issue a final agency decision, those decisions are *not* self-effectuating. Panel decisions must be "submit[ted] … to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e). Indeed, in response to comments, some of which expressed "concern[]" that the proposed rule *lacked* a specific enforcement mechanism, the agency rejected calls for more-specific provisions by explaining that ADR panels "may make recommendations to HRSA for sanctions, including referrals to the HHS Office of Inspector General for its consideration of civil monetary penalties," and that the absence of specific enforcement mechanisms in the Rule is designed "to permit HHS maximum flexibility in determining what is appropriate" when a panel determines a violation has occurred. *See* 85 Fed. Reg. at 80,642. Lilly's clamoring about "the threat of binding and self-executing judgments for money damages," claims that the Rule does "not leav[e] it to the agency to take subsequent enforcement action," and unsupported insistence that decisions "take immediate effect," Mot. 14, 12, 23, ignores the Rule's plain text requiring panels to submit decisions *to HRSA* "for appropriate action." § 10.24(e).

Tellingly, *not one* of Lilly's discussions of "equitable relief" cite to the regulation itself, Mot. 2, 12, 14, 16, 22, 25, 28, 29—and for good reason, since the Rule does not purport to authorize panels to issue sweeping injunctions. Rather, the "equitable relief" referred to in the Rule establishes a jurisdictional floor on the claims heard by a panel, to exclude *de minimis* claims. 42 C.F.R. § 10.21 (a), (b) (granting jurisdiction "to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000" within twelve months); 85 Fed. Reg. at 80,633 (explaining that provision is designed to exclude *de minimis* claims). Read in context, the "equitable relief" contemplated in the Rule means an order determining whether a manufacturer or covered entity has violated the statute—not a self-executing, judicial-style remedy. The 340B statute clearly contemplates that the new ADR process will resolve questions of program compliance, and that is all the Rule purports to authorize, since panel decisions must be referred to HRSA for enforcement. Nowhere does the Rule allow panels to grant a sweeping "injunction," under penalty of contempt, as can be issued by an Article III court. Rather, the "equitable relief" issued by a panel

would declare specified conduct to be unlawful—the equivalent of a cease-and-desist order, which can be obeyed or appealed—not a self-executing injunction.

Far from unusual, the orders contemplated in the ADR Rule find analogues throughout the federal bureaucracy. "Some agencies have the power in an adjudication, similar to the power that courts possess, to order the payment of money, either to the Government or to a third party, subject to judicial review. More typically, agencies will issue orders that resemble court-issued injunctions, though they may be called something else, such as 'cease and desist orders' (Federal Trade Commission (FTC)), 'exclusion orders' ([Securities and Exchange Commission]), or 'deportation orders' directing an alien to leave the country (U.S. Citizenship and Immigration Service)." Alan B. Morrison, *Administrative Agencies Are Just Like Legislatures and Courts-Except When They're Not*, 59 Admin. L. Rev. 79, 99-100 (2007); *see also id.* n.66 (noting that National Labor Relations Board can order an employee's reinstatement, with back pay, and Commodity Futures Trading Commission can order fines "of the higher of $100,000 or the gain of the wrongdoer" plus restitution).

Lilly's complaints about the ADR Board's authority to conduct proceedings are easily dispatched. Lilly urges this Court to find an Article III problem based on panels' "authority to award money judgments, issue equitable remedies, take evidence and hear testimony, impose sanctions, issue precedential and binding decisions, and decide ancillary legal issues." Mot. 23. Again, the assertions regarding remedies are false. And the adoption of court-like procedures makes no difference, because the Supreme "Court has never adopted a 'looks-like' test to determine if an adjudication has improperly occurred outside of an Article III court," since "[t]he fact that an agency uses court-like procedures does not necessarily mean it is exercising the judicial power." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1378 (2018) (rejecting argument that non-judicial patent adjudication "violates Article III because it shares 'every salient characteristic associated with the exercise of the judicial power," including "motion practice …; discovery, depositions, and cross-examination of witnesses; introduction of evidence and objections based on the Federal Rules of Evidence; and an adversarial hearing before the Board") (citation omitted). In short, the procedures adopted by the ADR Rule mirror those found, and upheld, in other agency adjudications.

That leaves only Lilly's argument that the Board usurps the power of federal courts. Article III prevents Congress from "withdraw[ing] from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty." *Stern v. Marshall*, 564 U.S. 462, 484 (2011) (quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1855)). In other words, non-judicial fora may not be assigned adjudication of "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789." *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*,, 458 U.S. 50, 90 (1982) (Rehnquist, J., concurring). But when Congress creates a new right by statute—*i.e.* a "public right[]"—"it depends upon the will of [C]ongress whether a remedy in the courts shall be allowed at all," so "Congress may set the terms of adjudicating" that right. *Stern*, 564 U.S. at 489 (citation omitted). The separation of powers is not offended by adjudication of public rights outside the judiciary because, when Congress creates new rights (such as through a novel, comprehensive regulatory scheme), it has broad latitude to grant jurisdiction to federal courts or assign adjudication in another branch.

