UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

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

and

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

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

ROBERT P. CHARROW, in his official capacity as General Counsel of Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

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

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852,

and

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

Defendants.

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

Document Electronically Filed

PLAINTIFFS' COMBINED MEMORANDUM IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT [DKT. 88]

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INTRODUCTION

The Department of Health and Human Services ("HHS") has promulgated two equally unlawful rules and has attempted to defend them on equally pretextual grounds.

First, in the guise of an "advisory opinion," HHS has promulgated a legislative rule requiring manufacturers to deliver their products at substantial discounts to an unlimited number of so-called "contract pharmacies." The agency says manufacturers must do this so long as the contract pharmacies have an undefined (and rather unlikely) "agency" relationship with the actual entities covered by the 340B program—a requirement that appears nowhere in the statutory text. The government claims that none of this is new, *i.e.*, that HHS's decision merely repeats what the 340B statute has always meant and what its guidance documents have always said. That revisionist history ignores HHS's own repeated statements to the contrary, as well as the basic chronology of the statutory regime. Either way, there can be no doubt that the agency's "advisory opinion" represents the culmination of the agency's decision-making process; tellingly, it has already been relied on by parties seeking to compel the government to take action against Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly"). Regardless of what the government wants to call it, that is a rule subject to immediate judicial review.

This Court should review and invalidate that rule as contrary to law. At the heart of virtually every issue in this case, both procedural and substantive, lies the same question: Does the 340B statute require manufacturers to deliver discounted drugs to contract pharmacies? The answer is that it does not. That is why the agency's attempt to engraft such a requirement via fiat is justiciable; that is why this lawsuit is not time-barred; and that is why the agency's decision cannot stand. Congress not only identified the precise kinds of entities covered by the 340B statute (omitting contract pharmacies), it also identified the precise kinds of "agency" relationships to which that statute extends (again omitting contract pharmacies). Besides that, the rule imposes a

transparently unconstitutional condition on participation in a government program: It forces private parties to give their property to other private parties—***not for any public use***, but for the benefit of contract pharmacies. Acts of Congress should not lightly be read to require such draconian wealth transfers, and this statute says nothing of the kind.

At a minimum, HHS acted arbitrarily and capriciously by imposing this regime without making any attempt to discover precisely ***how*** contract-pharmacy relationships actually work. The administrative record contains no such evidence, and HHS's decision contains no reasoned analysis about whether contract pharmacies in fact have common-law fiduciary relationships with covered entities and operate under the covered entities' legal control. Nor does HHS know how much of the revenue generated by 340B discounts stays in the pockets of giant, for-profit pharmacy chains rather than the needy patients Congress wished to serve (or even the covered entities). Attempting to force a private wealth transfer without even investigating where the money ends up is the definition of arbitrary agency behavior. Regardless, the record reflects no agency review of how contract pharmacies are siphoning off hundreds of millions of dollars at the expense of patients, taxpayers, and drug manufacturers. Whatever one may think of the 340B program, surely allowing for-profit enterprises to milk it for their benefit is not what Congress intended. Agencies wishing to subsidize favored private entities must ask Congress for appropriated funds; they cannot suddenly raid other private companies and then pretend it was all Congress's idea 30 years ago.

At bottom, for all of the government's misplaced rhetoric, it is not Lilly that has upset anything the ***statute*** requires. Rather, through accretion and agency neglect, the contract-pharmacy model has transformed 340B from a narrowly tailored program designed to serve the needy into a vast profiteering enterprise in which patients frequently pay full price, while for-profit pharmacies pocket the discounts. The agency's attempt to codify this untoward expansion in its "advisory

opinion" is a departure from the statute Congress adopted and should be invalidated.

Second, HHS promulgated an unlawful and unconstitutional Administrative Dispute Resolution ("ADR") rule to permit contract pharmacies to obtain "money damages" and "equitable relief" from unconstitutionally appointed tribunals exercising judicial power that does not belong to them. That rule was irregularly promulgated: HHS first withdrew it and told the public it lacked authority to finalize it, and then altered it and carried it into effect without notice and comment.

That, indeed, appears to be HHS's general *modus operandi* in this case. After years of consistently saying one thing to the regulated public, HHS turns around and issues a regulatory edict saying the opposite, without notice and comment, on the theory that its previous pronouncements should not be taken seriously or literally. That is not how a federal agency is supposed to operate. The Court should vacate both rules and grant summary judgment for Lilly.

BACKGROUND

A. The 340B Program

Congress established the 340B program in 1992 to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637, 638 (2015). In 2010, Congress amended the statute to require manufacturers in the program to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 827 (2010) (codified at 42 U.S.C. § 256b(a)(1)). In 1992, 2010, and today, the point of the 340B program has always been to "create[] a low-cost source of pharmaceutical medication ***for the indigent patients themselves***." Baer, *supra*, at 638 (emphasis added); *see* H.R. Rep. No. 102-384 (II), at 12 (1992).

To be sure, safety-net medical providers, called "covered entities" in the statute, *see* 42

U.S.C. § 256b, benefit from the 340B program. Under the statute's terms, covered entities pay significantly discounted prices for "covered outpatient drugs," a category which includes most drugs used on an outpatient basis, according to a prescribed statutory formula. *See id.* § 256b(a)(1), (a)(4), (b)(1). The resulting prices, known as "ceiling prices," are far lower than what other purchasers pay, and can even be as low as one penny per pill or per milligram. Covered entities are then able to bill patients or insurers the drug's full price, pocketing the (often large) difference. But that benefit to covered entities is a salutary byproduct of the program, not its prime directive.

The 340B statute exhaustively defines "covered entities," and does so in a manner consistent with its emphasis on aiding the needy. The statutory definition enumerates 15 categories of "covered entities" (*e.g.*, "A black lung clinic receiving funds under section 937(a) of title 30"), but not the specific eligible entities themselves (*e.g.*, the Philadelphia Black Lung Clinic). *See id.* § 256b(a)(4). The statute defines "covered entities" to include only organizations that naturally, and often predominantly, serve low-income individuals. *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020). For instance, Federally Qualified Health Centers, children's hospitals, rural hospitals, and other clinics serving vulnerable populations are all defined as "covered entities" eligible to enroll and participate in the 340B program. 42 U.S.C. § 256b(a)(4). The statute further makes clear that types of entities not included on the list—such as for-profit hospitals, and commercial businesses such as contract pharmacies that profit off manufacturer discounts—are not entitled to receive medications from manufacturers at 340B discounted prices.

The 340B statute also prohibits covered entities from causing "duplicate discounts or rebates," which means they may not generate both a 340B discount and a Medicaid rebate for the same unit of drug. *Id.* § 256b(a)(5)(A). And to help ensure that covered entities and others do not inappropriately benefit from the opportunity of 340B price arbitrage, the statute further forbids

any "covered entity" from engaging in "diversion," *i.e.*, from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In other words, covered entities may not transfer or sell the discounted drugs to any person or entity except their own patients. The statute does not extend this diversion prohibition to manufacturers—thereby ensuring that if a covered entity lacks an in-house pharmacy through which it can dispense medicines itself, manufacturers may lawfully opt to deliver discounted product to a dispensing pharmacy of the covered entity's choosing (as Lilly has always done and continues, in a more limited fashion, to do still today).

Manufacturers "opt into" the program by signing a Pharmaceutical Pricing Agreement ("PPA") with HHS "for covered drugs purchased by 340B entities." *Astra U.S.A., Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113, 117 (2011). "The statutory and contractual obligations [in the PPA] are one and the same." *Id.* at 118. HHS may terminate a PPA if it determines that a manufacturer has failed to comply with its obligations. 42 U.S.C. § 1396r-8(b)(4)(B)(v); PPA §§ IV(c), VI(c). Finally, while participation in 340B is formally optional, *Astra*, 563 U.S. at 117-18, manufacturers have no real choice but to opt in, as they cannot receive reimbursement for any of their products under Medicaid and Medicare Part B unless they participate, *see* 42 U.S.C. § 1396r-8(a)(1), (5).

Congress gave HHS specific, but limited, authority to implement and administer the 340B program. (HHS, in turn, has delegated these responsibilities to the Health Resources and Services Administration ("HRSA").) HHS must notify manufacturers of the identity of covered entities, monitor diversion, and audit both covered entities and manufacturers. *See id.* § 256b(a)(9), (d)(1)(B)(vi). But Congress did not give HHS any substantive rulemaking authority to define, much less expand, the scope of the program itself. Instead, Congress confined HHS's 340B rulemaking authority to (1) establishing an ADR process to resolve disputes between

manufacturers and covered entities; (2) issuing standards for calculating 340B ceiling prices; and (3) imposing monetary penalties for overcharging covered entities. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). The agency may thus evaluate manufacturer compliance with program requirements and impose civil monetary penalties ("CMPs") on manufacturers that knowingly and intentionally charge covered entities more than the 340B ceiling price for covered outpatient drugs of more than $5,000 "for each instance of overcharging" a covered entity. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020); *see* 42 U.S.C. § 256b(d)(1)(B)(vi). Beyond that, HHS has no authority to issue implanting regulations for the 340B program, let alone those that alter the program's core.

For many years, HHS recognized that it had no authority to require manufacturers to provide drugs at 340B prices to contract pharmacies. In 1996 and 2010, HHS issued guidance governing contract pharmacies, but made patently clear that such guidance did not create new rights and obligations. 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); 75 Fed. Reg. 10,272, 10,272 (Mar. 5, 2010). It confirmed this position in a string of public statements to manufacturers, contract pharmacy advocacy groups, and the public at large. First, HRSA told Lilly in writing on June 11, 2020, that the 1996 and 2010 "contract pharmacy advice" were "not binding" on manufacturers. Am. Compl. ¶ 90 (quoting Am. Compl. Exh. C at 1-2). Then, on July 8, 2020, HRSA Communications Director Martin Kramer wrote via email to 340B Health, an entity seeking to force Lilly to give 340B prices to contract pharmacies, "that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies … is limited' because Congress has not granted it 'comprehensive regulatory authority' 'to develop enforceable policy that ensures clarity in program requirements.'" *Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting Kramer email); *see also* Compl. ¶¶ 57-58, *Am. Hosp.*

Ass'n v. HHS, No. 4:20-cv-08806-YGR (N.D. Cal. Dec. 12, 2020), Dkt. 1. The very next day, HRSA reiterated this position to the entire public, stating in a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable" against manufacturers and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Am. Compl. ¶ 94 (quoting Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020)). Finally, the U.S. Government Accountability Office ("GAO") issued a report in early December noting that HRSA had stopped auditing contract pharmacies for diversion violations "because the 340B statute does not address contract pharmacy use." GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 15-16, https://bit.ly/3hfFVD8 ("2020 GAO Report") (cited at Am. Compl. ¶ 76).

That all changed at the end of December 2020. Despite its prior, uniform pronouncements, HHS did an abrupt about-face, issuing an "Advisory Opinion" "obligat[ing]" each "manufacturer in the 340B Program … to deliver its covered outpatient drugs to [ ] contract pharmacies and to charge … no more than the 340B ceiling price for those drugs" whenever a pharmacy purports to act as a covered entity's "agent." ADVOP_1-8 ("December 30 Decision" or "Decision").

B. The ADR Rule

In 2010, Congress amended the statute to require HHS to promulgate regulations within 180 days establishing an ADR process for resolving 340B price disputes between covered entities and manufacturers. *See* Pub. L. No. 111-148, § 7102(a), 124 Stat. at 827. HHS did not abide by that deadline; it took HHS nearly ***six years*** even to issue a Notice of Proposed Rulemaking suggesting ADR procedures. *See* 81 Fed. Reg. 53,381 (Aug. 12, 2016) ("NPRM").

The 2016 NPRM proposed to resolve ADR claims through three-member panels "chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting

member chosen from [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. ADR panelists would be "Federal employees … with demonstrated expertise or familiarity with the 340B Program," and would be appointed by the HHS Secretary. *Id.* They could be removed from a panel only "for cause," *id.*, by which the NPRM meant only a dispute-specific conflict of interest. *Id.* The NPRM also proposed how these panels would adjudicate 340B price disputes. ADR panel decisions would "be binding upon the parties involved." *Id.* at 53,385. There would be no administrative appeal process for these binding decisions and no opportunity for the HHS Secretary to oversee, review, or otherwise alter ADR panel decisions. Instead, panel decisions would remain binding "unless invalidated by an order of a court of competent jurisdiction." *Id.* Importantly, however, the NPRM did not authorize ADR panels themselves to impose any specific remedies; it proposed only that ADR panel decisions "be submitted to [HRSA's Healthcare Systems Bureau] to take enforcement action or apply sanctions, as appropriate." *Id.*

In October 2016, several manufacturers, including Lilly, filed timely comments pointing out several fundamental defects with the proposed rule. *See, e.g.*, Am. Compl. Exh. M (Comment of Eli Lilly and Co. on Proposed 340B Drug Pricing Program: Administrative Dispute Resolution (ADR) Process, Office of Mgmt. & Budget RIN 0906-AA90 (Oct. 11, 2016)). Most relevant here, Lilly argued that, given their appointment by the HHS Secretary, the proposed ADR panelists would likely be driven by the desire to implement the agency's policy goals, rather than simply exercise independent expert judgment. Lilly thus recommended that HHS instead employ a neutral and disinterested adjudicator such as an administrative law judge ("ALJ"). *Id.* at 8-10.