Public rights capable of resolution before an administrative agency are not limited, as Lilly suggests, to rights "collectively held by the entire community or which involve disputes between the government and a private party." Mot. 21. On the contrary, the Supreme Court long ago "rejected the limitation of the public rights exception to actions involving the Government as a party," instead explaining that it encompasses "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." *Stern*, 564 U.S. at 490-91 ("[W]hat makes a right 'public' rather than private is that the right is integrally related to particular Federal Government action."). Thus it matters not that the dispute may arise between private parties; it is the character of the *right* at issue—one specially created by Congress—that renders it amenable to non-judicial resolution. In fact, the argument Lilly presses here has been explicitly rejected by the Supreme Court. After canvassing various agency adjudicative schemes, all of which "surely determine liabilities of individuals," the Court explained that, "[i]f the identity of the parties alone determined the requirements of Article III … the constitutionality of many quasi-adjudicative activities carried on by

administrative agencies involving claims between individuals would be thrown into doubt." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 587, 589 (1985); *see also id.* 571-75, 584 (upholding binding arbitration to resolve disputes between private companies because "[a]ny right to compensation … results from [the statute] and does not depend on or replace a right to such compensation" under state or common law). These principles recently were reaffirmed in *Oil States*, which upheld a procedure whereby an administrative board, through adversarial proceedings between private parties, determines the validity of patent rights. The Court's conclusion was not displaced by the fact that patents might be "property for purposes of the Due Process Clause or the Takings Clause." 138 S. Ct. at 1379.

Lilly's assertion that the Rule violates Article III by allowing non-judicial adjudication of private rights, Mot. 21-24, rests on a warped interpretation of the disputes presented to the Board. The ADR process does not decide Lilly's "right to sell a product at the seller's price," *id.* at 22, nor can a panel "command[] one private party to convey its property to another without full payment," or extinguish "the right to private property," *id.* at 21. The ADR process, like other administrative determinations of public rights, *supra*, determines compliance with the statutory provisions enacted by Congress. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.3. The panels cannot determine "disputes over those prices" Lilly may charge for its product, Mot. 22; the statutory ceiling price accomplishes that task. The panels do not decide to whom Lilly must offer discounted drugs; the 340B statute determines this, too. The ADR panels, contrary to Lilly's portrayal, do not have independent authority to order the disgorgement of private property—only compliance with the statutory regime. And the statutory disputes ADR panels resolve emphatically are not "traditional actions at common law," *Stern*, 564 U.S. at 484, since they are entirely creatures of the 340B Program.

Tellingly, Lilly *admits* that "a covered entity's entitlement to 340B discounts may arise from a public right (given that it exists only as a matter of statute)," Mot. 22, but then asserts, in conclusory fashion, that *its* private rights still are at stake. As demonstrated above, the Supreme Court repeatedly has upheld administrative adjudication of statutory, public rights notwithstanding that the disputes arose between private parties and resulted in the exchange of property. The ADR Rule does not concern private rights any more than those sanctioned in, *e.g.*, *Union Carbide*, 473 U.S. at 587-89.

Congress created the 340B Program, thereby granting covered entities the statutory *right* to discounted medications, and pharmaceutical manufacturers, like Lilly, the statutory *right* to access incredibly valuable revenue streams (Medicaid and Medicare Part B) in exchange for providing its property in the form of discounted drugs. The rights of both covered entities and manufacturers under this scheme are quintessential public rights, created by a comprehensive and well-established regulatory system, and of precisely the same character as the administrative proceedings cited approvingly in *Union Carbide*. *See* 473 U.S. at 587-89. Lilly can opt out of the 340B Program and lose the right to access to Medicaid and Medicare Part B, but it cannot enjoy those rights while shirking its obligations under 340B.[8] The Board, for its part, is not deciding Lilly's "right to sell a product" at its price, Mot. 22, but rather whether manufacturers and covered entities each are complying with statutory requirements. *See Kalaris*, 697 F.2d at 388 ("The law is emphatically clear that when Congress creates a substantive federal right, it possesses substantial discretion to prescribe the manner in which that right may be adjudicated."); *id.* at 400 (upholding administrative resolution of workers' compensation claims, noting "the scores of administrative boards and tribunals in the Executive Branch that currently adjudicate claims to federal statutory rights").

Lilly's argument that the ADR process falls "well outside the realm of administrative review schemes the Supreme Court has been willing to accept" because panel decisions are "self-executing" without application "to a federal court for enforcement of an order," Mot. 23-24, is equally doomed. Decisions must be referred to HRSA, 42 C.F.R.§ 10.24(e), and HRSA (not the panel) is empowered to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," *id.* And the fact that enforcement can be initiated by the agency, without involvement by a court, matters not. Lilly relies for this argument on cases involving the adjudication of *private* rights, not public rights, where non-judicial schemes were considered "adjuncts" of the federal courts. *See CFTC v. Schor*, 478 U.S. 833, 853 (1986) ("The counterclaim asserted in this litigation is a 'private' right

[8] Lilly's insistence that it has not "consented to the 340B Program as it currently exists in the wake of the December 30 decision obligating [it] to offer full discounts to contract pharmacies," Mot. 24-25, is specious. As explained above, the General Counsel's Advisory Opinion reiterated guidance from 2010 regarding a practice that dates to the 1990s—nothing changed with its issuance. And manufacturers do not provide discounts to contract pharmacies; they fulfill orders from covered entities that are *shipped* to pharmacies. It is Lilly and its peers that seek to upend an established system.

for which state law provides the rule of decision.") (cited at Mot. 24). That doctrine is inapplicable here because only public rights are at stake, so Congress is free to assign initial review outside the judiciary.[9]

Any remaining doubt as to the character of the disputes resolved by the Board is answered by *Astra*, 563 U.S. at 110. The *Astra* Court rejected an attempt by covered entities to sue drug manufacturers for violating 340B requirements, explaining that Congress placed oversight in HHS and did not grant covered entities any right to sue for program violations. *Id.* at 117. Although the ADR Rule had not yet been promulgated, the Court explained that "Congress directed HRSA to create a formal dispute resolution procedure … to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements … and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA." *Id.* at 121-22 (citation omitted). True, the Court did not expressly consider the public/private rights doctrine. But in firmly rejecting the covered entities' ability to sue, *Astra* confirms that the rights created under the 340B statute—including the right *to purchase* covered drugs at the 340B ceiling price—are creatures of statute, the resolution of which Congress vested within the agency. Lilly ignores this precedent, likely because its assertion that the ADR Board resolves private rights that must be determined in federal court is irreconcilable with *Astra*'s holding that the very same claims *may not* be determined in federal court.[10]

[9] Lilly's contention that "private rights disputes must be adjudicated by Article III courts and Article III courts alone," Mot. 21, also is wrong. Private rights sometimes may be adjudicated by agencies serving as adjuncts of the Third Branch. *See Schor*, 478 U.S. at 853; *Crowell v. Benson*, 285 U.S. 22, 47 (1932) (upholding administrative scheme that displaced traditional common-law claim and created "expert and inexpensive method for dealing with a class of questions of fact … peculiarly suited to … determination by an administrative agency"); *Kalaris*, 697 F.2d at 386 ("Article III does not require Article III judges to perform every stage of adjudication where 'private rights' are at stake.").

[10] Lilly's complaint that the ADR Rule fails to "expressly authorize federal court review—much less *de novo* review" is absurd. *See* Mot. 23. Congress, not the Secretary of HHS, authorizes federal court review. And absent a contrary intent in a statute (none exists here), judicial review of final agency actions is authorized by the APA, 5 U.S.C. §§ 701 *et seq.* The Secretary could not, by regulation or otherwise, "authorize" federal courts to conduct more-sweeping review than provided in the APA.

"Congress has been creating quasi-judicial boards subject to Executive control for years, and the courts have not previously prevented them from doing so. To do so now 'would be to turn the clock back on at least a century of administrative law." *Kalaris*, 697 F.2d at 401 (citation omitted).

C. THE ADR RULE IS PROCEDURALLY COMPLIANT WITH THE APA

1. HHS did not terminate the ADR Rulemaking in advance of issuing the final rule.

Lilly also cannot succeed on the merits of its procedural APA claim. Under the APA, when an agency is required to undertake notice-and-comment rulemaking, the agency must publish a notice of proposed rulemaking that includes "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The agency must then "give 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). Noticeably absent from the APA is any requirement that a final rule follow an NPRM within a specified amount of time, or any provision that causes an NPRM to expire. Indeed, there is often a significant amount of time between the end of a comment period and the issuance of a final rule. *See, e.g.*, Food Labeling; Gluten-Free Labelling of Fermented or Hydrolyzed Foods, 85 Fed. Reg. 49,240, 49,244 (Aug. 13, 2020) (final rule issued nearly five years after notice of proposed rulemaking).

HHS fully complied with the APA's notice and comment procedures. HHS first issued an advanced notice of proposed rulemaking requesting comments on the development of an ADR process in 2010. 75 Fed. Reg. 57,233 (Sept. 20, 2010). It then issued an NPRM on the same topic in 2016. 81 Fed. Reg. 53,381 (Aug. 12, 2016). After reviewing the comments it received on both notices, HHS issued the final ADR Rule in 2020. 85 Fed. Reg. 80,632 (Dec. 14, 2020).

Plaintiffs' sole argument to the contrary is that HHS "withdrew" the rulemaking from the Unified Agenda of Regulatory and Deregulatory Actions ("Unified Agenda") after the NPRM's comment period and prior to issuance of the ADR Rule, supposedly nullifying the NPRM. *See* Mot. 25. But removing a rulemaking from the Unified Agenda alone is not sufficient to terminate a rulemaking or render an NPRM invalid. The Unified Agenda exists to provide "uniform reporting of

data on regulatory and deregulatory activities under development" in the Executive Branch. *About the Unified Agenda*, REGINFO.GOV.[11] It is not, however, a replacement for the Federal Register, a statutorily created periodical in which agencies must publish certain categories of documents. 44 U.S.C. § 1504 (designating the "Federal Register"); *id.* § 1505 (identifying documents to be published in Federal Register).

Indeed, courts generally recognize the termination of rulemakings as final only after a formal notice of withdrawal is published in the Federal Register. *See Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 42 (D.C. Cir. 2004) (acknowledging withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 844 (D.C. Cir. 1983) (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same). If HHS intended to permanently terminate the rulemaking, it would have, consistent with prior practice, published 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). Removing the rulemaking from the Unified Agenda alone does not constitute such a permanent termination.