After the close of the notice-and-comment period, the NPRM began appearing, with no changes made in response to manufacturer comments, on the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation of

information about federal regulations under agency development. On August 1, 2017, however, the NPRM was summarily withdrawn from the Unified Agenda without explanation. PI Exh. B.

Three years passed, with no indication that the ADR rulemaking remained pending. The NPRM never appeared again on the Unified Agenda, and no new NPRM ever appeared in the Federal Register. In fact, an HRSA official told a 340B-focused news publication in March 2020 that it had no plans to issue an ADR rule. According to the official, "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" that Defendants understood to be legally unenforceable. Am. Compl. ¶ 134 (quoting Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020)).

That all changed when groups of covered entities filed multiple lawsuits seeking to compel Defendants to promulgate the long-overdue ADR rules. *See, e.g.*, Compl., *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020), Dkt. 1. In the face of this mounting litigation pressure, Defendants abruptly published a final rule in December—without providing any advance notice or opportunity for public comment, including on any of the developments in the intervening six years. PI Exh. C, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule").

This hastily-issued rule rectifies none of the defects in the NPRM, and in many cases exacerbates them. The ADR Rule creates panels of HHS employees whose work is not subject to supervision by any Senate-confirmed officer to adjudicate disputes, rather than assign ALJs to perform such duties. It establishes a Board of "at least six members appointed by the [HHS] Secretary"—two each from HRSA, the Centers for Medicare and Medicaid Services ("CMS"), and the HHS Office of the General Counsel ("OGC"), plus one non-voting, ex-officio Board member selected from the staff of the HRSA Office of Pharmacy Affairs ("OPA")—and provides that each

panel will consist of one member drawn from each voting group. *Id.* at 80,634. It insulates these panels' judgments from review by any superior (much less Senate-confirmed) Executive Branch official. *Id.* at 80,640-41. It makes no provision for any Board member's removal from the Board, providing only that panelists can be removed from a panel "for cause," with "a conflict of interest" in a particular dispute listed as the only grounds for removal from a panel. And while it recognizes that commenters had raised concerns that such a system would result in biased decision-making, it cursorily brushes these concerns aside, simply noting that the panels "are uniquely situated to handle the complexities of the 340B Program and related disputes," and that the ex-officio Board member "would not exercise undue influence over the three voting members." *Id.* at 80,634-35.

The ADR Rule also grants each panel facsimiles of nearly every power enjoyed by federal judges. Panels may "determine, in [their] own discretion, the most efficient and practical form of the ADR proceeding." *Id.* at 80,645. They may require "submission of additional information," and they have discretion to choose from an array of formidable sanctions (including entry of judgment) if they conclude their instructions were not complied with. *Id.*; *see* 42 C.F.R. § 10.22(c). They also have "discretion in admitting evidence and testimony," and are even required to apply the Federal Rules of Civil Procedure and Evidence. 85 Fed. Reg. at 80,641; *see* 42 C.F.R. § 10.23. That said, while the ADR Rule permits covered entities to request discovery from covered entities and permits panels to issue requests to either side, it is one-sided; it does not include any express provision allowing discovery by manufacturers. *See* 42 C.F.R. § 10.22(a)-(b). Finally, the Rule vests the panels with "jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636; *see* 42 C.F.R. § 10.21.

Perhaps most striking of all, although the NPRM was silent on the issue, the ADR Rule provides that panels can resolve claims and issue self-executing judgments for "money damages," as well as other unspecified "equitable relief" sought by disgruntled litigants—not leaving it to the agency to take subsequent enforcement action, as contemplated by the NPRM. *Id.* at 80,633; *see* 42 C.F.R. § 10.24. Despite the sweeping grant of authority, the Rule does not purport to authorize *de novo* review by an Article III court. Instead, it says only that review may be available under the APA and that "[t]he form of judicial review for 340B ADR Panel decisions is beyond the scope of this final rule." 85 Fed. Reg. at 80,642. What is more, under the Rule a panel decision requiring manufacturers to offer 340B discounts to contract pharmacies carries "binding" force. In a notable departure from the NPRM, the final Rule provides that a panel decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d); *see* 85 Fed. Reg. at 80,641.

Lilly filed suit to vacate both the December 30 Decision and the ADR Rule, and moved to preliminarily enjoin the ADR Rule. This Court granted a preliminary injunction, finding that Lilly was likely to succeed on its claim that the government withdrew the ADR Rule in part because the government made representations to the public that it had done so. Dkt. 82 ("PI Order") at 19-21.

LEGAL STANDARD

The government's motion to dismiss is governed by Rule 12(b)(6). *See generally Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Summary judgment is appropriate for an APA challenger if it shows, based on the law and the administrative record, that the challenged action is inconsistent with applicable APA standards. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744-45 (1985).

ARGUMENT

I. The December 30 Decision Is An Invalid Legislative Rule And Final Agency Action.

Lilly's challenge to the December 30 Decision is justiciable, and this Court should resolve

it on the merits. At the heart of this dispute lies the statute. The 340B statute does not require manufacturers to deliver their property to an unlimited number of "contract pharmacies" at a discount; nor does it authorize the agency to impose such a requirement. Yet that is exactly what the December 30 Decision does: Through the mandatory language of regulation, it commands manufacturers to sell outpatient drugs at 340B discounts to contract pharmacies. Without the Decision, the agency would have no basis for any future adverse action against manufacturers for failing to divine and follow its requirements. That, in essence, is what turns agency guidance into an invalidly promulgated legislative rule. But whether legislative or interpretive, that rule is subject to judicial review because it constitutes final agency decision-making from which legal consequences will flow. And as explained below, this Court should not send the rule back for further, futile process; it should invalidate the rule on the merits and resolve the dispute.

A. The December 30 Decision Is a Legislative Rule Subject to APA Challenge.

"Legislative rules" are those that "create new law, rights, or duties." *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992). Legislative rules are subject to judicial review in federal court. *NRDC v. EPA*, 643 F.3d 311, 320-21 (D.C. Cir. 2011) ("[T]he inquiries into whether the agency action was final and whether the agency action was a rule were essentially the same.").

Agencies sometimes try to circumvent both the APA's procedural demands (which require rules to pass through notice and comment) and judicial oversight by issuing pronouncements that they label as mere "interpretive rules" or "general statements of policy," but that actually impose new substantive obligations. "An agency operating in this way gains a large advantage" over regulated entities. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000). It can quickly and inexpensively issue burdensome regulations that have the force and effect of law without receiving adequate public input, while also "immunizing its lawmaking from judicial review." *Id.* Courts routinely reject such efforts, and this Court should do the same here.

To determine whether an agency has issued a "disguised" legislative rule, courts inquire into the effect of the rule on the agency itself and on regulated parties. No matter how labeled, agency action is a legislative rule if it has binding effect—*i.e.*, it has not "genuinely [left] the agency … free to exercise discretion" and instead binds the agency to a particular legal policy position. *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017); *see also, e.g.*, *U.S. Tel. Ass'n v. FCC*, 28 F.3d 1232, 1234 (D.C. Cir. 1994). Where "[a]n agency action … purports to impose legally binding obligations or prohibitions on regulated parties" and "violations of those obligations or requirements" "would be the basis for an enforcement action," it "is a legislative rule." *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). In addition, the agency's own statements (whether formal or informal) may indicate that the agency itself considers a purported interpretive rule or guidance document to in fact be a binding legislative rule. *See, e.g.*, *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 947-48 (D.C. Cir. 1987).

The December 30 Decision is a classic example of a legislative rule. It requires for the first time that manufacturers provide 340B discounts to contract pharmacies; it can be the basis of an action brought by covered entities in the ADR process; and it is viewed as binding by the agency itself. Indeed, the Decision is chock-full of language to that effect. It proclaims that "a drug manufacturer in the 340B Program ***is obligated*** to deliver its covered outpatient drugs to those contract pharmacies," and it makes plain that "manufacturers ***may not refuse*** to offer the ceiling price" for contract-pharmacy sales (so long as the tenuous "agency" condition is met). ADVOP_1, 8 (emphases added); *see also* HHS, Press Release, *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020), https://bit.ly/3bp6m7R ("Through the new advisory opinion, HHS has clarified that drug manufacturers ***must provide*** 340B discounts when a contract pharmacy is acting as an agent of a covered entity[.]" (emphasis added)).

The December 30 Decision is also legislative because, "in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties." *Am. Min. Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)*; see also NRDC*, 643 F.2d at 321. As explained in Section II below, the 340B ***statute*** itself says ***nothing*** about requiring manufacturers to deliver discounted drugs to contract pharmacies. The statute enumerates 15 particular kinds of "covered entities"—all nonprofit healthcare providers that serve the needy as their mission—and omits any catchall provision or words like "including" that would suggest any broader reach. *See* pp. 24-27, *infra*. The statute also enumerates what kinds of agency relationships are permissible under the 340B statute, but excludes contract pharmacies (and, indeed, retailers of any sort). *See* pp. 27-28, *infra*. And because the obligation to deliver discounted drugs to an unlimited number of contract pharmacies would undermine the anti-diversion features of the statutory scheme and seemingly effectuate an uncompensated private wealth transfer, one would expect Congress to speak clearly if it wished to impose such a requirement. *See* pp. 28-37, *infra*. But it did not. In fact, the statute provides no notice that manufacturers must sell in the way required by the December 30 Decision. The December 30 Decision thus does not "derive a proposition from an existing document [here, the statute] whose meaning compels or logically justifies the proposition." *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 494 (D.C. Cir. 2010). Instead, only the December 30 Decision says that. Thus, because the December 30 Decision "cannot fairly be seen as interpreting a statute," *id.* (citation omitted), but instead "effects a substantive regulatory change to the statutory or regulatory regime," *Elec. Privacy Info. Ctr. v. DHS*, 653 F.3d 1, 6-7 (D.C. Cir. 2011) (citation omitted), it is a legislative rule. *See Hoctor v. USDA*, 82 F.3d 165, 170 (7th Cir. 1996).

The government's efforts to claim otherwise are remarkable. The government claims that

the 340B statute has contained the substance of the December 30 Decision—*i.e.*, the requirement that manufacturers provide discounts to an unlimited number of for-profit retail chains—since 1992, and that "the agency's position on the statutory question has not changed since the 1996 Guidance was issued." MTD/MSJ 17 n.3. That is revisionist history. The December 30 Decision relies on 42 U.S.C. § 256b(a)(1), which currently states that manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price," to conclude that manufacturers are required to honor an unlimited number of contract-pharmacy relationships and provide 340B discounts even for drugs dispensed by contract pharmacies. MTD/MSJ 25. The government claims that this requirement has been clear from its guidance documents issued in 1996 and 2010, MTD/MSJ 24-25, but that literally cannot be true. Both of those guidance documents were issued ***before the "must offer" language was added to the statute***. That language did not appear until March 23, 2010, *see* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 827 (2010), which postdates even the agency's 2010 guidance, *see* 75 Fed. Reg. 10,272 (Mar. 5, 2010). The government offers no argument as to how it could have required these arrangements between 1996 and 2010—because it could not.

The government also misrepresents what those guidance documents actually said. They told ***covered entities*** how ***covered entities*** could interact with contract pharmacies in a way that HRSA would consider permissible under the 340B statute's diversion prohibition. *See* 61 Fed. Reg. at 43,550; 75 Fed. Reg. at 10,272. They did not impose any affirmative obligation on manufacturers (in part because there was no must-offer requirement). In any case, the 1996 guidance by definition cannot reflect the government's current theory, since it explicitly limited its safe harbor to situations where a covered entity used ***no more than a single*** contract pharmacy,

not an unlimited number. *See* 61 Fed. Reg. at 43,551.[1]

The government's argument also flies in the face of the government's own statements to manufacturers, to contract-pharmacy advocacy groups, and to the public at large—cratering both its argument that the December 30 Decision is not legislative and that the Decision was not new. First, HRSA told Lilly in writing on June 11, 2020, that the 1996 and 2010 "contract pharmacy advice" were "not binding" on manufacturers. Am. Compl. ¶ 90 (quoting Am. Compl. Exh. C at 1-2). Then, on July 8, HRSA Communications Director Martin Kramer wrote via email to 340B Health, an entity seeking to force Lilly to pay 340B prices to contract pharmacies, "that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies … is limited' because Congress has not granted it 'comprehensive regulatory authority' 'to develop enforceable policy that ensures clarity in program requirements.'" *Am. Hosp. Ass'n*, 2021 WL 616323, at *3. The very next day, HRSA reiterated this position to the entire public, stating in a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable" against manufacturers and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Mirga, *supra* (quoted at Am. Compl. ¶ 94). Finally, the GAO issued a report just a few weeks before the December 30 Decision issued noting that HRSA had stopped auditing contract pharmacies for diversion violations "because the 340B statute

[1] The government also claims that its CMP regulations make clear that "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." MTD/MSJ 27 (citation omitted). That too is wrong. In reality, the regulation does not make this pronouncement; that text appears only in the accompanying Federal Register preamble and only as a passing response to a comment that addressed a wholly separate question—namely, whether a manufacturer could apply for an exemption from a CMP based on suspicion of statutory noncompliance—not the scope and meaning of 42 U.S.C. § 256b(a)(1). *See* 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017).

does not address contract pharmacy use." 2020 GAO Report, *supra*, at 16 (cited at Am. Compl. ¶ 76); *see also* 61 Fed. Reg. at 43,550 (clarifying that the 1996 guidance, before which no contract-pharmacy relationships were permissible, "create[s] no new rights or duties"); 75 Fed. Reg. at 10,273 (clarifying that the 2010 guidance likewise imposes no "additional burdens upon manufacturers").[2] The government simply ignores all of this—but the law does not.

If these numerous public statements were not enough to sound the death knell for the government's position, the government's response to Lilly's 2020 changes to its distribution plan hammers the final nail in the coffin. HRSA told Lilly that it was "considering whether [Lilly's] new proposed policy constitutes a violation of section 340B." Am. Compl. Exh. H at 1. But if the obligation to provide 340B prices to contract pharmacies were so clear, and so long-settled, and so unquestionable, then there would have been nothing left for the agency to "consider." After all, Lilly's new policy is one of not honoring all contract-pharmacy arrangements as a matter of course.

But even aside from the government's attempts to walk back its public statements, the December 30 Decision is clear on its face that it embodies a new obligation. It begins by noting that a definitive decision was needed due to the "numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies." ADVOP_1. And it "concluded," for the first time, that the "plain meaning" of the statute requires manufacturers to do so. ADVOP_2.

The government nonetheless tries to portray the December 30 Decision as a mere "interpretive rule," *i.e.*, an "advise[ment] … of the agency's construction of the statute[] … it

[2] That suffices to distinguish *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 100 (1995), on which the government relies for the proposition that agency statements that do not "adopt[] a new position" are just interpretive rules, MTD/MSJ 23; HHS undoubtedly adopted a new position here.

administers," *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015), which are exempt from notice-and-comment procedures, *see* 5 U.S.C. § 553(b). *See* MTD/MSJ 22-24. That gambit fails. "A key feature of [interpretive] rules is that … they are not supposed to … bind private parties." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). As just explained, however, "the Rule itself evinces the agency's intent to speak with the force of law." *NRDC v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020). The December 30 Decision unequivocally changed the agency's position that requiring manufacturers to provide contract pharmacies with 340B prices was legally unenforceable to a binding mandate that manufacturers must follow or else face binding judgments from ADR panels commanding them to do so. There can thus be no doubt that the December 30 Decision will "bind private parties" in an immediate and immediately consequential way unless set aside by this Court. "Given that the [December 30 Decision] changed the law, the first merits question—whether [it] is a legislative rule that required notice and comment—is easy." *NRDC*, 643 F.3d at 320-21.

This is not the first time the agency has tried this maneuver. Indeed, in a strikingly similar context, HRSA sought to recast a legislative rule as mere "interpretive" guidance with "no legal force 'independent of any binding effect that the statute itself may have.'" *PhRMA v. HHS*, 138 F. Supp. 3d 31, 44 (D.D.C. 2015) ("*Orphan Drug*"). The court correctly saw through the agency's attempt "'to express its definitive position on a general question of statutory interpretation'" through "a purportedly non-binding Interpretive Rule," and accordingly invalidated HRSA's attempt to end-run the APA. *Id.* at 47 (quoting *CSI Aviation Servs., Inc. v. DoT*, 637 F.3d 408, 412 (D.C. Cir. 2011)). The same result is warranted here. Without the December 30 Decision, "there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties." *Am. Mining Congress*, 995 F.2d at 1108.

Finally, similar reasoning dispels the government's statute-of-limitations defense. *See*

MTD/MSJ 17-22. For one thing, the assertion that "the agency's position on the statutory question has not changed since the 1996 guidance was issued, MTD/MSJ 17 n.3, is just not true. While the agency had long read the statute not to prohibit covered entities' use of contract pharmacies, it had never before made "a definitive pronouncement of [agency] policy" on the separate question of whether it could compel manufacturers to provide discounts on drugs dispensed by contract pharmacies. *Home Builders Ass'n of Greater Chicago v. U.S. Army Corps of Eng'rs*, 335 F.3d 607, 615 (7th Cir. 2003). And of course it had not done so, because the statutory language on which the December 30 Decision relies did not exist when the prior guidance documents issued. What is more, if the government is right that the ***statute*** really has always required what the Decision now imposes, then the 1996 guidance was unlawful ab initio; after all, the 1996 guidance only contemplated the use of ***just a single*** contract pharmacy. Simply put, the notion that Lilly should have challenged the government's new interpretation of the "must offer" language based on guidance that predated that language (and created no binding obligations) is meritless. The December 30 Decision is a legislative rule properly subject to APA challenge.[3]

B. Even if the December 30 Decision is Not Legislative, It Remains Final Agency Action Subject to the APA.

Even if the Court concluded that the December 30 Decision is a mere interpretive rule, it still would remain subject to judicial review because it constitutes final agency action under 5 U.S.C. § 702. Under Supreme Court precedent, "two conditions … generally must be satisfied for agency action to be 'final' under the APA": the action (1) "must mark the consummation of the agency's decisionmaking process" and (2) "must be one by which rights or obligations have been

[3] If the Court holds otherwise, it should make clear that, "in the adjudicatory process," the December 30 Decision cannot be "accorded that weight" given to rules with "the force and effect of law." *Perez*, 575 U.S. at 97 (quoting *Shalala*, 514 U.S. at 99). And in doing so, it should plainly state that the HHS officials who sit on ADR panels must be free to interpret the 340B statute *de novo*, as if the December 30 Decision had never been issued, and free from the Secretary's control.

determined, or from which legal consequences will flow." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). While legislative rules more-or-less automatically satisfy that standard, interpretive rules can as well. *See, e.g.*, *Appalachian Power Co.*, 208 F.3d at 1021, 1022 ("an agency's other pronouncements can, as a practical matter, have a binding effect" that satisfies the test); *U.S. Army Corps of Eng'rs*, 136 S. Ct. at 1814 (agency action may be final even when the agency explicitly reserves the right to "revise" it, as such an end-run "does not make an otherwise definitive decision nonfinal").

Here, for the same reasons discussed above, the December 30 Decision marks the consummation of the agency's decision-making process about manufacturers' obligation to deliver discounted drugs to covered entities. In a stark departure from its prior statements to the contrary, the agency now says that manufacturers are obligated to deliver such drugs. *See* p. 13, *supra*. This represents "a definitive pronouncement of [agency] policy," *Home Builders*, 335 F.3d at 615, and it likewise provides the interpretation the agency "believes is the only permissible interpretation of the statute," *Cal. Cmties. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019). That is what it means to mark the consummation of the agency's decision-making process.

The December 30 Decision also "determined" "rights or obligations," and it is inarguable that real "legal consequences will flow" from it. *U.S. Army Corps of Eng'rs*, 136 S. Ct. at 1813 (quoting *Bennett*, 520 U.S. at 178). The "core question" in this regard is whether the agency's decision will "directly affect the parties" and have a "direct effect on … day-to-day business." *W. Ill. Home Health Care v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998). The answer to that question is self-evidently "yes," as the Decision commands Lilly and other manufacturers either to transfer their property to contract pharmacies at a severe discount (and potentially at a loss) or risk severe penalty and possible expulsion from the program. Courts have not hesitated to conclude that even

changes in internal business practices to maintain compliance with an announced rule constitute final agency action. *See, e.g.*, *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010) (agency action that "forced" a company to offer products in a particular way was final because it had a "direct effect on [the company's] day-to-day business"). This Court should do the same.

The December 30 Decision also has "direct and appreciable legal consequences," as "fail[ure] to heed the determination" carries "the risk of significant criminal and civil penalties." *Cal. Cmties.*, 934 F.3d at 637. The government glosses over the fact that, a mere ten days before issuing the Decision, HHS finally issued the ADR rules that were ten years overdue. But just like the agency's public statements (which the government also ignores), this history throws cold water on the agency's arguments that the Decision does not alter the legal landscape. For the first time, and in conjunction with the ADR rules, covered entities and contract pharmacies now can hale Lilly into an (unconstitutional) forum and forced by an (unlawfully constituted) ADR panel to relinquish its property to contract pharmacies at 340B prices, or else face sanctions and other penalties. *See* 42 C.F.R. § 10.24(e) (allowing ADR panel to make referrals for monetary penalties).

The government also ignores that, before the December 30 Decision, HHS could not have imposed CMPs against manufacturers that declined to honor contract-pharmacy arrangements, given the agency's prior articulated position that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies," Mirga, *supra* (quoted at Am. Compl. ¶ 94), and the fact that CMPs are available only for "knowing[] and intentional[]" overcharging, 42 U.S.C. § 256b(d)(1)(B)(vi)(III). But the situation is different now—or at least it will be if the Decision is upheld. That is what it means for agency action to have legal consequences. *See Ipsen Biopharm., Inc. v. Azar*, 943 F.3d 953, 956-57 (D.C. Cir. 2019) (holding that "'legal consequences will flow'" from an agency's statement of position if it "increase[s] the probability that in the

future [the plaintiff] could be found to have 'knowingly'" violated the law (citation omitted)).

The government responds in conclusory fashion (and without citation) that "[w]here, as here, Lilly continues to operate its new distribution plan until some further action is taken, it cannot claim that the finality test is satisfied." MTD/MSJ 16. Perhaps the government provides no elaboration because it has tried, and failed, to mount this argument before. *See Orphan Drug*, 138 F. Supp. 3d at 40-41 (finding an HHS interpretive rule satisfied the test for final agency action). As the *Orphan Drug* court correctly recognized, the "argument that 'final agency action … requires the completion of a full enforcement action' is 'mistaken.'" *Id.* at 41 (quoting *CSI Aviation Servs.*, 637 F.3d at 413); *see also Sackett v. EPA*, 566 U.S. 120, 126 & n.2 (2012) (not deciding whether "the Government's position" that an agency order exposed the plaintiffs to "penalties in a future enforcement proceeding" "is correct," but nonetheless concluding that "legal consequences … flow from issuance of the order" given the "consequences of the order [that] the Government asserts"). In sum, because the Decision raises the likelihood that a manufacturer could be found to have "knowingly" violated the must-offer requirement, legal consequences will flow from it. *See Ipsen*, 943 F.3d at 956-57; *see also Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000) (making regulated entities "subject to an enforcement action and fines … constitute[s] final agency action"). The December 30 Decision is final agency action.

C. The Court Should Decide The Merits of the Statutory Question.

For the reasons discussed above, Lilly has a cause of action under the APA to challenge the December 30 Decision as final agency action that is contrary to law, arbitrary and capricious, or unlawfully promulgated without notice and comment. Once assured of the justiciability of the dispute, however, the Court should proceed to the merits of the statutory question.

At the outset, it is certainly right that, if the Court agrees that the Decision is a legislative rule, it should at the very least vacate that decision as procedurally deficient under 5 U.S.C.

§ 706(2)(D). Legislative rules require notice-and-comment rulemaking. *Metro. Sch. Dist.*, 969 F.2d at 489. To issue a valid rule, an agency "shall … publish[]" "[g]eneral notice of proposed rule making" "in the Federal Register," and shall include in that notice "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). After providing notice of a proposed rule, the agency shall "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c). As the Supreme Court recently made clear in *Azar v. Allina Health Services*, "the agency overseeing Medicare can't evade its notice-and-comment obligations for new rules that bear the 'force and effect' of law by the simple expedient of 'call[ing]' them mere 'statements of policy.'" 139 S. Ct. 1804, 1819 (2019). Just as the agency could not evade the APA in *Orphan Drug* or *Allina* by denying the legal consequences of the challenged rule, the agency cannot evade the APA here by pretending that the December 30 Decision does not bind manufacturers. So, at the very least, the Decision must be vacated as procedurally deficient.

But in this case, following precedent, the Court should resolve the merits of Lilly's substantive challenge to the December 30 Decision. *See NRDC*, 643 F.3d at 322 ("Because [the agency's action] violates the statute's plain language and our precedent, nothing would be gained by postponing a decision on the merits" by vacating and allowing the agency to try again through notice-and-comment). HHS is a "creature of statute," *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001), and thus has no valid power to act "unless and until Congress confers power upon it," *Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin.*, 988 F.2d 1480, 1486 (7th Cir. 1993). "In the absence of statutory authorization for its act, an agency's action is plainly contrary to law and cannot stand." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002). Here, HHS has attempted to mandate that Lilly and others provide steep discounts to hundreds of

contract pharmacies across the country, claiming that such pharmacies act as "agents" for the covered entities that are actually specified in the 340B statute. But because it is contrary to the text of the statute, no amount of notice and comment will allow HHS to enact such a rule, and there is no reason to permit HHS to waste the time of the regulated entities on that quixotic project.