The context and timing of HHS's removal of the rulemaking from the Unified Agenda only provide further support for the interim nature of its decision. On January 20, 2017, President Trump's Chief of Staff issued a memorandum to agencies implementing a "regulatory freeze pending review," consistent with the common practice of transitioning administrations. *See, e.g.*, Memorandum for the Heads of Executive Departments and Agencies ("Regulatory Freeze Memorandum"), 74 Fed. Reg. 4435 (Jan. 26, 2009); *see also* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 Nw. U. L. Rev. 471, 509 (2011) (discussing actions at the beginning of Clinton and Bush administrations). In accordance with the Regulatory Freeze Memorandum, HHS reviewed its ongoing rulemakings and updated the removal status of the ADR rulemaking in the next available edition of the Unified Agenda,

[11] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp (last visited Feb. 16, 2021).

a twice-yearly publication.[12] Reginfo.gov, Historical Unified Agenda and Regulatory Plan.[13] After further review, HHS eventually issued the final rule challenged here.[14]

2. The ADR Rule is a logical outgrowth of the NPRM.

Because the NPRM gave Lilly adequate notice of the topics covered by the ADR Rule, as required by the APA, Lilly is similarly unlikely to succeed on the merits of its "logical outgrowth" claim. *See* Mot. 26-27. 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.* "[A] final rule is not invalid for lack of adequate notice if the rule finally adopted is a 'logical outgrowth' of the original proposal." *Id.* (citation omitted).

Lilly argues that two aspects of the ADR Rule fail under these standards "because they are completely absent from the NPRM:" (1) ADR panels' supposed "authority to issue binding judgments for money damages;" and (2) the "precedential" weight of ADR decisions." Mot. 27. But that argument cannot succeed, as it is based on a demonstrably false reading of the ADR Rule and, in any event, concerns topics that were clearly addressed in the NPRM.

First, as shown above, Lilly is incorrect that an ADR Panel has authority to issue binding judgments for money damages. The ADR Rule requires the Panel to make a decision on the merits of the alleged statutory violation, but only empowers it to "make recommendations to HRSA," Rule at 80,646, "for appropriate action regarding refunds, penalties, removal, or referral," 40 C.F.R. § 10.24(e).

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[12] Though Lilly accuses HHS of "not treat[ing] the memorandum as applicable to ADR," because HHS did not act "immediately," in freezing the ADR rulemaking, Lilly fails to acknowledge that HHS froze the ADR rulemaking in the next Unified Agenda. Mot. 26-27. It is difficult to see how HHS might have acted any more "immediately" without actually withdrawing the NPRM from the Federal Register, which, as discussed above, it declined to do.

[13] https://www.reginfo.gov/public/do/eAgendaHistory (last visited Feb. 16, 2021).

[14] Lilly suggests that the ADR rulemaking was "exempt" from the Regulatory Freeze Memorandum because it was subject to a statutory deadline. *See* Mot. 26. But by 2017, the deadline for ADR rulemaking had already passed. It is clear that, given the circumstances, HHS did not consider the Memorandum's "exemption" as an impediment to removing the rulemaking from the Unified Agenda.

Lilly's misunderstanding of the Rule appears to stem from language in response to comments on an unrelated provision of the Rule. In the NPRM, HHS advised, "covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for de minimis claims given the investment of the time and resources required of the parties involved." NPRM at 53,382. Commenters urged HHS to "clarify" what would constitute such a de minimis claim. Rule at 80,633. HHS set a threshold monetary value for claims raised with the ADR Panel in response, stating, "[w]e believe that an appropriate threshold for a claim or claims for money damages should be $25,000." *Id.* But nowhere does HHS state that the Panel would have authority to award such damages. Lilly cannot rely on its misreading of the Rule to support its assertion that HHS failed to give proper notice to interested parties, particularly when, as here, the agency was properly "refin[ing], modify[ing], and supplement[ing]" its proposal "in the light of evidence and arguments presented in the course" of the rulemaking. *See Alto Dairy v. Veneman*, 336 F.3d 560, 569 (7th Cir. 2003).

As properly read, the provision of the Rule requiring the Panel to submit its decisions to HRSA is also "materially identical" to the NPRM, further dooming Lilly's claim. *See Post Acute Med. at Hammond, LLC v. Azar*, 311 F. Supp. 3d 176, 185 (D.D.C. 2018). Just as the Rule provides that the Panel "will submit the final agency decision to all parties, and to HRSA for appropriate action regarding refunds, penalties, removal, or referral," 42 C.F.R. § 10.24(e), the NPRM proposed regulatory language requiring the Panel to "submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action." NPRM at 53,388 (proposed 42 C.F.R. § 10.23(b)(2)). Simply spelling out the type of enforcement actions that HRSA may take does not constitute a change in the agency's position, much less a material change.

Second, Lilly takes issue with HHS's alleged change in position on the precedential nature of ADR Panel decisions. In the NPRM, HHS proposed that the Panel's decisions would be "binding upon the parties involved." NPRM at 53,385. In the Rule, however, HHS determined that the Panel's decision would also be "precedential" in other ADR proceedings, in addition to being "binding on the parties." 85 Fed. Reg. at 80,641. But the fact that HHS expanded the effect of the Panel's decisions does not mean that Lilly had inadequate notice. *See Am. Med. Ass'n*, 887 F.2d at 768 (noting "that

courts have upheld final rules" which represented "outright reversal of the agency's initial position"). The relevant question is simply "whether or not potential commentators would have known that an issue in which they were interested was 'on the table' and was to be addressed by a final rule," and "if interested parties favor a particular regulatory proposal, they should intervene in the rulemaking to support the approach an agency has tentatively advanced." *Id.* Here, the effect of the Panel's decision was clearly "on the table." *Id.* And, particularly where HHS was "writing on a clean slate" in developing the ADR process, Lilly cannot claim that it lacked notice of the agency's intent to define the effect of Panel decisions. *Id.* at 769.

As the Seventh Circuit has opined, "[i]f every modification is to require a further hearing at which that modification is set forth in the notice, agencies will be loath to modify initial proposals, and the rulemaking process will be degraded." *Alto Dairy*, 336 F.3d at 569-70. "The object, in short, is one of fair notice," *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007), and Lilly is not likely to prevail on its claim that it lacked sufficient notice here.

D. The ADR Rule is Substantively Compliant with the APA.

1. The ADR Rule does not exceed HHS's statutory authority.

Lilly is unlikely to succeed on the merits of its claim that the ADR Rule exceeds HHS's authority under 42 U.S.C. § 256b(d)(3)(A). *See* Mot. 27–28 (citing 5 U.S.C. § 706(2)(C)). This statutory provision grants the Secretary broad authority, in developing an ADR process, to establish "appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process." 42 U.S.C. § 256b(d)(3)(A). Lilly contends that the ADR Rule fails to provide for "*appropriate* procedures for the provision of remedies" because it confers upon ADR Panels remedial powers that violate Article III. Mot. 28 (emphasis added). As explained above, *supra* § I.B, however, Lilly's Article III claim fails. ADR Panels do not possess the remedial powers that Lilly suggests—the Rule expressly states that panels' decisions must be submitted to HRSA "for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal

authorities," 42 C.F.R. § 10.24(e), after the panel has issued an order deciding the statutory claim presented to it.

2. The ADR Rule is not arbitrary and capricious.

Lilly is also unlikely to succeed on the merits of its arbitrary-and-capricious claims. *See* Mot. 28–31 (citing 5 U.S.C. § 706(2)(A)). These arguments face a high hurdle, to be sure. Agency action must be upheld in the face of such attacks so long as the agency "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). Under this narrow and deferential standard of review, "a court is not to substitute its judgment for that of the agency … and should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted); *see also Schneider Nat'l, Inc. v. Interstate Com. Comm'n*, 948 F.2d 338, 344 (7th Cir. 1991) ("This court will not condemn an agency decision as arbitrary and capricious unless we are very confident that the agency overlooked something important or seriously erred in appreciating the significance of the evidence.").

First, HHS was not required to predict and address Lilly's meritless constitutional challenges. *See* Mot. 29. At the outset, Lilly waived any such objection to the ADR Rule by failing to raise it during the comment period. *See Bank of N. Shore v. Fed. Deposit Ins. Corp.*, 743 F.2d 1178, 1183 (7th Cir. 1984); *see also Toledo, Peoria & W. Ry. v. Surface Transp. Bd.*, 462 F.3d 734, 749 n.21 (7th Cir. 2006) (applying waiver to constitutional claim not raised in agency proceedings). Lilly challenges a rule produced through notice-and-*comment* rulemaking, but it never alleges that it (or any other party) submitted comments raising Appointments Clause or Article III concerns during the rulemaking process, and the government is aware of no such objection. Whether it be in the interest of fairness, judicial economy, or simply to discourage "sand-bagging," *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868, 895 (1991) (Scalia, J., concurring in part and concurring in the judgment), "courts should not topple

over administrative decisions unless the administrative body not only has erred but has erred against objection," *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952).

At any rate, Lilly's unraised constitutional theories would not have warranted a response because they are meritless. As explained above, the ADR Rule fully comports with Articles II and III. *Supra* §§ I.A, B. And even if an agency must "account for legal developments" (as Lilly suggests), *see* Mot. 29, Lilly fails to identify any legal developments relevant to its constitutional arguments. The Supreme Court's decision in *Lucia v. Securities and Exchange Commission*, 138 S. Ct. 2044 (2018), did not modify or refine the distinction between "inferior" and "principal" officers, *see id.* at 2051, which is the only dispute presented here. Furthermore, Lilly misrepresents the import of the grant of certiorari in *Anthrex*, *see* Mot. 29, which neither "suggest[s] a view on the merits," *Schwab v. Sec'y, Dep't of Corr.*, 507 F.3d 1297, 1299 (11th Cir. 2007); *accord Clinton v. Jones*, 520 U.S. 681, 689 (1997), nor "constitute[s] new law," *Ritter v. Thigpen*, 828 F.2d 662, 665–66 (11th Cir. 1987).

Second, HHS provided a sufficient explanation for its decision to utilize ADR panelists to resolve 340B disputes rather than employing ALJs. Lilly objects to this decision on two grounds, neither of which demonstrates that the ADR Rule is arbitrary and capricious.