The inefficiency of avoiding the merits by a remand is heightened in this case because the threshold justiciability issues already require the Court to expound on the precise question presented by the merits of this case: Does the 340B ***statute*** require manufacturers to offer discounted drugs to contract pharmacies? Or does the 340B statute not impose such a requirement? To preserve judicial economy and the parties' resources, having that issue at the threshold stage of this case, the Court should proceed to resolve it definitively.

II. The December 30 Decision Is Contrary To Law Because The 340B Statute Does Not Require Manufacturers To Sell Discounted Product To Contract Pharmacies.

The December 30 Decision is contrary to law. *See* 5 U.S.C. § 706(2). The 340B statute defines who must receive 340B discounts and does not include contract pharmacies. The December 30 Decision's so-called "agency" theory for circumventing this limitation has no basis in the statute and raises serious constitutional problems. The Court should reject it.

A. The 340B Statute Enumerates the Fifteen Types of "Covered Entities" that Must Receive 340B Discounts, and Does Not Include Contract Pharmacies.

The 340B statute's plain language does not require manufacturers to deliver discounted drugs to contract pharmacies. "We begin, as always, with the text of the statute." *Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 173 (2009). And when, as here, the text is clear, the inquiry "ends there as well." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018). The 340B statute obligates manufacturers to provide 340B discounts to "each covered entity"—no less, but no more. It requires the HHS Secretary to enter "into an agreement with each manufacturer of covered outpatient drugs" "requir[ing] that the manufacturer offer each covered entity covered

outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Notably, although it was created to benefit patients of covered entities, the 340B statute does not provide for discounts to be given to the ***patients*** themselves, only to the covered entities. The statute further authorizes the HHS Secretary to penalize "any manufacturer with an agreement under this section that knowingly and intentionally charges a ***covered entity*** a price for purchase of a drug that exceeds" the 340B ceiling price. *Id.* § 256b(d)(1)(B)(vi)(III) (emphasis added). But if a healthcare provider or other business is not a covered entity, then it is not entitled to 340B discounts—period.

That simple reality ends this case, because contract pharmacies are not covered entities. Under 42 U.S.C. § 256b(a)(4)—titled "'Covered entity' defined"—the term "covered entity" is defined to "mean[] an entity that meets the requirements described in paragraph (5)," which prohibits diversion and duplicate discounts, and which "***is*** one of the following," going on to list certain children's hospitals, cancer hospitals, critical access hospitals, and family planning clinics, among others. (Emphasis added.) Notably absent is any mention of large commercial entities like for-profit retail pharmacies such as Walgreens or CVS. Indeed, as recently as a few months ago, HRSA agreed that "the 340B statute does not address contract pharmacy use." 2020 GAO Report, *supra*, at 16. That was for good reason. Consistent with 340B's focus on reducing costs for "facilities that provide medical care for the poor," *Astra*, 563 U.S. at 115, the 15 statutorily enumerated entities are overwhelmingly "providers of safety net services," *id.* at 113—not large commercial enterprises that serve the general public (and that, more to the point, exist to maximize profits for shareholders, not to provide services to the at-risk-patient population).

Congress's conscious omission of such contract pharmacies (and any for-profit entities even remotely like them) should be the end of the matter. Under the well-known interpretive canon

expressio unius est exclusio alterius, "the mention of some implies the exclusion of others not mentioned." *United Dominion Indus. v. United States*, 532 U.S. 822, 836 (2001). This canon carries particular force when, as here, "the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence." *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003). The statute sets up an intricate program and precisely defines the 15 kinds of covered entities that are entitled to participate in and claim discounts through the 340B program. The entities on the list—*i.e.*, the ones statutorily eligible to receive 340B discounts—"dominantly" share the common characteristic of being "providers of safety net services to the poor." *Orphan Drug*, 138 F. Supp. 3d at 34. Large commercial businesses that profit off of manufacturer discounts are nowhere to be found. Stretching the statute's text to include large commercial retail chains with little in common with the entities Congress included on the list would thus result not in "a construction of [the] statute, but, in effect, an enlargement of it." *Lamie v. United States Tr.*, 540 U.S. 526, 538 (2004).

Other textual indicia likewise indicate that the statute's carefully circumscribed definition of "covered entities" cannot be fairly read to include contract pharmacies. First, the statute introduces the list of defined covered entities with the word "means," *see* 42 U.S.C. § 256b(a)(4), and courts have correctly interpreted Congress's deliberate choice to use the word "means" as setting forth an exhaustive list, as compared to a representative list beginning with the word "including." *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1015 (D.C. Cir. 2009) (citing *Helvering v. Morgan's, Inc.*, 293 U.S. 121, 126 n.1 (1934)). Second, the list does not end with any sort of catch-all phrase, let alone one capacious enough to include contract pharmacies; nor does it include an exceptions clause of any kind. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 163 (2012); *United States v. Davis*, 16 F.3d 212, 217 (7th Cir. 1994). Finally,

the "particularization and detail" Congress took in selecting and defining covered entities further demonstrates that it did not leave out contract pharmacies through sheer inadvertence. *Iselin v. United States*, 270 U.S. 245, 250 (1926); *see also, e.g.*, *Voyk v. Brotherhood of Locomotive Eng'rs*, 198 F.3d 599, 604 (6th Cir. 1999) (detailed list of required disclosures provided in ERISA indicates exhaustive list that cannot be supplemented). That is particularly true given that the list of covered entities has not been static over time; Congress added three categories of entities to the list as part of the Affordable Care Act. *See* Pub. L. No. 111-148, § 7101(a), 124 Stat. at 821-22 (codified as amended at 42 U.S.C. § 256b(a)(4)(M)-(O)) (adding certain "children's hospital[s]," "free-standing cancer hospital[s]," "critical access hospital[s]," and "community hospital[s]"). But it did not add contract pharmacies—or anything remotely resembling them—to the list.

In sum, the statute defines 15 kinds of nonprofit entities entitled to participate in, and claim discounts through, an intricate statutory program. In that context, there is no basis for requiring manufacturers to ***also*** provide discounts to entities not included on the list—least of all to for-profit contract pharmacies that have nothing in the common with the entities on the list.

B. The December 30 Decision's "Agency" Theory Has No Basis in the Statute.

Despite the clarity of the statute, the December 30 Decision obligates Lilly to provide commercial pharmacies with 340B discounts for covered outpatient drugs, even though they are not on Congress's list. HHS reasons that its position can be reconciled with the statute because contract pharmacies simply act as "agents" of covered entities. But this interpretation runs directly contrary to the text, structure, and purposes of the 340B statute, and attempts to end-run HHS's limited rulemaking authority in this space. The Court should reject it.

First, HHS's "agency" theory has no support in the statutory text. In fact, the statutory text precludes it. As with its detailed definition of covered entities, the 340B statute precisely specifies when agency-like relationships are permitted. *See, e.g.*, 42 U.S.C. § 256b(d)(3)(B)(vi) (referring

separately to "associations or organizations representing the interests of [] covered entities," rather than simply calling them "covered entities"); *id.* § 256b(d)(1)(B)(v) (same for "wholesalers"); *id*. § 256b(d)(2)(B)(iv) (same for "distributors"). If Congress had wanted to allow for-profit pharmacies to act broadly as "agents" of covered entities, it knew how to say so. Indeed, the statute's precise language confirms that contract pharmacies ***are not among the statute's contemplated "agents."*** Rather, contract pharmacies are retailers, not "wholesalers" or "distributors." And they are certainly not organizations "of which the covered entities are members" that represent the interests of covered entities. They are private, for-profit businesses that represent their own interests and have no membership-style affiliation with covered entities.

Second, HHS's "agency" argument undermines the basic structure of the comprehensive and reticulated statute Congress adopted. It is a fundamental principle of statutory interpretation that statutes must not be interpreted in ways that are "inconsisten[t] with the design and structure of the statute as a whole," *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013), and agency rules that "have no limiting principle" should not be adopted, *Dirks v. SEC*, 463 U.S. 646, 664 (1983). Defendants' rule runs afoul of both precepts. The agency's argument boils down to a contention that, so long as a covered entity ***prescribes*** a covered outpatient drug, manufacturers must deliver the product wherever and to whomever directed—apparently by the patient, though the government pretends it is the covered entity so directing.[4] Under the government's approach, the covered entity simply lends its name to the prescription—nothing more—which means that a covered entity could claim entire institutions that are ***not covered entities*** are acting as their

[4] That, in fact, bears no resemblance to what actually occurs in the real world of contract pharmacy dispensing, in which demands for 340B drugs from manufacturers are made ***by a contract pharmacy***, ***after*** it dispenses a drug to an alleged patient of a covered entity, not before. *See* HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://bit.ly/3eWKmBQ ("2014 HHS-OIG Report") (discussing "replenishment" model).

purported "agents," thus flouting the statutory limits on covered entities and diversion.[5]

But the plain text of the statute of course does not bless such arrangements; rather, its prohibition against diversion ***explicitly disallows them***. *See* 42 U.S.C. § 256b(a)(5)(A). It would be passing strange if covered entities could circumvent the statutory prohibition on diversion simply by forcing manufacturers to divert discounted drugs for them. The December 30 Decision contravenes the statute by facilitating, rather than preventing, such diversion and duplicate discounts. Indeed, the government has long sounded the alarm about contract-pharmacy usage, finding that it "creates more opportunities for drug diversion compared to in-house pharmacies." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, at 28, GAO-11-836 (Sept. 2011), https://bit.ly/2JvWKgJ (cited at Am. Compl. ¶ 68). Even HRSA had previously acknowledged that contract pharmacies violate the statutory prohibitions on diversion and duplicate discounts at outsized rates. *See, e.g.*, HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/3fcAALF. The December 30 Decision exacerbates the problem Congress carefully crafted its regime to avoid.

Third, Defendants' interpretation would also undermine the statute's goal of ensuring that the 340B program actually serves to benefit uninsured and otherwise vulnerable patients, as opposed to diverting funds into the pockets of for-profit intermediaries. The statute contains a number of interlocking statutory provisions that make sense in a world in which manufacturers ***may*** deliver discounted product to non-in-house pharmacies (*e.g.*, when a covered entity lacks an in-house pharmacy), but are ***not*** required to do so on pain of severe penalty. One sets a "ceiling price" that caps the amount manufacturers may charge covered entities. 42 U.S.C. § 256b(a)(1).

[5] This is not fanciful—states have passed laws to explore just that tactic. *See* N.C. H.B. 106, Sess. Law 2019-135, § 7 (2019), *available at* https://bit.ly/3nWSZk1; *see also* Recommendations for a 340B Correctional Partnership in North Carolina (May 7, 2019), https://bit.ly/33lvWpP.

Another limits the universe of covered entities to entities that exist to serve predominantly (if not exclusively) vulnerable populations. *See id.* § 256b(a)(4). A third prohibits covered entities from diverting 340B discounted drugs, *i.e.*, from sending them to any person or entity other than their eligible patients, but does ***not*** extend that prohibition to manufacturers. *See id.* § 256b(a)(5)(A). And a fourth authorizes HHS to penalize manufacturers that charge covered entities more than the 340B ceiling price. *See id.* § 256b(d)(1)(B)(vi). Put together, these provisions require manufacturers to deliver discounted product to entities that serve vulnerable populations as their mission, but they do ***not*** require manufacturers to deliver discounted products to anyone else—least of all for-profit enterprises that serve their shareholders as a matter of state and federal law.

Yet that is precisely what Defendants' position permits. Indeed, even before the government obligated manufacturers to provide 340B discounts to contract pharmacies, it has found that contract pharmacies have been "purchas[ing] covered outpatient drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status," "receiving reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs," but ***not*** passing along the savings to patients. GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* at 5, GAO-20-108 (Dec. 2019), https://bit.ly/34Vj6zK ("2019 GAO Report") (cited at Am. Compl. at 3). The result has been that billions of dollars are flowing from manufacturers directly to contract pharmacies like CVS and Walgreens—without any corresponding benefits *to the patients* the 340B program is ultimately intended to serve. *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. ENG. J. MED. 539, 539 (Feb. 8, 2018) (cited at Am. Compl. ¶ 63) (for-profit pharmacies' "[f]inancial gains" under the program post-2010 "have not been associated with clear evidence of expanded care or lower mortality among

low-income patients"). An interpretation that so drastically undermines the purposes of the statute "provides strong indication that something in [that] interpretation is amiss." *Freeman v. Quicken Loans, Inc.*, 566 U.S. 624, 632 (2012); *see also* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 167 (2012) ("[T]he judicial interpreter [shall] consider the entire text, in view of its structure and the physical and logical relation of its many parts.").