Lilly first suggests that HHS disregarded concerns that ADR Panelists "are likely to hold biases, policy positions, or other objectives outside the limited facts of the dispute at issue." Mot. 30. Putting aside the fact that Lilly's claim is speculative,[15] HHS did consider these concerns. *See* 85 Fed. Reg. 80,634–35. In response, HHS established multiple procedures and safeguards "[t]o ensure fairness and objectiveness" in the ADR process, *id.*, chief of which is the requirement that "[a]ll individuals who serve on a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim," 42 C.F.R. § 10.20(b), and no individual will "be allowed to conduct a review if *any* conflicts of interest exist," *see* 85 Fed. Reg. 80,635 (emphasis added). Additionally, ADR panelists are removable

[15] If Lilly's "contention of bias" is to be credited, it "must overcome a presumption of honesty and integrity in those serving as adjudicators." *See Amundsen v. Chi. Park Dist.*, 218 F.3d 712, 716 (7th Cir. 2000) (alteration adopted) (quoting *Withrow v. Larkin*, 421 U.S. 35, 47 (1975)); *see also Fed. Trade Comm'n v. Owens-Corning Fiberglas Corp.*, 626 F.2d 966, 975 (D.C. Cir. 1980) ("[U]ntil evidence appears to the contrary, agencies are entitled to a presumption of administrative regularity and good faith."). There being no indication in the record of any such bias among ADR panelists, the Court should reject this contention outright.

from a panel "for cause," 42 C.F.R. § 10.20(a)(ii), with no express restrictions on the causes that may qualify. HHS need not *agree* with commenters' concerns, so long as they are considered, and these safeguards demonstrate adequate consideration.

Lilly also contends that it was irrational for HHS not to adopt an ALJ structure for the ADR process because "the lion's share" of decisions in resolving a 340B dispute are "quintessentially judicial task[s]" that do not require "specialized agency expertise." Mot. 30. HHS (and several commenters) drew the contrary conclusion, however. *See, e.g.*, 85 Fed. Reg. 80,634 ("HHS disagrees that ALJ's are best positioned to resolve 340B disputes."). As HHS explained, its "established cadre of ALJs . . . resolve disputes between the Department and private entities involving federal funds whether through grants, contracts, or under benefit programs such as Medicare," but have no familiarity with "the complexities of the 340B program" or the "complex commercial arrangements" that would form the basis for 340B disputes. *Id.* at 80,634–35. Accordingly, several commenters thought it critical "that the 340B ADR Panel members should have demonstrated expertise or familiarity with the 340B Program," such that they would be "uniquely situated to handle" its "complexities." *Id.*; *see also id.* at 80,634 (expressing concerns that ADR panelists, if not frequently empaneled, may not acquire *enough* 340B expertise). HHS agreed, and therefore required that each ADR Panel have two members with "drug pricing, drug distribution, and other relevant 340B expertise," as well as "a non-voting member of [the Office of Pharmacy Affairs] who would bring additional 340B Program expertise to the ADR proceedings." *Id.*; *see also* 42 C.F.R. § 10.20. And given that ADR proceedings require application of procedural and evidentiary rules and other litigation-based tasks, each panel, in addition to members with 340B Program expertise, include an official from the Office of General Counsel with "expertise and experience in handling complex litigation." 42 C.F.R. § 10.20. HHS's decision to utilize ADR panelists to bring their respective expertise in resolving 340B disputes was a product of its reasoned judgment.

Lastly, HHS was not required to respond to comments recommending that it revise HRSA's manufacturer auditing guidelines before moving forward with the ADR Rule. *See* Mot. 31. Still, Lilly faults HHS for failing to elaborate on its conclusion that such comments were not pertinent to the

development of the ADR process. *See* 85 Fed. Reg. 80,633. But whether HHS "adequately responded to these comments makes no difference" under the APA because the agency "had no obligation to respond to them in the first place." *See City of Portland v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007). Agencies "need not respond to every fact or contention in the comments submitted" on a proposed rule, *St. James Hosp. v. Heckler*, 760 F.2d 1460, 1469 (7th Cir. 1985), and they are under no obligation to respond to comments raising issues beyond the scope of the rulemaking process, *see Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 549 (D.C. Cir. 1997). An agency is required to address only comments raising "significant points" or "major issues," *St. James Hosp.*, 760 F.2d at 1470 (citation omitted); *accord Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015)—*i.e.*, those "comments that are 'relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule,'" *Nat'l Mining Ass'n*, 116 F.3d at 549 (citation omitted); *see also Cook Cty. v. Wolf*, 962 F.3d 208, 229-30 (7th Cir. 2020) ("When conducting rulemaking," an agency need only consider "*relevant* factors" and "*important* aspect[s] of the problem" to survive arbitrary-and-capricious review) (emphasis added and citation omitted)).

Here, HHS proposed a rule to develop requirements and procedures for an ADR process, as mandated under 42 U.S.C. § 256b(d)(3). NPRM at 53,381. Congress required the Secretary to develop a dispute-resolution mechanism, and the Secretary was not required to expand the scope of that mandatory rulemaking to encompass a separate matter—potential revisions to HRSA's auditing guidelines. *See, e.g.*, *Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 230-31 (1991) ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures, and priorities … [A]n agency need not solve every problem before it in the same proceeding.") (internal citations omitted). Comments regarding HRSA's auditing guidelines raised an issue that was simply beyond the scope of this rulemaking process. In fact, these comments did not even seek "a change in [the] proposed [ADR] rule," *see Nat'l Min. Ass'n*, 116 F.3d at 549 (citation omitted), but instead asked HHS to abandon the rule altogether and to turn its attention to a different course of action, *see* Rule at 80,633 ("Commenters recommend that, *before* HRSA develops the ADR process, HRSA should . . . reform its guidelines regarding manufacturer audits of covered entities.")