Fourth and relatedly, Defendants' reading runs contrary to the principle that "Congress … does not 'alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions'"; it does not "'hide elephants in mouseholes.'" *Owner-Operator Indep. Drivers Ass'n, Inc. v. DoT*, 840 F.3d 879, 889 (7th Cir. 2016) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001)). Defendants rely heavily on the term "purchased by a covered entity" to claim that, so long as the covered entities ostensibly "purchase" the drugs, it does not matter where or how they are distributed. MTD/MSJ 22 (citing 42 U.S.C. § 256b(a)(1)). But this reading ignores the entire subsection of the statute, *viz.* 42 U.S.C. § 256b(5), aimed at preventing exactly the type of price arbitrage that this system promotes. Congress would not hide the "elephant" of expanding the 340B program to tens of thousands of for-profit pharmacies, in the "mousehole" of permitting discounted drugs to be "purchased by" covered entities. The government's interpretation thus reads the phrase "purchased by" in a "vacuum," without "a view to [its] place in the overall statutory scheme." *Loja v. Main St. Acquisition Corp.*, 906 F.3d 680, 683 (7th Cir. 2018).

The government responds by accusing Lilly of mischaracterizing the transactions at issue, alleging that "pharmacies cannot—under the Advisory Opinion or at any time in the history of the 340B Program—purchase 340B-discounted drugs." MTD/MSJ 13-14. But for all of its concerns over on-the-ground "realities," the government ultimately exalts form over substance. The government ignores that contract pharmacies keep no 340B product in stock; instead, they dispense

drugs from their own supply, claim that a patient is eligible, and request that the covered entity "replenish" their supply post hoc at 340B prices. 2014 HHS-OIG Report, *supra*, at 5. That acknowledged practice—itself created out of whole cloth by a 2013 HRSA statement, and in direct contradiction to the 2010 guidance—means that, although contract pharmacies may not formally make the purchases, they certainly drive the transactions. Moreover, the formal dispenser of the drug is irrelevant to any of Lilly's arguments. Lilly simply argues that "purchased by" cannot be interpreted in such a way as to allow diversion—as conduct specifically proscribed by the statute.

In sum, recourse to every traditional tool of statutory construction leads to the same conclusion: The statute simply does not permit the government to manufacture an "agency" theory that forces Lilly to provide 340B prices to contract pharmacies. It would be bad enough if the government's interpretation ran afoul of these basic principles. But it does much more—attempting to end-run the carefully limited rulemaking authority that the 340B statute affords. As one court already recognized in a similar context, "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." *PhRMA*, 43 F. Supp. 3d at 42. Rather, Congress expressly confined that authority to three areas: establishing an administrative dispute resolution process; issuing standards for calculating of ceiling prices; and imposing of civil monetary penalties. *Id.*; *see* 42 U.S.C. § 256b(d)(1)(B)(i)(I), (d)(1)(B)(vi)(I), (d)(3)(A). Because the statute affords HHS only a "limited, specific, grant of rulemaking authority" confined to certain narrow categories, any rule or guidance that goes beyond the text is by definition *ultra vires*. *PhRMA*, 43 F. Supp. 3d at 41 (vacating rule that fell outside the three narrow statutory grants of authority). "If Congress had meant the scope of HHS's rulemaking authority to reach as far" as unlimited contract-pharmacy arrangements, "it would have said so." *Id.* at 45 n.16.

That bedrock administrative-law principle is dispositive here. Nothing in the 340B statute

authorizes HHS or HRSA to directly expand (or contract) the list of covered entities eligible to participate in, and receive discounts pursuant to, the 340B program. Nor can it do so by inventing a purported "agency" theory, which has no basis in the statute, to achieve the same ends. Thus, for the covered entity list to change, Congress itself would need to act—just as it did 18 years after first enacting the statute, when it added three new categories of entities to the list. Pub. L. No. 111-148, § 7101(a), 124 Stat. at 821-22 (codified at 42 U.S.C. § 256b(a)(4)(M)-(O)).

C. Defendants' Construction Also Raises Grave Constitutional Concerns.

Construing the 340B statute to authorize the December 30 Decision would also violate the canon of constitutional avoidance. *See United States v. Orona-Ibarra*, 831 F.3d 867, 876 (7th Cir. 2016). The Fifth Amendment protects private property—both personal and real—from being taken for public use without just compensation, regardless of whether the taking occurs through legislation or regulation. *Squires-Cannon v. Forest Preserve Dist. of Cook Cnty.*, 897 F.3d 797, 798 (7th Cir. 2018); *see Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015); *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922). Courts have long held that the government cannot effectuate "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit." *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008); *see Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (op. of Chase, J.). Indeed, private takings are always unconstitutional, "since [n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005). Yet that is exactly what the Decision 30 Decision requires: It forces Lilly to give the outpatient drugs it manufactures to for-profit retail chains at sub-market prices (and often at a loss). And it does so for the for-profit contract pharmacies' ***private use***—*i.e.*, they get to keep the money—not for one of the narrow kinds of public uses that the Constitution recognizes.

The government argues that forcing manufacturers to subsidize contract pharmacies serves

a public use because it "benefit[s] both [uninsured and under-insured] patients." MTD/MSJ 33. Even setting aside the evidence demonstrating that patients do not benefit from contract pharmacy participation in the 340B program, *see* 2019 GAO Report, *supra*, at 5; Desai & McWilliams, *supra*, this argument stretches the term "public use" far beyond what the Constitution permits and what the Supreme Court has recognized. Even in *Kelo v. City of New London*, 545 U.S. 469 (2005), by far the most expansive interpretation of the Takings Clause, the Court not only reaffirmed that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation," *id.* at 477, but made clear that it would ***not*** have upheld the taking under the Fifth Amendment had the taking benefitted "a particular class of identifiable individuals" rather than the public at large, *id.* at 478 (citation omitted).

That dooms the government's position here. The government explicitly admits that its expansion of the statute seeks to benefit "a particular class of identifiable individuals," *i.e.*, contract pharmacies. Nor can the government find refuge in the outer limits of the Public Use Clause. Giving contract pharmacies Lilly's property does not abate some public nuisance; HHS is perfectly indifferent about whether the contract pharmacies keep a substantial portion of the money. It follows that the Court should not read the statute to authorize unconstitutional private wealth transfers of the kind the Decision requires, since "[n]o amount of compensation can authorize such action." *Lingle*, 544 U.S. at 543. As "[a] purely private taking," the Decision "serve[s] no legitimate purpose of government" and is "void." *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984). It therefore must be set aside as "contrary to constitutional right." 5 U.S.C. § 706(2)(B).

But even if the Court believed that Congress ***could*** impose this kind of private wealth transfer, ***this*** statute contains no such authorization. As explained, the 340B statute is best read not to obligate manufacturers to deliver discounted drugs to contract pharmacies ***at all***, and it

certainly contains no clear statement that Congress wanted to embark on such a constitutionally dubious scheme. Congress's insertion of anti-diversion and anti-duplication provisions evince just the opposite intention: to keep far away from confiscatory abuses of the discount program.

The government's primary response is to allege, erroneously, that Lilly cannot bring a takings claim because it has "voluntarily" participated in the 340B program with the attendant condition that Lilly provide drugs at 340B prices to contract pharmacies. MTD/MSJ 30. That is wrong. The PPA Lilly signed with HHS to participate in the program makes clear that "Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution." ADVOP_52. In any case, it would be absurd to say that Lilly assented to HHS's current (flawed) position on the statute's requirements when it joined the 340B program; after all, HHS itself repeatedly took the contrary position—*i.e.*, that it could not "compel" manufacturers to provide prices to contract pharmacies—including ***in response to Lilly's distribution plan***. *See* pp. 16-17, *supra*. So even if voluntariness were relevant, Lilly has never "voluntarily" participated in the program with this unconstitutional requirement.

The government then pivots to arguing that if Lilly does not like the new terms of the 340B program, it can simply cease participating in it. The unconstitutional conditions doctrine forecloses that argument. That doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, including the right to retain one's own property unless properly taken by the government (*i.e.*, taken for a public purpose and reimbursed). *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). That one can simply reject the government's offer is irrelevant, as *Dolan v. City of Tigard*, 512 U.S. 374 (1994), makes clear. The petitioner in *Dolan* applied for a permit, which was approved so long as she "deed[ed] portions of the property to the city." *Id.* at 385. Just

like Lilly, the petitioner technically had the ability simply to refuse the offer. But that purported "voluntariness" made no difference to the Court, as it "forced her to choose between the building permit and her right under the Fifth Amendment to just compensation for the public easements." *Id.* at 385-86; *see also Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834 (1987) (similar).

The same analysis applies here. The "choice" the government has put to Lilly has all the hallmarks of an "[e]xtortionate demand," in clear violation of the unconstitutional conditions doctrine. *Koontz*, 570 U.S. at 605. The December 30 Decision purports to require, as a condition of continued participation in the 340B program—a program that now accounts for millions of prescription drugs sales each year—that manufacturers charge below-market (and often below-cost) prices for their drugs that are re-sold at market prices by for-profit retailers. If manufacturers will not agree to provide discounts to for-profit retailers whenever a covered entity demands (and claims that they are acting as its "agents"), they will lose access not only to the second-largest drug purchaser in the nation, but to coverage and reimbursement under Medicare and Medicaid, trillion-dollar programs that provide a huge share of all drug manufacturers' revenues. Such a "financial 'inducement' … is much more than 'relatively mild encouragement'—it is a gun to the head." *NFIB v. Sebelius*, 567 U.S. 519, 581 (2012). And whether applied to states seeking to protect their constitutional federalism interests or to private entities seeking to protect their constitutional property interests, the Constitution forbids the federal government from "us[ing] financial inducements to exert a power akin to undue influence." *Id.* at 577. When, as here, "pressure turns into compulsion," *id.*, the choice to continue participating in a government program cannot be called voluntary; on the contrary, it must be called what it is: "economic dragooning" that leaves parties with "no real option but to acquiesce" to the government's preferred policy, *id.* at 582.

In arguing to the contrary, the government insists that Lilly's participation in the program

forecloses its takings claim. But in nearly all of the government's cases—including *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), and *Rancho de Calistoga v. City of Calistoga*, 800 F.3d 1083 (9th Cir. 2015)—the challenged conditions appeared on the face ***of the statute***, and thus inarguably existed when the regulated parties chose to participate. That is not the case here. And the government's two remaining cases—*Baptist Hospital East v. Secretary of Health & Human Services*, 802 F.2d 860 (6th Cir. 1986), and *St. Francis Hospital Center v. Heckler*, 714 F.2d 872 (7th Cir. 1983)—were decided long before the Supreme Court's modern takings cases cited herein.

In sum, the government cannot condition pharmaceutical manufacturers' participation in Medicare on allowing for-profit pharmacy chains to take hundreds of millions (if not billions) of dollars straight out of their pockets, with no regard for public use. If Congress wants to levy taxes and then appropriate funds to subsidize CVS and Walgreens, it can do so—subject to the constraints of the Constitution and re-election. But in the absence of such taxing and spending legislation, a federal agency cannot force massive private wealth transfers as a condition of participation in public programs and then pretend that it was all Congress's idea. That is what the December 30 Decision does, and this Court need not—indeed, cannot—go along with the pretense.

III. The December 30 Decision Is Arbitrary And Capricious.

The APA requires an agency to "examine the relevant data," *Sparre v. U.S. Dep't of Labor*, 924 F.3d 398, 402 (7th Cir. 2019), consider important aspects of the problem its regulations implicate or create, and "articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Otherwise, the action cannot withstand arbitrary and capricious review. The December 30 Decision fails that basic test.

At the outset, the government has not adequately explained how the "agency" theory that serves as the entire foundation of the December 30 Decision is consistent with the 340B statute's text, structure, and purposes. That alone is reason enough to vacate it. *See, e.g.*, *FDA v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 139-143 (2000) (rejecting agency interpretation of statute that was at odds with the text and structure of the statutory and regulatory scheme); *Ill. Cent. Gulf R. Co. v. ICC*, 702 F.2d 111, 115 (7th Cir. 1983) (rejecting agency action where it was based on an interpretation "contrary to the command" of other applicable statutory provisions).

But the "agency" theory must also be rejected on the merits, as it is not "reasonable and reasonably explained." *Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 506 (D.C. Cir. 2016) (Kavanaugh, J.). "Agency" is a common-law term of art with well-established elements: (1) a manifestation of consent by the principal that the agent will act for it; (2) a consent to act by the agent; and (3) subjection to the control of the principal. *See Restatement (Second) of Agency* § 1(1) (1958). The December 30 Decision is utterly devoid of any findings (much less substantial evidence to support them) that the contracts between covered entities and contract pharmacies meet any of these requirements, particularly the "essential element[,] … the principal's right to control the agent's actions." *Restatement (Third) of Agency* § 1.01, cmt. f (2006). That is because such control likely does not exist—and, certainly, such control is not required under HHS's rule for manufacturers' new obligations to be triggered. Instead, HHS's approach would necessarily permit covered entities to compel manufacturers to send drugs to anyone, without the need for the covered entities to have any involvement in, let alone control over, what happens to those drugs.