(emphasis added). But comments cannot "unilaterally expand the scope of [a proposed rule]," nor can they compel an agency "to initiate a separate rulemaking to address" a different problem. *See Sec. Indus. & Fin. Mkts. Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 429 (D.D.C. 2014). At bottom, HRSA's auditing guidelines were not a "significant point[]" or "major issue[]" that HHS was required to consider in the ADR rulemaking, particularly in light of the fact that Congress expressly mandated development of the ADR process. *See St. James Hosp.*, 760 F.2d at 1470 (citation omitted).

II. LILLY HAS NOT ESTABLISHED IRREPARABLE HARM

A. Allegations of structural constitutional harms are insufficient to support a preliminary injunction.

Lilly claims that "subjection to an unlawful dispute resolution process will cause it irreparable injury"; in other words, that the alleged constitutional violation is the irreparable harm itself. *See* Mot. 31. First, as explained above, the ADR Rule is lawful and constitutional. *See* §§ I.A, B, *supra*. Setting the merits aside, Lilly has not alleged the type of deprivation contemplated by the authorities it cites—*i.e.*, the deprivation of an individual constitutional right. *See, e.g. Bernard v. Individual Members of Ind. Med. Licensing Bd.*, 392 F. Supp. 3d 935, 955 (S.D. Ind. 2019) (addressing constitutional right to terminate pregnancy); 11A Charles Alan Wright & Arthur P. Miller, *Federal Practice & Procedure* § 2948.1 (3d ed.) ("When an alleged deprivation of a constitutional right is involved, *such as the right to free speech or freedom of religion*, most courts hold that no further showing of irreparable injury is necessary.") (emphasis added); *see also id.* at nn.24-26 (collecting cases involving constitutional rights).[16]

Lilly seeks preliminary relief on the basis of structural constitutional claims involving Article II's Appointments Clause and Article III's vesting of judicial authority. *See* Mot. 16-25. "[W]hile a violation of constitutional rights can constitute *per se* irreparable harm, … *per se* irreparable harm is caused only by violations of 'personal' constitutional rights … to be distinguished from provisions of

[16] *See also Preston v. Thompson*, 589 F.2d 300, 303 (7th Cir. 1978) (addressing violations of prisoners' due process rights); *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1026-28 (S.D. Ind. 2014) (addressing violations of equal protection and due process clause in context of marriage non-recognition statute).

the Constitution that serve 'structural' purposes, like the Supremacy Clause." *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 545 F. Supp. 2d 363, 367 (S.D.N.Y. 2008), *rev'd on other grounds*, 556 F.3d 114 (2d Cir. 2009) (quotation omitted); *Pub. Serv. Co. of N.H. v. Town of W. Newbury*, 835 F.2d 380, 382 (1st Cir. 1987); *Am. Petroleum Inst. v. Jorling*, 710 F. Supp. 421, 431 (N.D.N.Y. 1989); *see also Minerva Dairy, Inc. v. Brancel*, No. 17-cv-299-jdp, 2017 WL 3575710 at *2 (W.D. Wis. Aug. 18, 2017) ("Not every allegation of a constitutional violation automatically fulfills the irreparable harm prong of the preliminary injunction analysis."). Because Lilly has not even alleged, let alone demonstrated, that it will be deprived of a personal constitutional right, it cannot rely on that nonexistent constitutional injury to establish irreparable harm.

Nothing in *United Church of the Medical Center v. Medical Center Commission*, 689 F.2d 693 (7th Cir. 1982), or its progeny compels a different conclusion. In that case, the court determined that subjection to a particular decision-making body violated a Church's individual right to due process. *Id.* at 700. Then, consistent with the distinction between violation of individual and structural rights, the court concluded, "[s]ubmission to a fatally biased decision-making process" was "itself a constitutional injury sufficient to warrant injunctive relief." *Id.* at 701. Where, as here, Lilly has alleged only violations of the constitutional *separation of powers,* not the violation of an individual right, *United Church* and its progeny have no relevance.

B. Litigation Expenses Are Not Irreparable Harm.

In addition to its purported constitutional harms, Lilly attempts to manufacture economic harm as a result of "responding to the deluge of ADR threats and incoming ADR petitions, and defending itself in the unconstitutional tribunals."[17] Mot. 33-34. It is axiomatic, however, that "[m]ere litigation expense, even substantial and unrecoupable cost, does not constitute irreparable injury." *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980) (quoting *Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 24 (1974)); *Sherwood v. Marquette Transp. Co.*, 587 F.3d 841, 845 (7th Cir. 2009) ("[T]he

[17] To the extent that Lilly relies on other possible "damages" it may "accrue," *see* Mot. 33, such harms are speculative. Lilly fails to show that there is "more than a mere possibility that the harm will come to pass," so any such harms cannot supply the basis for injunctive relief. *See Michigan v. U.S. Army Corps of Eng'rs*, 667 F.3d 765, 788 (7th Cir. 2011).

expense of litigation is not irreparable injury.") (citation omitted); *see also Bader v. Wernert*, 178 F. Supp. 3d 703, 741 n.35 (N.D. Ind. 2016) (rejecting argument that plaintiffs suffered irreparable harm when they incurred approximately $400,000 in professional fees, including attorneys). This rule also extends to expenses incurred in arbitration proceedings. *See, e.g. Triangle Const. & Maint. Corp. v. Our Virgin Islands Labor Union*, 425 F.3d 938, 947 (11th Cir. 2005) ("[T]he expense of participating in an arbitration proceeding would not constitute irreparable injury."). Thus, Lilly's allegations of economic harm as a result of the ADR Rule are insufficient to support injunctive relief.