Additionally, the government contends that generating revenue for covered entities is one of the 340B statute's goals and that, because most covered entities lack in-house pharmacies, it ***must*** be the case that Congress intended for such pharmacies to be included. The government does not cite a single case to support this atextual interpretation. Moreover, aside from regurgitating this alleged "purpose" in the December 30 Decision, the Decision does not support that contention with any evidence whatsoever concerning how much revenue covered entities receive (versus how

much contract pharmacies keep) or how it is used. ADVOP_3. The government cannot rest a decision with such far-reaching consequences on such conclusory statements unsupported by any evidence. *See Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) ("Conclusory statements will not do; an agency's statement must be one of reasoning.").

Finally, Defendants' agency theory runs directly counter to the evidence. *See Boucher v. U.S. Dep't of Agric.*, 934 F.3d 530, 531 (7th Cir. 2019) (holding that an agency acts arbitrarily and capriciously where it "disregard[s] compelling evidence" undermining its application of a regulatory scheme). As described above, *see* pp. 29-30, *supra*, the contract-pharmacy model has already been linked to a host of program integrity concerns, documented by the ***government itself***, including increased diversion and duplicate discounts. HHS paid mere lip service to these grave concerns, placing the burden on ***manufacturers*** to police diversions by going through the cumbersome process of auditing contract pharmacies and submit claims to the ADR process. ADVOP_5. Far from providing a reasonable explanation supporting the agency's decision, this cursory sentence only serves to compound the error. Faced with evidence that the agency's chosen path may lead to prohibited activity, the agency cannot throw up its hands and offload the problems associated with its approach onto manufacturers. *Cf. Panhandle E. Pipe Line Co. v. FERC*, 890 F.2d 435, 439-41 (D.C. Cir. 1989) (deeming it arbitrary and capricious for an agency not to take a "hard look at the salient problems before it" and to merely "assum[e] away the problem").[6]

Diversion and duplicate discounts are hardly the only program integrity concerns at play

[6] Indeed, HHS itself has taken the position that the 340B program needs to be reined in due to abuses that do not benefit the program's intended recipients. In part because of concerns that 340B hospitals were overprescribing 340B drugs to receive revenue through reimbursement, HHS cut the reimbursement rate to such hospitals by 28.5%. *See Am. Hosp. Assoc. v. Azar*, 967 F.3d 818, 821 (D.C. Cir. 2020); *see also* Am. Compl. ¶ 54. Apparently, the government finds it proper to take action to protect ***itself*** from 340B abuses, but faults private parties for trying to do the same.

here. The government has also found that "large numbers of low-income patients" do not receive ***any*** discounts when they acquire drugs through contract pharmacies, H.R. Rep. No. 102-384, at 9, and that "uninsured patients" instead "pay the full non-340B price for their prescription drugs at contract pharmacies," even when they are eligible for 340B discounts and even when the contract pharmacy is purporting to act as a covered entity's common-law agent, 2014 HHS-OIG Report, *supra*, at 2; *see also* H. Energy & Commerce Comm., *Review of the 340B Drug Pricing Program*, at 75 (Jan. 10, 2018) (raising "concerns about whether the money" the 340B program exacts from manufacturers "is truly devoted to improving patient care"). HHS made no mention of of this in the December 30 Decision; nor did it try to reconcile its approach with these well-documented abuses. This, too, provides reason enough to set the Decision aside.

Nor can the agency make up for the deficiencies in the December 30 Decision now. As the Supreme Court has explained, it is a "foundational principle" of administrative law that "a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015); *Byers v. C.I.R.*, 740 F.3d 668, 681 (D.C. Cir. 2014). Thus, a court may not "supply [its] own justifications for an order nor uphold an order based on [the agency's] post hoc rationalization," even if such explanation is given by the agency's lawyer before the court. *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 839 (D.C. Cir. 2006); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

In addition to these fatal flaws, the Decision cannot stand because the agency failed to "display awareness that it ***is*** changing position" from its prior interpretation of the statute, "show that there are good reasons for the new policy," or consider that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct.

2117, 2126 (2016). Even now, the government refuses to do so, instead claiming the "obligation" imposed in the December 30 Decision is not new. For the myriad reasons explained above, this contention is erroneous, rendering the government's decision arbitrary and capricious.

In sum, the December 30 Decision is textbook arbitrary and capricious agency action. Requiring manufacturers to provide massive discounts to contract pharmacies would fly in the face of the text and structure of the 340B statute, flout its basic purposes, and unmoor the 340B program from its contemplated and constitutionally permissible scope. On the flip side, Lilly's interpretation of the statute places a check against for-profit entities distorting the program to their own ends and ensure that patients will be able to get the medications they need, and Lilly's current approach—under which covered entities may use contract pharmacies, but only so long as the contract pharmacies agree to pass on the entire discount to the patient, *see* Am. Compl. ¶ 82—allows covered entities to keep 100% of the 340B discount that does not go to patients. Defendants' decision to condemn rather than embrace that model is arbitrary and capricious.

IV. The ADR Rule Is Procedurally And Substantively Defective.

A. The ADR Rule Needed to Proceed through Notice and Comment.

Turning to the ADR Rule, the government did not even try to comply with the APA before promulgating it. Instead, it withdrew the NPRM on ADR on August 1, 2017, took no action on ADR for three years, and then abruptly announced that it was resurrecting the interred NPRM, while adding significant (and unconstitutional) changes. The Rule does not purport to invoke any statutory ground for excusing notice and comment—because there is none. None of that is remotely consistent with the APA. Because the agency formally withdrew the NPRM—a fact that the Administrative Record makes plain for all to see, *see* PI Exh. B—it was required to undergo notice and comment before promulgating any final rule, as this Court has already correctly ruled.

According to the government, however, none of that matters. In its view, determining

whether an agency "effectively communicated a withdrawal of the proposed rule to the public" is verboten because it "imposes a new procedural requirement on agencies not found in the APA." MTD/MSJ 51. The government insists that even publicly withdrawing the NPRM "is not sufficient to terminate a rulemaking," because a rulemaking can be terminated only if the agency "formally withdraw[s]" it and issues an "accompan[ying] … statement explaining its reasons for the withdrawal." MTD/MSJ 50-51. That is not the law. *See* PI Order at 21 ("[T]he APA imposes no such requirement," and courts cannot impose requirements "that have no basis in the APA.").

The government's position also makes no sense. For one thing, it is the government, not Lilly, that "essentially imposes a new procedural requirement on agencies not found in the APA." MTD/MSJ 50. After all, the APA does not specify that withdrawal can only occur "formally," or via a "statement," or through "the Federal Register," or by any other particular means. *See* 5 U.S.C. § 553. The government's position thus gets the law exactly backwards, as it depends on the notion that agencies cannot "terminate[] a rulemaking" without jumping through formal hoops nowhere found in the APA. MTD/MSJ 51. For another, neither this Court nor Lilly is asking for any particular "procedural requirement" before withdrawal can be deemed effective. All this Court held, and all Lilly argues, is that agencies cannot tell the public one thing and later claim that they did not really mean it. That commonsense principle is neither novel nor contrary to the APA—which likely explains why the government cites no case from any court approving HHS's tactics here as a legitimate means of continuing the rulemaking process, and why Lilly is aware of none.

The government nonetheless contends that the approach this Court adopted in its PI Order, under which the relevant question is whether the agency's public-facing actions would lead a reasonable regulated entity to conclude that the agency had withdrawn the rulemaking, is "foreclosed by well-established Supreme Court precedent." MTD/MSJ 51. But the sole Supreme

Court precedent the government cites is *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978) (cited at MTD/MSJ 51), which on this point held only that courts cannot impose on agencies new procedural requirements not found in the APA. *See id.* at 524. Exactly. It is precisely because of *Vermont Yankee* that no case holds that an agency can withdraw a rulemaking only by jumping through particular procedural hoops, such as publication in the Federal Register.

The government lastly claims that the NPRM was frozen as a result of the January 2017 *Memorandum for the Heads of Departments*, but that claim is inconsistent with the *Memorandum* itself which expressly does not apply to "regulations subject to statutory … deadlines." Reince Priebus, Asst. to the President and Chief of Staff, *Memorandum for the Heads of Executive Departments and Agencies* (Jan. 20, 2017), https://bit.ly/2KIutnM. That plainly includes the ADR Rule, which Congress subjected to a 180-day deadline. That explains why Defendants did not remove the ADR NPRM from the Unified Agenda until eight months after the *Memorandum*, despite the *Memorandum*'s directive that agencies should remove pending regulations to which it applies "immediately." *Id.* Simply put, there is no indication that the agency understood the *Memorandum* to apply to ADR at the time—and its current litigating position cannot change that.

Nor is there any question that, here, the agency's actions "would have led a reasonable observer to believe the ADR Rule had in fact been withdrawn." MTD/MSJ 52 (quoting PI Order at 22). The agency permanently removed the NPRM from the Unified Agenda in 2017 and took no further action. The consequence of that decision was that the NPRM was publicly declared to be a "Completed Action," *see* HHS/HRSA, *View Rule, RIN: 0906-AA90* (Spring 2017), https://bit.ly/2ZydLLo, a status reserved for "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking," HHS/HRSA, *About the Unified Agenda*, https://bit.ly/2OYh3FZ (last visited May 8, 2021). The government ***still*** does not

acknowledge that reality, likely because it knows that that reality dooms its position. Instead, it argues that what an "HRSA official" told the public "in a news publication" makes no difference. MTD/MSJ 53. That is wrong, but also irrelevant. The point is not that an agency official told a news outlet that the agency had no plans to issue an ADR rule, although that is surely relevant. The point is that every single thing the agency did—all the way up to assigning the new Rule a new Regulatory Identification Number, *compare* 81 Fed. Reg. 53,381, *with* 85 Fed. Reg. 80,632—made clear that the NPRM had been interred and no rulemaking was forthcoming. "Considering these actions and circumstances together, the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA." PI Order at 23. The government still has no answer.

That conclusion is confirmed by the reality that, even if the NPRM were properly withdrawn (it was not), the final Rule is not a logical outgrowth of the NPRM, which did not provide for money actions. The government's only response is to repeat its *ipse dixit* that the Rule does not really allow money actions, but that is no response at all. The plain language of 42 C.F.R. § 10.21(a) could not be clearer that aggrieved parties may file "action[s] for monetary damages." The law is clear that "[i]f a final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal." *Public Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7, 14 (D.D.C. 2006). The government cannot evade that requirement by telling a reviewing court, through its lawyers, that none of the departures from its original proposal has any meaning. Nor can it evade the APA by claiming that a Rule that explicitly authorizes actions and proceedings for money damages, *see* 42 C.F.R. § 10.21, does not actually do so.

The government does not even pretend that the NPRM foreshadowed the final rule's requirement that ADR panel decisions would be "precedential"—which provides HRSA with a

backdoor means of doing what courts have said it may not do: adopt "binding rules that carry the force of law." *Orphan Drug*, 138 F. Supp. 3d at 48. Instead, the government says Lilly should have "divine[d]" that HHS would depart from the NPRM by giving panels the power to issue binding ***and*** precedential judgments. *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000). But "binding" and "precedential" mean different things. A "precedential" decision establishes how future disputes will be resolved and greatly increases the burdens placed on a regulated entity to conform its affairs to the conduct of others. And while "binding decisions" are at least contemplated by the statute, 42 U.S.C. § 256b(d)(3)(C), ***precedential*** decisions are not. Lilly had no reason to believe (and no way to anticipate) in the wake of the agency's multiyear silence on ADR that the panel's regulatory powers would suddenly be broadened in such a fashion. The ADR Rule thus violates the logical outgrowth test, *see Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 256-57 (3d Cir. 2010), which confirms that the Rule is procedurally defective.

B. The ADR Rule Violates Article II.

Article II of the Constitution requires principal officers of the United States to be appointed by the President with the advice and consent of the Senate, and permits only "inferior officers" to be appointed by the heads of Executive departments. U.S. Const. art. II, § 2, cl. 2. ADR panelists are plainly officers of the United States, as the government admits. *See* MTD/MSJ 37. The government denies, however, that ADR panelists are principal officers who must be appointed by the President with the advice and consent of the Senate. The government is wrong. ADR panelists have authority to make significant final decisions on behalf of the Executive Branch and bear all the traditional hallmarks of principal-officer power. And neither the statute nor the Rule supports any of the government's proposed "fixes" to that problem.

Under the express terms of the 340B statute and the ADR Rule, ADR panel decisions are the "final" word of the Executive Branch, "binding on the parties," and "precedential" within HHS.

42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). ADR panels' "final," "binding," and "precedential" decisions cannot be modified or undone by any superior officer within the Executive Branch—not even by the Secretary. Indeed, in issuing the Rule, HHS actively rejected comments asking to "incorporate an [administrative] appeals process," instead choosing a scheme under which ADR panel decisions are "final agency decision[s]" that are "precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 85 Fed. Reg. at 80,641; 42 C.F.R. § 10.24(d). That suffices to make ADR panelists principal officers, and it means that the Rule's vesting of panelists' appointment in the Secretary violates Article II.

The government's efforts to resist that conclusion fail. The government first claims that ADR panel decisions can be supervised through roundabout means, "because the agency head retains plenary authority to revise or rescind the regulations." MTD/MSJ 40. From that (faulty) premise, the government insists that any defect in the ADR Rule is illusory because the Secretary can always just "rescind" the ADR Rule's delegation of authority to panels and "adjudicate these matters personally" or, alternatively, "revise" the Rule to allow him to exercise "at will" removal power over ADR panelists. MTD/MSJ 41-43. That is not how this works. Lilly is challenging the ADR Rule—not some hypothetical, future regulation that right now exists only in Justice Department lawyers' minds. The government's evident belief that the ADR Rule can be saved only by "rescind[ing]" or "revis[ing]" it confirms the Rule's invalidity.

The Secretary cannot solve the constitutional problem by "personally" "adjudicat[ing]" ADR disputes (MTD/MSJ 41) either. Under the ADR Rule, the Secretary is not a panelist; neither is any other principal officer appointed by the President. The Rule specifies where ADR panelists will come from (HRSA, CMS, and the OGC) and who will appoint them (the Secretary). *See* 42 C.F.R. § 10.20; 85 Fed. Reg. 80,632, 80,634 (Dec. 14, 2020). So, unless the Secretary formally

rescinded the Rule and began anew—which would require a full round of notice-and-comment rulemaking—he cannot "adjudicate these matters personally" (MTD/MSJ 41). The government all but concedes the point by concluding that the Rule can be upheld ***not*** on its own terms, but only because "[t]he Secretary retains plenary authority to revise the Rule and, in so doing, modify the workings of the Board." MTD/MSJ 43. And, again, while the Secretary may revise the Rule, he cannot "modify the workings of the Board" unless he first complies with notice and comment—a task that last time eluded HHS for more than a decade.

The government next asserts that ADR panel "decisions" "are ***not*** self-effectuating" under the Rule because (it says) HRSA retains authority to review them pursuant to 42 C.F.R. § 10.24(e). MTD/MSJ 44. That is incorrect. While the ADR Rule does authorize HRSA, following a panel decision, to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," 42 C.F.R. § 10.24(e), that authorization is limited. It does not empower HRSA to ***modify***, let alone reverse, panel decisions; all it does is provide a mechanism for further enforcement. Nor could it. After all, the 340B statute itself provides that an ADR panel decision "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." 42 U.S.C. § 256b(d)(3)(C). The statute does not say, *e.g.*, that panel decisions are final and binding only "once approved by HRSA." The government's argument that § 10.24(e)'s general remedial authorization trumps the specific language of ***the statute*** flouts the text and violates basic principles of administrative law.

The argument that the Secretary has plenary removal power over ADR panelists, *see* MTD/MSJ 40-41, fares no better. It is again contrary to the text of the Rule, which says that "individuals serving on a 340B ADR Panel may be removed ***for cause***." 85 Fed. Reg. at 80,634 (emphasis added); *see also* 42 C.F.R. § 10.20(a)(ii). "For cause" does not mean "without cause."

And while the government now insists that this express limitation does not apply to removal from the Board itself (as opposed to from a panel), that claim belies everything the government says to justify its decision to eschew independent, impartial ALJs (in favor of existing agency employees likely to hold positions consistent with HHS policy). The government cannot on the one hand assure the Court that ADR panelists will be fully objective and impartial adjudicators while simultaneously touting on the other hand the "Secretary's ability to remove an individual from a panel, or from the Board, at will—with or without a conflict of interest." MTD/MSJ 42.

In all events, plenary removal authority would not suffice to make ADR panelists inferior officers, for two reasons. First, the 340B statute itself makes clear that ADR panelists are principal officers by conferring authority to issue "final agency decision[s]" that "shall be binding upon the parties involves, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C). That is exactly what Justice Alito explained in *American Railroads* may be done only by principal officers. *See DoT v. Ass'n of Am. R.R.s*, 575 U.S. 43, 64 (2015) (Alito, J., concurring) ("Inferior officers can do many things, but nothing final should appear in the Federal Register unless a Presidential appointee has at least signed off on it."). Accordingly, as a matter of statute, the position of ADR panelist must be filled by a principal officer appointed by the President, or by no one at all. *See Weiss v. United States*, 510 U.S. 163, 170 (1994). The ADR Rule does not do that; it instead vests panel appointments only in the Secretary.

Second, even the power to remove at will would not be enough to fix the constitutional problem. To be sure, the power to remove an officer may be a "powerful tool for control." *Edmond v. United States*, 520 U.S. 651, 664 (1997). That is why the D.C. Circuit found it a sufficient remedy to sever the limitations on removability in *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board*, 684 F.3d 1332 (D.C. Cir. 2012) (cited at MTD/MSJ 40, 43); there, the

Register of Copyrights had the authority to "review[] ***and correct***[]" CRJs' decisions. *Id.* at 1338-39 (emphasis added). But that is not the case here. And, contrary to the government's suggestion, the Supreme Court has never held that an officer is inferior just because he can be removed.

In fact, the Supreme Court has made clear that removal power suffices to render an officer inferior only when that power is buttressed by or tantamount to the power to review, modify, or otherwise undo the officer's decisions. *Edmond* drew that precise distinction: The Judge Advocate General ("JAG") had unfettered power to remove the Coast Guard judges "without cause," but that did not suffice to make the Coast Guard judges inferior officers. The JAG's oversight powers were "not complete" because he "ha[d] no power to reverse decisions"; it was only because other Article II officers ***did*** have that power that the Coast Guard judges were inferior officers. 520 U.S. at 664. The government buries this critical point in a footnote, *see* MTD/MSJ 38 n.8, but it is no ancillary issue. The Coast Guard judges were inferior officers not because someone could remove them, but because they lack "power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Edmond*, 520 U.S. at 665. ADR panelists, in contrast, ***do*** have power to issue "final," "binding" decisions that cannot be reviewed or set aside by any superior Executive Branch official ***as a matter of statute***. *See* 42 U.S.C. § 256b(d)(3)(C). Accordingly, the Secretary's supervision of ADR panelists here is "not complete," *Edmond*, 520 U.S. at 664, and it cannot be made so without Congress intervening and enacting a new statute.

That distinguishes the government's cases. In *Pennsylvania v. HHS*, 80 F.3d 796 (3rd Cir. 1996) (cited at MTD/MSJ 39), the court held that officers within HHS who ***lack*** "the authority to render a final decision" on behalf of the Executive Branch for "any of the … proceedings" within their regulatory bailiwick are not principal officers within the meaning of the Appointments Clause. *Id.* at 804. Likewise, in *Fleming v. USDA*, 987 F.3d 1093 (D.C. Cir. 2021) (cited at

MTD/MSJ 40), the court held that USDA ALJs are inferior officers because—unlike here or in *American Railroads*—"the Secretary" has authority to "step in and act as final appeals officer in any case," which means, unlike here, that the "ALJ's decision" is ***not*** necessarily the agency's final word. *Id.* at 1103. But here, ADR panelists ***do*** render "final agency decision[s]" that by statute are "binding upon the parties," 42 U.S.C. § 256b(d)(3)(C), but nonetheless are "appealable only to courts of the Third Branch," *Edmond*, 520 U.S. at 665. That also distinguishes *In re Grand Jury Investigation*, 916 F.3d 1047 (D.C. Cir. 2019) (cited at MTD/MSJ 40-43), where removal effectively allowed plenary control of the removed officer's decisions. The Attorney General there not only could remove the Special Counsel at will, but could unilaterally rescind the Special Counsel's entirely-regulatory authority, terminate his investigation, and discharge the grand jury. The Secretary possesses no comparable authority vis-à-vis ADR panels here, and no amount of tinkering with the Rule can change that. Under the statute itself, even removed ADR panelists' decisions would remain the agency's "final" word on the adjudication, "binding upon the parties involved, unless invalidated by an order of" an Article III court. 42 U.S.C. § 256b(d)(3)(C).

C. The ADR Rule Violates Article III.

The Supreme Court has held that "[w]hen a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789, and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts." *Stern v. Marshall*, 564 U.S. 462, 484 (2011). The ADR Rule assigns that responsibility to Executive officials instead. Under the Rule's express terms, an "action" for "monetary damages or equitable relief" brought by a "covered entity" claiming "that it has been overcharged" will be adjudicated by a "340B ADR Panel," an Article II body that, under the Rule, has exclusive "jurisdiction" over any such "action." 42 C.F.R. § 10.21(a)-(c). That flatly violates Article III.

1. The government first contends that Lilly's Article III claim "rests on a

fundamentally inaccurate portrayal of the Board's remedial powers and of the claims it is empowered to hear," MTD/MSJ 43, because, it says, ADR panels cannot "issue binding judgments for money damages," MTD/MSJ 54. But the ADR Rule plainly states that a "covered entity or manufacturer may initiate ***an action for monetary damages*** … by filing a written petition for relief"; that filing such a petition initiates "***a proceeding for damages***"; that exclusive "jurisdiction to entertain any [such] petition" rests with an "ADR Panel"; that the majority decision of an ADR panel "regarding the claim" "constitutes a ***final agency decision***"; and that the ADR panel's "final agency decision" "is ***precedential and binding*** on the parties involved unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. §§ 10.21, 10.24 (emphases added); *see also id.* § 10.21(e). If those provisions do not grant ADR panels "authority to issue binding judgments for money damages," MTD/MSJ 54, then the ADR Rule's words have no meaning.

The government tries to evade that reality by claiming that ADR panels just "determine[] compliance" with the statute. MTD/MSJ 44. That cannot be reconciled with the Rule's many references to "claims for damages" and "proceedings for damages." Nor does it make a difference that "a sale of … medications to a covered entity at the statutory ceiling price is full payment." MTD/MSJ 44. The same could be said about any court proceeding under any statute that defines a party's entitlement. No one can get damages in any case unless a law says they are entitled to something and an adjudicator determines that the defendant did not provide it. An order at the end of such an adjudication that the defendant owes the plaintiff what it is entitled to is plainly an order for damages. *See, e.g.*, Frank Gahan, *The Law of Damages* 1 (1936) ("Damages are the sum of money which a person wronged is entitled to receive from the wrongdoer as compensation for the wrong."). In short, no amount of imaginative retelling can change "proceedings for damages" before the "340B ADR panel" into anything other than proceedings for damages.

The government's novel interpretation of "equitable relief" is even more remarkable. The ADR Rule states that panels may award "equitable relief"—full stop. 42 C.F.R. § 10.21(a); *see also* 85 Fed. Reg. at 80,633. Normally, when a term "is obviously transplanted from another legal source, it brings the old soil with it." *Taggart v. Lorenzen*, 139 S. Ct. 1795, 1801 (2019). Here, that includes the quintessential form of equitable relief—an injunction. But the government's brief, without citing anything, announces that "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." MTD/MSJ 44. What the government is describing is a declaratory judgment, or perhaps a cease-and-desist letter, and the government offers no explanation why HHS would choose to use the term "equitable relief" to describe it. *See AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341 (2021) (noting that, in 15 U.S.C. § 45(*l*), "Congress explicitly provided" district courts with authority to grant "other and further equitable relief" "where the [SEC] has ***issued cease and desist orders***"). The confusion is heightened by the fact that the ADR Rule separately tells ADR panels to apply "the Federal Rules of Civil Procedure," 42 C.F.R. § 10.23(b), which authorize courts to issue "preliminary injunction[s]" and "restraining order[s]," Fed. R. Civ. P. 65. While Lilly is pleased that the government thinks ADR panels lack such powers, one would not know that from the Rule; nor is there any way to tell ***which*** provisions of the Federal Rules of Civil Procedure the government thinks do and do not apply.

The point of the government's creative editing is to obfuscate that the ADR Rule unequivocally grants ADR panels authority to hold that a manufacturer must convey its property (*i.e.*, money) to a covered entity in the event they determine that the former overcharged the latter by vesting ADR panels with "jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility." 85 Fed. Reg. at

80,636; *see also* 42 C.F.R. § 10.21(b), (c). The Rule also authorizes ADR panels to determine that an entity (*e.g.*, a contract pharmacy) is covered by the statute; to determine that refusal to sell to such entity at 340B prices violates "statutory requirements" (MTD/MSJ 47); and to issue "precedential and binding" judgments that manufacturers are legally required to do just that. The Rule thus authorizes ADR panels to issue binding determinations of the liability of one private party to another. That is the definition of unconstitutional adjudication of private rights outside Article III. *See Oil States Energy Servs. v. Greene's Energy Group*, 138 S. Ct. 1365, 1378 (2018).

The government may now realize that what the Rule actually says creates a constitutional problem, but that realization does not permit it to rewrite the Rule in a brief. Agencies cannot cure defective regulations by offering "*post hoc* rationalizations" in a legal brief that have no basis in the rule, let alone offer fixes that conflict with the statute. *State Farm*, 463 U.S. at 50. "[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.*; *see SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("We may not supply a reasoned basis for the agency's action that the agency itself has not given."); *Phila. Gas Works v. FERC*, 989 F.2d 1246, 1250 (D.C. Cir. 1993) ("FERC, not we (or FERC's appellate lawyers), must adopt" the "grounds … FERC's counsel suggest."). Yet that is precisely what the government tries to do.

As a failsafe, the government claims it makes no difference to Article III what vast common-law powers ADR panels enjoy. That is wrong. The Supreme Court has made crystal clear that the suite of powers exercised by an administrative tribunal is directly relevant to the degree of infringement on the judicial power—and that the suite of powers exercised by ADR panels is well over the constitutionally permissible line. *See CFTC v. Schor*, 478 U.S. 833, 851 (1986). Here, the Rule authorizes ADR panels to resolve claims by a private party that it is entitled to another private party's property below cost, to issue money-damages judgments for past failures

to convey that property, and to use the official rules that govern federal-court proceedings. And it does this while simultaneously limiting Article III courts' review—even though the Supreme Court deems constitutionally suspect administrative schemes that allow federal-court review of agency decisions only under the deferential APA standard that applies here. *See, e.g.*, *id.* at 853. By these devices, the Rule removes any meaningful "control by Article III judges over the interpretation, declaration, and application of federal law," and usurps the "constitutional role of the judiciary." *United States v. Johnston*, 258 F.3d 361, 368 (5th Cir. 2001) (quoting *Pacemaker Diagnostic Clinic, Inc. v. Instromedix, Inc.*, 725 F.2d 537, 544 (9th Cir. 1984) (en banc) (Kennedy, J.)).

2. More ambitiously, the government claims that "it matters not" to the Constitution that the dispute may impact private rights because the 340B program is tied to a federal statute. MTD/MSJ 46. That is both wrong and dangerous. The right to sell a product at the seller's price arises from the right to private ownership, not government grace or federal regulatory regimes, and is at the core of the private rights manufacturers hold at common law. As a result, disputes over those prices are "matter[s] which, from [their] nature, [are] the subject of a suit at the common law." *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856).

The government's contrary position is based on a misreading of the Supreme Court's decision in *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985). In that case, a non–Article III tribunal was allowed to adjudicate disputes between private parties. But, crucially, ***neither party*** there had any asserted private rights at stake. *Union Carbide* arose in the context of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), under which pesticide registrants generally were required to submit to the EPA data regarding the safety and efficacy of their products. By submitting the data, the registrant extinguished any common-law property right it might have had. *See id.* at 584. The EPA could then use the first registrant's data to evaluate a

second registrant's application. *Id.* FIFRA created a novel scheme under which registrant 2 would owe registrant 1 compensation if the EPA used its data to approve registrant 2's application; in such a case, the statute required binding arbitration of disputes between registrants. *Id.* And because—unlike here—each party's rights were wholly created by FIFRA, Congress could require such disputes over public rights to be adjudicated outside Article III. *Id.* at 584.

The claims at issue here bear no resemblance to the bilateral public-rights claims at issue in *Union Carbide*. Lilly's right to sell its property at its chosen price derives from the common law, not federal statute, and existed long before the 340B program came into being. That was not true of the entirely-statutory rights in *Union Carbide*, where the private party's right to compensation depended entirely on how ***the government*** used its data. Unlike *Union Carbide*, then, the claims that ADR panels are empowered to adjudicate under the Rule include claims seeking proper compensation (*i.e.*, money) for private property that has value separate and apart from a federal regulatory regime—hardly an instance where "it depends upon the will of congress whether a remedy in the courts shall be allowed at all." *Stern*, 564 U.S. at 488-49.

The government's contrary position flatly contradicts *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989)—a decision the government continues to refuse to acknowledge. *See* Lilly PI Reply 15. The question there was whether bankruptcy courts, non–Article III fora, could constitutionally adjudicate fraudulent conveyance claims between a bankrupt estate's trustee and a non-creditor that arose under the federal bankruptcy statute, *viz.* 11 U.S.C. § 548(a)(2). The Court held that bankruptcy courts could not do so consistent with Article III, because—even though the claims are entirely statutory—resolving them would require the adjudicator to decide how much money one private party owed another, separate and apart from the bankruptcy priority regime. 492 U.S. at 51-56. That meant the claims were "quintessentially suits at common law"

that could not be heard by non–Article III fora, *id.* at 55-56, even though they arose under a federal statute and in the context of a pervasive statutory regime. So too here. The 340B statute did not give Lilly the "substantive federal right" (MTD/MSJ 48) to sell its drugs; it only impaired a pre-existing, independent common-law right by essentially placing ***restrictions*** on making sales for one-fifth of the Nation's population. Thus, unlike in *Union Carbide*, 340B pricing disputes and claims that certain entities are not entitled to discounts are "quintessentially" common-law suits with "a long line of common-law forebears," *Granfinanciera*, 492 U.S. at 34, 51, which "from [their] nature, [are] the subject of a suit at the common law," *Murray's Lessee*, 59 U.S. at 284, and which "must" be resolved by "the Article III courts," *Stern*, 564 U.S. at 494.

3. The government's remaining arguments do not change that conclusion. The government argues that *Astra* "confirms" that the Rule's procedures comport with the Constitution. MTD/MSJ 49. Not so. *Astra* did not discuss Article III at all. The question in the case was simply whether the 340B PPA manufacturers sign creates a private right of action. In holding that it does not, the Court observed in passing that the statute contemplates ADR procedures. *Astra*, 563 U.S. at 121-22. Noting that Congress required HHS to set up ADR procedures is obviously not an opinion on the merits of the ADR procedures that HHS promulgated ***nine years later***.

Nor can it be said that manufacturers like Lilly have consented to the 340B program ***as it currently exists in the wake of the December 30 Decision***. On the contrary, Lilly has filed suit challenging that interpretation of the statute and unlawful exercise of authority. So, while the Supreme Court has held that "Article III is not violated when the parties knowingly and voluntarily consent[ed] to adjudication by a bankruptcy judge," a non–Article III officer, *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1939 (2015), that principle does not move the needle here. A manufacturer's decision to participate in the 340B program, lest it lose the ability to participate

in and receive reimbursements under Medicaid and Medicare altogether, is nowhere close to the sort of voluntary "consent" the Supreme Court requires in this context. *See, e.g.*, *Stern*, 564 U.S. at 493 ("Pierce did not truly consent to resolution of Vickie's claim in the bankruptcy court proceedings," because "[h]e had nowhere else to go if he wished to recover from Vickie's estate.").

Finally, even if manufacturers' original decision to participate in the 340B program was voluntary, that decades-old decision is obviously not consent to allowing HHS to force them to transfer their private property to other for-profit entities on pain of massive financial sanction—let alone consent to adjudication of such core private rights by an unconstitutionally constituted agency tribunal. ADR procedures were not proposed publicly until 2016, more than two decades after most manufacturers signed PPAs. And once those procedures were revealed, Lilly (and a host of others) ***specifically objected to them***, including by filing this lawsuit. That is the opposite of consent. In any event, the Supreme Court made clear in *Wellness* that consent can transform an otherwise-unconstitutional Executive adjudication into a permissible one only when "Article III courts retain supervisory authority over the process." 135 S. Ct. at 1944. Here, Article III courts ***do not*** retain sufficient supervisory authority over ADR panels. Consent cannot cure the violation.

D. The ADR Rule Is Arbitrary, Capricious, and Beyond the Agency's Authority.

1. The ADR Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and must be set aside on that basis too. *See* 5 U.S.C. § 706(2)(A).

First, the Rule fails to account for changed legal circumstances in the years since it was withdrawn. An agency is "susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem" if it does not account for legal developments. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2384 (2020). That is precisely the case here. The Supreme Court brought significant clarity to its Appointments Clause jurisprudence since the NPRM was withdrawn—jurisprudence entirely

ignored in the ADR Rule. The same is true with respect to the Article III concerns. The ADR Rule does not even acknowledge, let alone attempt to justify, how a process that affords Executive Branch employees full adjudicative powers, including the ability to exercise common-law interpretive authority and the power to issue binding money judgments or equitable relief touching private property, without being subject to an Article III court's plenary control, could be constitutional. Because Defendants provided no explanation—let alone a reasoned one—the Rule cannot stand. *See, e.g.*, *Teva Pharm. USA, Inc. v. FDA*, 441 F.3d 1, 4 (D.C. Cir. 2006).

The government claims that it simply could not have "predict[ed]" Lilly's constitutional concerns. MTD/MSJ 56. But notice-and-comment rulemaking would have removed the need for any "prediction" on the government's part. And an agency cannot ignore its overriding obligation to promulgate only constitutional rules. HHS had an independent obligation to ensure that, when creating this novel adjudicative body, it did so in keeping with current Supreme Court precedent and other constitutional developments. Because HHS completely failed to grapple with this vitally important aspect of the problem, the ADR Rule is arbitrary and capricious.

The government asserts that Lilly "waived" any constitutional claims "by failing to raise [them] during the comment period." MTD/MSJ 56. That argument is, to borrow a word, brazen. Lilly objected to the lack of impartiality and accountability for panelists in response to the original NPRM. *See* Am. Compl. Exh. M. More important, the availability of "monetary damages" and "equitable relief" appeared ***for the first time in the final Rule***, as did the power to issue "precedential decisions." Those proposals were not subject to notice and comment, and Lilly had no obligation to guess that HHS would alter the NPRM in a way that ran afoul of the Constitution.

Second, the government failed to adequately explain the structure it chose for administrative dispute resolution. Multiple manufacturers pointed out in response to the NRPM

that staffing ADR panels with the same individuals responsible for creation and implementation of HRSA policy could create serious problems. Given that the individual ADR panel members serve in other functions for the agency, they are likely to hold biases, policy positions, or other objectives outside the limited facts of the dispute at issue. The ex-officio OPA member compounds these risks, with its potential to exert undue influence over the panel. The Rule disregards these concerns, and the government's unsupported response that manufacturers should simply accept that no bias will exist is "not a statement of reasoning, but of conclusion," *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 737 (D.C. Cir. 2001), which is the definition of arbitrary and capricious action.

The government's last response is self-defeating. The government insists that "HHS established multiple procedures and safeguards 'to ensure fairness and objectiveness,'" including "remov[al] from a panel 'for cause.'" MTD/MSJ 57. But that flouts its purported remedy for the Appointments Clause problem—*viz.* that the Secretary can remove panelists ***at will***. *See* pp. 46-48, *supra*. The government cannot have it both ways: It cannot insist that panelists need not be ALJs because they will be insulated from "policy positions or other objectives outside of the limited facts of the dispute at issue," MTD/MSJ 57, while arguing that the removal protections are mere window dressing that the Secretary can ignore if panelists do not agree with his policy goals.

The choice of ADR panelists instead of more independent ALJs is thus both unreasonable and unreasonably explained. Despite appeals to agency expertise, the lion's share of what panelists do—hearing evidence, making credibility determinations, applying the Federal Rules of Evidence and Civil Procedure, and even imposing sanctions—***has nothing whatsoever to do*** with specialized agency expertise. These instead are the tasks of judges. The government makes no effort to justify having panels with two non-lawyers apply the Federal Rules and render "final," "binding," and "precedential" decisions; instead, it simply repeats that expertise is required

because it says so, without pointing to any difference between the 340B program and, *e.g.*, other labyrinthine Medicare programs adjudicated by HHS ALJs. Such *ipse dixit* is not enough.

Third, the Rule fails to address manufacturers' concerns regarding HHS's outdated and burdensome auditing guidelines. Though it acknowledges that commenters raised this issue, the Rule gives those concerns short shrift, stating without explanation that "updated manufacturer audit guidelines" are not "needed" and that ADR panels can "determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts." 85 Fed. Reg. at 80,633. Such conclusory explanations cannot stand. *See, e.g.*, *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1405 (D.C. Cir. 1995) (finding an explanation to be unreasoned where, "[a]lthough the Board … briefly recited the facts alleged by petitioners, and then found that a waiver would not be in the interest of justice, it omitted the critical step—connecting the facts to the conclusion").

2. The ADR Rule also unlawfully exceeds the scope of Defendants' "statutory … authority." *See* 5 U.S.C. § 706(2)(C). The statute allows HHS/HRSA to "promulgate regulations to establish and implement an administrative process … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions." 42 U.S.C. § 256b(d)(3). The term "appropriate procedures for the provision of remedies" is general and undefined; it does not specify which remedies are to be made available by the ADR regulations—only that they be "appropriate." *See id.* Allowing ADR panels to impose self-executing money judgments would not be "appropriate" under the statute—they would be illegal under Article III. At the very least, the canon of constitutional avoidance counsels strongly against such an interpretation. *See INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001).

CONCLUSION

The Court should deny the government's motion to dismiss, deny the government's motion for summary judgment, and grant summary judgment for Lilly.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **May 10, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

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