Lilly's complaints of harm resulting from litigation expenses also fall flat in light of its aggressive and, no doubt, expensive litigation choices—not only in filing this suit to challenge a straightforward, statutorily mandated ADR mechanism *and* an Advisory Opinion reiterating decade-old guidance—but also in moving to intervene in separate cases, brought by covered entities, *supra* Background § B, seeking to compel enforcement action by HHS.

Even putting that aside, Lilly has not alleged sufficiently concrete economic harm to support a preliminary injunction. Although some courts in this district have found that irreparable injury may occur where a party is unable to recover economic losses from the Government, *see Cmty. Pharmacies of Ind. v. Ind. Family & Social Servs. Admin.*, 801 F. Supp. 2d 802, 806 (S.D. Ind. 2011),[18] "not every conceivable injury entitles a litigant to a preliminary injunction," and "speculative injuries do not justify this extraordinary remedy." *E. St. Louis Laborers' Local 100 v. Bellon Wrecking & Salvage Co.*, 414 F.3d 700, 704 (7th Cir. 2005). Here, Lilly argues that, "unless the ADR process is enjoined," it will "be forced to expend enormous resources." Mot. 34. This conclusory statement "gives the Court little insight into the magnitude of its loss during the pendency of this case," and does "not rise to the level of irreparable harm." *CoverDyn v. Moniz*, 68 F. Supp. 3d 34, 47, 48 (D.D.C. 2014); *see also id.* at 49 ("[A] party seeking injunctive relief due to the inability to recover economic losses must nonetheless demonstrate that its harm will be sufficiently great to warrant a preliminary injunction"); *Cal Pharmacists Ass'n v. Maxwell-Jolly*, 596 F.3d 1098, 1113–14 (9th Cir. 2010), *vacated & remanded sub nom*, *Douglas v.*

[18] *But see Dinner Bell Mkts., Inc. v. United States*, 116 F. Supp. 3d 905, 914 (S.D. Ind. 2015) (recognizing, in the context of staying government action, that "if a showing of mere economic loss was sufficient to establish irreparable injury, issuance of a stay would be automatic") (citation omitted).

Indep. Living Ctr. of S. Cal., Inc., 565 U.S. 606 (2012) (Medicaid providers must show that they "will lose considerable revenue through the reduction in payments that they will be unable to recover" due to sovereign immunity); *Otsuka Pharm. Co. v. Burwell*, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) ("That [Plaintiff] is unable to recover monetary damages from [Defendants] does not . . . automatically make its harm irreparable."); *Ariz. Hosp. & Healthcare Ass'n v. Betlach*, 865 F. Supp. 2d 984, 1000 (D. Ariz. 2012). Because Lilly fails to allege any cognizable irreparable harm, it cannot satisfy the requirements for issuance of a preliminary injunction.

III. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST WEIGH AGAINST THE REQUESTED INJUNCTION.

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). "[T]here is inherent harm to an agency in preventing it from enforcing regulations that Congress found [to be] in the public interest to direct that agency to develop." *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.*, 2014 WL 2192052, at *3 (N.D. Cal. 2014). Here, Congress required HHS to promulgate regulations "establishing and implementing a binding ADR process for certain disputes arising under the 340B Program." 85 Fed. Reg. 80,633. HHS has done so, and any injunction prohibiting the enforcement of these statutorily required regulations would cause injury to the agency and to the public interest.

This is particularly so when it is *Lilly* which has upended the status quo by abandoning its decades-long practice (and the agency's longstanding guidance) of fulfilling orders placed by covered entities using contract pharmacies, causing significant uncertainty for safety-net healthcare providers serving low-income patients amidst a global pandemic. The public interest strongly militates against delaying the agency's efforts to resolve this uncertainty through the statutorily mandated administrative process intended for such disputes. *See Spencer v. Dist. of Columbia*, 416 F. Supp. 2d 5, 13 (D.D.C. 2006) (denying request for injunction when administrative process was available and injunction "would represent a major disruption of a carefully crafted legislative scheme"). The need

for prompt resolution of the contract-pharmacy dispute before the agency is heightened by the fact that covered entities and manufacturers cannot sue to enforce 340B Program requirements, *Astra*, 563 U.S. at 117-21, and must resolve their disputes in the ADR process.

Finally, although it is generally true that upholding constitutional rights is in the public interest, Mot. 35, Lilly has not asserted a violation of its own constitutional rights (or any individual rights). *See* §§ I.A, B, *supra*. And its constitutional claims, in any event, are meritless, so any alleged constitutional violations are irrelevant to this inquiry.[19]

CONCLUSION

Because Lilly's attacks on the ADR Rule are meritless, it has failed to show any irreparable harm from responding to disputes in the agency process Congress mandated, and the public interest strongly favors allowing the Rule to take effect, HHS respectfully requests that this Court deny Lilly's emergency motion.

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Respectfully submitted,

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[19] Lilly appears to seek to forestall the ADR process only as to itself but, to the extent it seeks a broader injunction, such relief would be improper. *See Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933-34 (2018) ("[A] plaintiff's remedy must be tailored to redress *the plaintiff's* particular injury."); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (explaining that an injunction should "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs").