UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:21-cv-00081-SEB-MJD
	)	
NORRIS COCHRAN, et al.	)	
	)	
Defendants.	)	

ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

This cause is before the Court on Plaintiffs' Motion for Preliminary Injunction [Dkt. 18], filed on January 25, 2021. Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Plaintiffs" or "Lilly") seek to have Defendants Norris Cochran, in his official capacity as Acting Secretary of Health and Human Services, Daniel J. Barry, in his official capacity as Acting General Counsel of Health and Human Services, United States Department of Health and Human Services, Diana Espinosa, in her official capacity as Acting Administrator of Health Resources and Services Administration, and Health Resources and Services Administration (collectively, "Defendants") enjoined from implementing or enforcing against Plaintiffs the Administrative Dispute Resolution Regulation published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§ 10.20-24 ("ADR Rule"), which sets forth the administrative dispute resolution process for certain disputes regarding the 340B Drug Pricing Program, established by § 340B of the Public Service Act, 42 U.S.C. § 256b.

The Court heard arguments on February 26, 2021. Having now considered those arguments, along with the parties' evidentiary and written submissions, the *amicus* brief, and the controlling principles of law, we hereby GRANT Plaintiffs' Motion for Preliminary Injunction.[1]

Factual Background

Background of the 340B Drug Pricing Program

Plaintiffs' lawsuit relates to the 340B Drug Price Program ("340B Program"), a drug-discount regime established by Congress in 1992 and administered by the Secretary of Health and Human Services ("HHS"), which requires, as a condition of participating in Medicaid and Medicare Part B,[2] that pharmaceutical manufacturers, like Plaintiffs, sell outpatient drugs at a heavily discounted price to "covered entities," which are defined by

[1] In the days following oral argument, the parties submitted multiple filings addressing issues raised at the hearing. On March 1, 2021, in response to the Court's question regarding the manner in which 340B Program disputes were resolved prior to the ADR Rule, Plaintiffs sought leave to file a Notice of Supplemental Authority directing the Court to 61 Fed. Reg. 65,406-01 (Dec. 12, 1996), entitled *Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19*. Because that information aids the Court's understanding of the dispute resolution procedures previously governing 340B disputes, Plaintiffs' motion is hereby GRANTED. On March 5, 2021, Defendants interposed objections to several slides Plaintiffs' counsel had provided to the Court and opposing counsel immediately in advance of oral argument. We have resolved Plaintiffs' request for injunctive relief without reference to the challenged slides; therefore, Defendants' objections have been noted but have not affected our ruling. Finally, also on March 5, 2021, Defendants requested that we take judicial notice of the publicly available links to two letters sent to the HHS Secretary and Acting HHS Secretary, respectively, by groups of bipartisan lawmakers, urging HHS to take action with regard to drug manufacturers' restrictions on contract pharmacies and the 340B ADR process. We have reviewed these letters but do not find it necessary to take judicial notice of the publicly available links.

[2] Because pharmaceutical manufacturers cannot receive coverage or reimbursement for their products under Medicaid and Medicare Part B unless they participate in the 340B Program, though they are technically free to opt out of the 340B Program, if they do so, they lose access to "billions of dollars in revenue" annually through drug coverage in federal health-insurance programs. Am. Compl. ¶ 157.

statute to include 15 enumerated types of public and not-for-profit hospitals, community centers, and other federally funded clinics serving low-income patients. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), *codified at* § 340B Public Health Service Act, 42 U.S.C. § 256b (1992). More specifically, pharmaceutical manufacturers participating in the 340B Program 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." 42 U.S.C. § 256b(a)(1). The resulting 340B "ceiling prices," which are calculated according to a prescribed statutory formula, *see id.* § 256b(a)(1), (a)(4), (b)(1), are significantly lower than the amount(s) other purchases would pay and, in some cases, can be as low as one penny per pill. These drug discounts are intended to "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report). Although not required, one way in which covered entities may utilize the discounts is to pass the savings along to uninsured and underinsured patients to help them afford otherwise too costly medications.

To enter the Program, manufacturers are required to sign a form contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"), which incorporates the statutory obligations of the 340B Program and memorializes the manufacturers' agreement to abide by those obligations. *See* 42 U.S.C. § 1396r-8(a)(1), (5). If the government determines that a drug manufacturer has failed to comply with its 340B Program obligations, it can terminate the manufacturer's PPA, thereby also preventing the

manufacturer from receiving coverage under Medicare and Medicaid. *See id.* § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

Under the 340B Program, covered entities are prohibited from requesting "duplicate discounts or rebates," which means that covered entities may not request both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered entities are also prohibited from engaging in "diversion," which is defined by the statute as the practice of "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).

HHS's 1996 Advisory Opinion Regarding Contract Pharmacies

For the first few years of operation of the 340B Program, covered entities purchased and dispensed 340B drugs exclusively through in-house pharmacies. However, it soon became clear that fewer than five percent of the covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies. Instead, the vast majority of such providers relied on arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). Covered entities participating in the 340B Program who did not operate in-house pharmacies began relying on contract pharmacies to take delivery from manufacturers of 340B drugs purchased by the covered entity in order to dispense those drugs to the covered entities' low-income patients. *Id.* at 43,549.

Acknowledging this practice, HHS issued non-binding guidance in 1996, observing that "[i]t would defeat the purpose of the 340B program if these covered entities [without in-house pharmacies] could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. The 1996 Guidance advised "that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," regardless of whether the covered entity directs that the 340B drugs be shipped for handling and dispensing to a contract pharmacy. *Id.* at 43,549. HHS further advised that restricting covered entities' access to 340B discounts to only those operating an in-house pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* at 43,550. The 1996 Guidance explicitly stated that permitting the use of contract pharmacies does not constitute an unauthorized expansion of the 340B Program because "[t]he statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549.

HHS's 2010 Advisory Opinion Regarding Contract Pharmacies

While the 1996 Guidance restricted covered entities to the use of a single contract pharmacy, in 2010 HHS issued additional non-binding guidance specifying that covered entities need not be limited to a single contract pharmacy and were free to contract with

as many pharmacies as they chose, even if they also operated an in-house pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) (hereinafter "2010 Guidance"). HHS reasoned that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more widespread use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* at 10,273. No pharmaceutical manufacturer, trade association, or other similar entity filed suit to challenge the substance or impact of the 2010 non-binding guidance.

Congressional Action Regarding the 340B Program

That same year, in 2010, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to "[i]mprove[] program integrity" with regard to manufacturer and covered-entity compliance. The HHS Secretary was granted authority to issue new regulations imposing civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R § 10.11(a).

In a related provision of the ACA, Congress instructed the Secretary to establish within 180 days a 340B Program administrative dispute-resolution process ("ADR

process") for covered entities and manufacturers.[3] Specifically, Congress directed as follows:

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

42 U.S.C. § 256b(d)(3)(A). Congress granted the Secretary the authority to "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices" above the statutory ceiling price, as well as "claims by manufacturers that violations" of prohibitions on duplicate discounts or drug diversion have occurred. *Id.* § 256b(d)(3)(B)(i). The Secretary was also given authority to "establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously," and to "establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim." *Id.* § 256b(d)(3)(B)(ii), (iii). With regard to claims brought by manufacturers against covered entities, Congress mandated that, "as a prerequisite to initiating" such a

[3] Prior to this Congressional directive, there was no formal ADR process in place for addressing disputes between covered entities and drug manufacturers regarding implementation of the 340B Program. Rather, there existed a voluntary dispute resolution process manufacturers and covered entities were "only encouraged to participate in" before seeking remedies in a court of law. 61 Fed. Reg. 65,406-01.

proceeding, the manufacturer must audit the covered entity. *Id.* § 256b(d)(3)(B)(iv). The statute also provides that ADR decisions "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

HHS Notice of Proposed Rulemaking Regarding ADR Procedures

Although Congress directed in 2010 that HHS promulgate regulations within 180 days establishing an ADR process for resolving price, diversion, and duplicate discount disputes between covered entities and drug manufacturers, HHS did not issue a Notice of Proposed Rulemaking ("NPRM") proposing ADR procedures until August 12, 2016. *See* 81 Fed. Reg. 53,381 (Aug. 12, 2016). It is not clear the reason for the delay.

When it finally took up the assigned task, HHS's 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 the staff of [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. ADR panel members would be "Federal employees … with demonstrated expertise or familiarity with the 340B Program" and would be appointed by the HHS Secretary. Once assigned to a panel, panel members could be removed from that assignment only "for cause," such as dispute-specific conflicts of interest. *Id.* ADR panel decisions would "be binding upon the parties involved … unless invalidated by an order of a court of competent jurisdiction." *Id.* 53,383. Panel decisions would then "be submitted to [HRSA's Healthcare Systems Bureau] to take enforcement action or apply sanctions, as appropriate." *Id.*

In October 2016, several drug manufacturers, including Lilly, filed timely comments raising concerns regarding 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)). Among other issues, Lilly voiced concerns regarding the potential biases of the ADR panelists, given their appointment by the HHS Secretary. Lilly recommended that HHS instead employ a neutral adjudicator such as an administrative law judge. *Id.* at 8–10.

Following the close of this notice and comment period, the NPRM, without reflecting any changes in response to manufacturer comments, began appearing on the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation about federal regulations under agency development. However, on August 1, 2017, the NPRM was removed entirely from the United Agenda without any explanatory comment. *See* Exh. B.

Plaintiffs Restrict Shipment of 340B Drugs to Contract Pharmacies

For approximately ten years, Lilly followed the guidance set forth in the HHS's 2010 Advisory Opinion by shipping 340B drugs purchased by covered entities to the covered entities' designated contract pharmacies when and as requested to do so. However, in the summer of 2020, Lilly announced that it was "discontinu[ing] its practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." Am. Comp. Exh. F (August 19, 2020 Letter from Lilly to HRSA); *see also* Exh. G (notifying covered entities that they "will not be eligible to purchase [Lilly]

products at the 340B ceiling price for shipment to a contract pharmacy"). Lilly stated that it would continue to honor orders by covered entities to ship 340B drugs to contract pharmacies in two instances: (1) where the covered entity lacks an in-house pharmacy and thus needs to partner with an outside pharmacy to dispense outpatient drugs; and (2) where the covered entity wholly owns the outside pharmacy and thus can assure the pharmacy's compliance with the 340B Program.[4] According to Lilly, it issued this notice in response to documented and widespread abuses of the 340B Program that had been increasing over the years since the HHS issued its 2010 guidance permitting covered entities to utilize an unlimited number of contract pharmacies to dispense 340B drugs.

In line with the policy outlined in its notice to the HRSA, beginning in September 2020 and continuing through the present, Lilly has restricted access to 340B discounts through contract-pharmacy arrangements, subject to the exceptions set forth above. Several other drug manufacturers have since followed suit, imposing similar restrictions with regard to covered entities' use of contract pharmacies. In response to these actions, several covered entities have filed lawsuits against HHS,[5] seeking to compel HHS to reverse the drug manufacturers' policies regarding contract pharmacies and/or to promulgate regulations establishing an ADR process as Congress had previously directed in 2010.

[4] Lilly is not restricting insulin to only a single contract pharmacy so long as insurance is not billed for the insulin, no markup or dispensing fee is charged to the patient, and the covered entity provides Lilly detailed information demonstrating compliance with these conditions.
[5] These lawsuits are currently pending in other districts. *See, e.g., Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020).

HHS's Final ADR Rule

On December 14, 2020, approximately two months after the covered entities' lawsuits were filed against HHS, the agency published a final rule regarding ADR procedures ("the ADR Rule"). Before doing so, however, HHS provided no advance notice or opportunity for public comment. By way of explanation, the preamble to the final ADR Rule states that the NPRM was not withdrawn when it was removed from the Unified Agenda in August 2017, but instead merely paused as part of an "immediate[]" freeze implemented by the Trump Administration on January 20, 2017 of all regulatory actions that were not "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).

By the time the ADR Rule was promulgated, more than three years had passed since the agency removed its 2016 NPRM from the Unified Agenda, no new NPRM had appeared in the Federal Register, and no other action had been taken by the agency with regard to ADR rulemaking. Additionally, approximately nine months earlier, in March 2020, a 340B-focused news publication reported the following statement from an HRSA official in response to an inquiry regarding the status of ADR rulemaking: "[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 … HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance." Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), *available at*

https://340breport.substack.com/p/your-340b-report-for-thursday-march-eae (last visited Mar. 9, 2021).

The final ADR Rule creates "a decision-making body within the Department that, acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision for a claim brought under the ADR process." 85 Fed. Reg. 80,644, codified at 42 C.F.R. § 10.3. Claims that can be brought under the ADR Rule are limited to: "(1) [c]laims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers; and (2) [c]laims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity (pursuant to section 340B(a)(5)(C) of the Act), that a covered entity may have violated the prohibitions against duplicate discounts or diversion." 42 C.F.R. § 10.3. Under the ADR Rule, "[a]ny covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with the HRSA …." 85 Fed. Reg. 80,644.

The ADR Rule provides that the HHS Secretary is to select at least six members to serve on an ADR Board, comprised of individuals selected in equal numbers from HRSA (an HHS component to which implementation of the 340B Program has been delegated), the Centers for Medicare and Medicaid Services ("CMS"), and HHS's Office of General Counsel ("OGC"), plus a non-voting member from HHS's Office of Pharmacy Affairs ("OPA"). *Id.* When a particular claim is presented, the HRSA Administrator selects three members from the Board—one member each from HRSA, CMS, and OGC—to

serve on a 340B ADR Panel. Once assigned to a panel, all panel members will be screened prior to reviewing the claim for "conflicts of interest" and a panel member may be removed "for cause" and replaced by another individual from the Board. *Id.* The ADR Rule contains no provision regarding the procedure for removing a Board member from the Board itself.

The ADR Rule acknowledges certain concerns raised by commenters in response to the 2016 MPRM, including drug manufacturers' concern that the use of panel members appointed by the HHS Secretary as opposed to administrative law judges could result in biased decisonmaking. In rejecting that suggestion, the ADR Rule states that the panels "are uniquely situated to handle the complexities of the 340B Program and related disputes" and that the diversity of experience among the members of each panel ensures "relevant expertise and experience in drug pricing or drug distribution" and "in handling complex litigation." *Id.* at 80,634–35. The ADR Rule further provides that the non-voting Board member from OPA "would not exercise undue influence over the three voting members." *Id.*

ADR proceedings are governed by the Federal Rules of Civil Procedure, including the procedural mechanisms established therein. *Id.* at 80,644–45; 42 C.F.R. § 10.23(b). ADR panels are provided significant discretion during the pendency of a claim to "permit a covered entity limited discovery,"[6] to require the "submission of additional information," to "[r]eview and evaluate documents and other information" as necessary,

[6] There is no correlating express provision permitting discovery by manufacturers.

and to "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," including through conducting an evidentiary hearing. *Id.* at 80,644–45; 42 C.F.R. § 10.20(c)(1), 10.22(a), 10.23(a). If a panel concludes that its instructions are not being followed, the panel has discretion to choose from an array of sanctions to impose, up to and including entry of judgment. 42 Fed. Reg. at 80,645. Finally, the ADR 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." *Id.* at 80,636.

Once an ADR Panel renders a decision, the panel "submit[s] the final agency decision to all parties and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities." *Id.* at 80,646; 42 C.F.R. § 10.24(e). Any dissatisfied party may seek judicial review under the APA. 42 Fed. Reg. at 80,641; 42 C.F.R. § 10.23(d). However, the ADR Rule provides that "[t]he form of judicial review for 340B ADR Panel decisions is beyond the scope of this final rule." 85 Fed. Reg. 80,642.

HHS's 2020 Advisory Opinion Regarding Contract Pharmacies

Approximately two weeks after HHS published its final ADR Rule, on December 30, 2020, HHS's General Counsel issued an Advisory Opinion providing "that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract

pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("2020 Advisory Opinion") at 1, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last visited March 9, 2021). The 2020 Advisory Opinion explains that "the core requirement of the 340B statute … is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities" and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Id.* at 2. The 2020 Advisory Opinion provides that HHS's interpretation is compelled by the statute itself, no rulemaking was required, and that no expansion of the 340B Program was effectuated because Congress did not permit drug manufacturers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. *Id.* at 2–4.

ADR Panel Petitions are Filed Against Plaintiffs

On January 12, 2021, the day before the ADR Rule went into effect, HRSA posted a new webpage about the ADR process and informed "[s]takeholders" that they could "begin submitting petitions." Exh. E; *see also* 42 C.F.R. § 10.21(a). Following this announcement, covered entities filed petitions against several drug manufacturers, including Lilly, challenging the manufacturers' restrictions on the sale of 340B drugs to covered entities utilizing contract pharmacies, relying on HHS's 2020 Advisory Opinion as their central authority. These petitions remain pending due to the 340B ADR

procedures, to our knowledge, still being finalized. It is not clear when the parties expect the ADR panels to be created and begin reviewing petitions.

The Instant Litigation and Motion for Preliminary Injunctive Relief

Plaintiffs filed their complaint in this action on January 12, 2021 challenging the General Counsel's December 2020 Advisory Opinion on various grounds under the APA.[7] On January 25, 2021, Plaintiffs amended their complaint to add new claims related to the ADR Rule, including that the Rule violates the Appointments Clause of Article II and impinges on the province of the courts under Article III of the United States Constitution and is both procedurally and substantively invalid under the APA. That same day, Plaintiffs filed the instant motion for preliminary injunction, seeking injunctive relief solely on their claims related to the ADR Rule. Accordingly, those are the only issues we shall address in this order.

Legal Analysis

I. Preliminary Injunction Standard

To obtain a preliminary injunction, the moving party must demonstrate: (1) a reasonable likelihood of success on the merits; (2) no adequate remedy at law; (3) irreparable harm absent the injunction. *Planned Parenthood of Ind., Inc. v. Comm'r of*

[7] Two other pharmaceutical manufacturers filed similar lawsuits the same day as Lilly filed this action. *See Sanofi-Aventis U.S., LLC v. United States Dep't of Health and Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J. Jan. 12, 2021); *AstraZeneca Pharm. LP v. Azar*, No. 1:21-cv-00027-LPS (D. Del. Jan. 12, 2021). Two additional, similar lawsuits were filed shortly thereafter. *See Novo Nordisk Inc. v. United States Dep't of Health and Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-00198-PWG (D. Md. Jan. 22, 2021).

Ind. State Dep't of Health, 699 F.3d 962, 972 (7th Cir. 2012). If the moving party fails to demonstrate any one of these three threshold requirements, the injunctive relief must be denied. *Girl Scouts of Manitou Council, Inc. v. Girl Scouts of the United States, Inc.*, 549 F.3d 1079, 1086 (7th Cir. 2008) (citing *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 11 (7th Cir. 1992)). At this stage of the analysis, "the court decides only whether the plaintiff has any likelihood of success—in other words, a greater than negligible chance of winning …." *AM Gen. Corp. v. DaimlerChrysler Corp.*, 311 F.3d 796, 804 (7th Cir. 2002).

If these threshold conditions are met, the Court must then assess the balance of the harm—the harm to Plaintiffs, if the injunction is not issued, against the harm to Defendants, if it is issued—and determine the effect of an injunction on the public interest. *Girl Scouts*, 549 F.3d at 1086. "The more likely it is that [the moving party] will win [their] case on the merits, the less the balance of harms need weigh in [their] favor." *Id.* at 1100.

II. Discussion

A. Likelihood of Success on the Merits

Plaintiffs have moved for injunctive relief preliminarily enjoining Defendants from implementing or enforcing against them the ADR Rule on grounds that they are likely to be successful on the merits of their claims that the Rule violates the Appointments Clause set forth in Article II and usurps the exclusive power of the judiciary in violation of Article III of the United States Constitution and/or that it is procedurally and substantively invalid under the APA. We turn first to address Plaintiffs'

claim that, because Defendants violated the notice-and-comment rulemaking requirements in promulgating the ADR Rule, the Rule is procedurally invalid under the APA.

When an agency such as HHS is required to undertake notice-and-comment rulemaking, the APA requires the agency to publish a notice of proposed rulemaking ("NPRM") in the Federal Register that includes "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The agency must then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). Pursuant to § 553 of the APA, an agency's rule is considered void when it is subject to notice-and-comment rulemaking and the agency fails to follow the APA's administrative requirements.

Here, the parties do not dispute that the ADR Rule was subject to the notice-and-comment requirements set forth in the APA; they dispute only whether HHS complied with those requirements. Accordingly, we turn to address whether Plaintiffs have shown a likelihood of success on the merits in establishing that HHS failed to comply with the APA's procedural requirements in promulgating the final ADR Rule. For the following reasons, we find that Plaintiffs have at this early stage of the litigation succeeded in making such a showing.

In 2010, following Congress's direction to HHS that it propose an ADR procedure to handle 340B drug disputes between drug manufacturers and covered entities, HHS issued an advanced notice of proposed rulemaking requesting comments on the

development of an ADR process. 75 Fed. Reg. 57,233 (Sept. 20, 2010). Six years later, in 2016, HHS issued an NPRM on the same topic and a comment period followed. 81 Fed. Reg. 53,381 (Aug. 12, 2016). It is undisputed that, up to this point, HHS's actions complied with the APA's notice-and-comment requirements. After the comment period ended, HHS removed the NPRM from the Unified Agenda of Regulatory and Deregulatory Actions ("Unified Agenda")[8] but never published a notice of withdrawal in the Federal Registry.[9] Specifically, the Unified Agenda entry for the NPRM on the Office of Management and Budget's website displays that it was "Withdrawn" as of August 1, 2017 and identifies the Agenda Stage of Rulemaking for the NPRM as a "Completed Action[],"[10] which is a term used to describe "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking."[11]

Over the ensuing approximately two and a half years, no further action was taken with regard to the NPRM. Then, in March 2020, the previously described 340B-focused news publication reported that, according to an official speaking on behalf of the HRSA, the HRSA had no plans to create a binding ADR process for 340B "until such time that

[8] The Unified Agenda provides "uniform reporting of data on regulatory and deregulatory activities under development" in the Executive Branch. *About the Unified Agenda*, REGINFO.GOV, *available at* https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA-_About.myjsp (last visited March 9, 2021).
[9] The Federal Register is a statutorily created periodical in which agencies must publish certain categories of documents. 44 U.S.C. § 1504 (designating the "Federal Register"); *id.* § 1505 (identifying documents to be published in the Federal Register).
[10] HHS/HSRA, *View Rule, RIN: 0906-AA90* (Spring 2017), *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last visited Mar. 9, 2021).
[11] HHS/HSRA, *About the Unified Agenda*, https://bit.ly/2OYh3FZ (last visited Mar. 9, 2021).

HRSA receive[d] regulatory authority for the issues that would be addressed" because "[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" and therefore "HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance." Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020).

Nine months after this statement appeared, and more than three years after the NPRM was removed from the Unified Agenda, HHS issued in December 2020 the final ADR Rule without providing any additional notice or comment period. 85 Fed. Reg. 80,632 (Dec. 14, 2020). The final Rule, in fact, was issued under a different Regulatory Identification Number ("RIN")[12] than the NPRM. *Compare id.* (RIN 0906-AB26) *with* 81 Fed. Reg. 53,381 (RIN 0906-AA90). Apparently anticipating some pushback by interested parties, the preamble to the ADR Rule included a statement that the NPRM was never withdrawn, but instead merely paused as part of a freeze of regulatory actions implemented by the Trump Administration on January 20, 2017.

Plaintiffs argue that the removal of the NPRM from the Unified Agenda, coupled with the representations made by the HRSA that rulemaking as to the ADR process had

[12] A RIN is an identification number included in the headings of Rule and Proposed Rule documents when published in the Federal Register "to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development." HHS/HRSA, *Frequently Asked Questions*, *available at* http://www.reginfo.gov/public/jsp/Utilities/faq.myjsp (last visited March 9, 2021).

been halted, effected a withdrawal of the NPRM requiring Defendants to engage in a second notice-and-comment period before promulgating a valid final ADR Rule, particularly given the significant revisions in the final rule, including that decisions reached by the ADR Panels will not only be binding on the parties, but precedential as well. Defendants rejoin that, because no notice of withdrawal was ever published in the Federal Register, the NPRM was never officially withdrawn, the agency was therefore free to move ahead to finalize the ADR Rule without additional notice and comment.

We have not found, nor have the parties pointed us to any case law, provision in the APA, or regulation of the Office of the Federal Register which requires notice of the withdrawal of an NPRM to be published in the Federal Register to be considered effective. While this may be the manner in which HHS has in some previous instances noticed a withdrawal to the public,[13] the APA imposes no such requirement, and "courts are not free to impose upon agencies specific procedural requirements that have no basis in the APA." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S.Ct. 2367, 2385 (2020) (quotation marks and citation omitted). Because the "object" of the APA is "fair notice," *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007), the relevant inquiry is whether, through their actions and statements, Defendants effectively communicated a withdrawal of the proposed rule to the public. Based on the record before us, we find that Plaintiffs have demonstrated a fair likelihood of

[13] Defendants cite several examples in which HHS has used the Federal Register to publish notice of withdrawals of other proposed rules when it intended to terminate rulemaking. *See, e.g.*, 78 Fed. Reg. 12,702-01 (Feb. 25, 2013); 79 Fed. Reg. 19,848-01 (Apr. 10, 2014); 83 Fed. Reg. 60,804-01 (Nov. 27, 2018); 84 Fed. Reg. 37,821-01 (Aug. 2, 2019).

establishing that the actions taken by the agency in this case indicated to regulated entities that the NPRM on the ADR process had been withdrawn and no rulemaking was being considered, despite the fact that no notice of withdrawal was published in the Federal Register. Lacking an opportunity to engage in the comment process, Lilly's rights and interests have been violated.

The primary fact Defendants reference in arguing that the NPRM was *not* withdrawn is that, following its removal from the Unified Agenda, no notice of withdrawal was published in the Federal Register. However, as discussed above, there is no evidence that such action is required to effectuate withdrawal. More importantly, all other indications from the agency, beginning with the Unified Agenda entry for the ADR Rule displaying that it was "withdrawn" on August 1, 2017, would have led a reasonable observer to believe the ADR Rule had in fact been withdrawn. More than two and a half years of agency silence regarding any pending ADR rulemaking followed the NPRM's removal from the Unified Agenda. Then, in March 2020, an HRSA official made a public statement indicating that, absent additional congressional authority, there were no plans to engage in rulemaking with regard to the ADR process, further confirming to a reasonable observer that the NPRM was withdrawn. Approximately nine more months of silence ensued before HHS's "surprise edict" in December 2020 that a final ADR Rule was being promulgated. Further buttressing the conclusion that the NPRM had been terminated is the fact that, when the final ADR Rule was promulgated, it was given a different RIN from the NPRM, which numbers are assigned to allow the public to track a rule's regulatory history.

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. Accordingly, we find that Plaintiffs have demonstrated a likelihood of establishing that a withdrawal of the NPRM was effected, thus requiring the agency to have engaged in notice-and-comment procedures before promulgating the final ADR Rule, which it failed to do.[14] Having found that Plaintiffs have established with a fair likelihood of success that Defendants violated notice-and-comment rulemaking requirements under the APA, we need not, and do not, at this time reach Plaintiffs' substantive APA and constitutional claims. We turn now to address the remaining requirements for injunctive relief.

B. Irreparable Harm and Inadequate Remedy at Law

In addition to showing that they have a likelihood of success on the merits of their claims, Plaintiffs are also required to show that, absent injunctive relief, they will suffer irreparable injury for which there is no adequate remedy at law. These requirements merge in most cases, in recognition of the fact that irreparable harm is "probably the most common method of demonstrating that there is no adequate legal remedy." 11A Charles A. Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* § 2944 (2d ed. 1995). "Irreparable harm is harm which cannot be repaired, retrieved, put down again, atoned for …. [T]he injury must be of a particular nature, so that compensation in money cannot atone for it." *Graham v. Med. Mut. of Ohio*, 130 F.3d 293, 296 (7th Cir.

[14] We note that Defendants have not argued that any of the exceptions to the APA's notice-and-comment requirements, such as good cause or harmless error, apply here.

1997) (quotation marks and citation omitted). To preclude a grant of equitable relief, "an available remedy at law must be plain, clear and certain, prompt or speedy, sufficient, full and complete, practical, efficient to the attainment of the ends of justice, and final." *Interstate Cigar Co. v. United States*, 928 F.2d 221, 223 (7th Cir. 1991) (quotation marks and citation omitted).

Here, Plaintiffs have shown a likelihood of establishing that their procedural right to advance notice and comment was violated, depriving them of the protections afforded to them under the APA. Courts recognize that parties suffer actionable harm when they are "depriv[ed] of a procedural protection to which [they are] entitled…." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002); *see also Itserve Alliance, Inc. v. Scalia*, No. 20-14606 (SRC), 2020 WL 7074391, at *9 (D.N.J. Dec. 3, 2020). Moreover, "many courts have found that a preliminary injunction may be issued solely on the grounds that a regulation was promulgated in a procedurally defective manner." *Itserve*, 2020 WL 7074391, at *11 (citing *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (affirming in relevant part the district court's grant of a preliminary injunction, which was issued because the government failed to comport with the notice and comment procedure); *Tenn. Hosp. Ass'n v. Azar*, 908 F.3d 1029, 1046–47 (6th Cir. 2018) (holding that, because the challenged regulation did not comply with the notice and comment rule, a permanent injunction was warranted until the agency put forth a procedurally valid rule); *Nat'l Fam. Plan & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 242 (D.C. Cir. 1992) (reinstating the district court's injunction after the Circuit Court ruled that the APA's notice and comment procedure was not followed); *Levesque v.*

Block, 723 F.2d 175, 177 (1st Cir. 1983) (affirming in relevant part the district court's injunction based on finding that the challenged regulation failed to comply with the notice and comment rule); *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17, 22 (D.D.C. 2009) (issuing a preliminary injunction on grounds that the plaintiff was likely to succeed on its claim that the agency did not have good cause to bypass the APA's notice and comment procedure)).

Given the scope of the regulatory process and the extensive, intrusive, and consequential impact of exercises of regulatory power, the APA's procedural protections are far from pro forma. Rather, they provide an essential pathway by which the interested public may inform the agency of the ways and extent any potential policy changes will impact those being regulated. The purpose of the notice and comment requirement is to permit regulated entities to influence rulemaking at the beginning of the process and not simply after rules are already in place, at which point the agency "is far less likely to be receptive to comments." *N. Mariana Islands*, 686 F. Supp. 2d at 18; *accord U.S. Steel Corp. v. U.S. EPA*, 595 F.2d 207, 214 (5th Cir. 1979) (observing that the notice-and-comment requirement is "designed to ensure that affected parties have an opportunity to participate in and influence agency decision making at an early stage, when the agency is more likely to give real consideration to alternative ideas."). Thus, if the ADR Rule were permitted to go into effect and was later determined to have been promulgated without an adequate, fair opportunity for advance notice and comment, Plaintiffs would be deprived of their right, under the APA, to provide meaningful input into the agency's decision at a time when it is most likely to be carefully considered, a

harm which the Court would be unable to fully remedy after the fact. For these reasons, we hold that Plaintiffs have succeeded in establishing that, in the absence of preliminary injunctive relief, they are likely to suffer irreparable injury for which there is no adequate remedy at law.

C. Balance of Harms and the Public Interest

Having concluded that, absent a preliminary injunction, Plaintiffs will suffer irreparable harm for which there is no adequate remedy at law, we turn to the balance of harms and the public interest. These factors merge when, as in this case, the government is the defendant. *See Niken v. Holder*, 556 U.S. 418, 435 (2009). Defendants argue that, having now implemented a binding ADR process as ordered by Congress, if a preliminary injunction were to issue, they would suffer the "inherent harm" courts recognize an agency suffers when it is prevented "from enforcing regulations that Congress found [to be] in the public interest to direct that agency to develop." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). This harm cannot tip the scales in Defendants' favor here, however, where it has been shown that the ADR Rule was likely promulgated in a procedurally invalid manner.

Defendants also argue, in line with the arguments set forth in the *amicus* brief filed by several covered entities, that the public interest strongly militates against delaying the agency's efforts to resolve the uncertainty regarding covered entities' use of contract pharmacies through the statutorily mandated administrative process intended for such disputes. *See Spencer v. Dist. of Columbia*, 416 F. Supp. 2d 5, 13 (D.D.C. 2006) (denying request for injunction when administrative process was available and injunction

"would represent a major disruption of a carefully crafted legislative scheme"). Specifically, the *amici* argue that, as covered entities, they and their patients are being irreparably harmed by Lilly's and other drug manufacturers' restrictions on providing 340B discounts to covered entities that use multiple contract pharmacies to distribute 340B drugs, and that the public interest is not served by a preliminary injunction that will prolong that irreparable harm by cutting off the only form of recourse available, to wit, the ADR process.

While we recognize and appreciate the arguments set forth in the *amicus* brief addressing the ways in which Lilly's and other drug manufacturers' policies regarding contract pharmacies are impacting the covered entities and their patients, regardless of whether we grant or deny Plaintiffs' motion for preliminary injunctive relief, that harm will not be lessened. Rather, the only impact an award of preliminary injunctive relief will have on the covered entities will be to delay their ability to pursue an ADR petition against Lilly until a procedurally valid rule is promulgated, which we assume HHS will want to undertake expeditiously in order to reduce or alleviate any harm from further delay, noting however that the entirety of this process has been conducted with little regard to an efficient timetable. However, while petitions have been filed, again to our knowledge, the ADR process is still being finalized and we have been given no indication as to when the ADR Board will be named and ADR Panels will be assigned and begin the process of reviewing petitions. In these circumstances, where granting a preliminary injunction will put on hold a process that is not even currently operational, we find that the balance of harms and the public interest factors weigh in favor of Plaintiffs.

D. Bond

Finally, "Rule 65(c) makes the effectiveness of a preliminary injunction contingent on [a] bond having been posted." *BankDirect Capital Fin., LLC v. Capital Premium Fin., Inc.*, 912 F.3d 1054, 1057 (7th Cir. 2019). However, the Seventh Circuit recognizes that "[u]nder appropriate circumstances bond may be excused, notwithstanding the literal language of Rule 65(c)." *Wayne Chem. Inc. v. Columbus Agency Serv. Corp.*, 567 F.2d 692, 701 (7th Cir. 1977) (citations omitted). Given that Defendants are not facing any monetary injury as a result of the issuance of the preliminary injunction, we hold that, due to the nature and effect of the preliminary injunction, no bond is required here. *See Habitat Educ. Ctr. v. United States Forest Serv.*, 607 F.3d 453, 458 (7th Cir. 2010) (recognizing there is no reason to require a bond in cases in which "the court is satisfied that there's no danger that the opposing party will incur any damages from the injunction"). The parties have not argued otherwise.

III. Conclusion

For the reasons detailed above, we GRANT Plaintiffs' Motion for Preliminary Injunction [Dkt. 18]. Defendants, as well as their officers, agents, employees, attorneys, and all persons in active concert or participation with them, are hereby PRELIMINARILY ENJOINED until further order of this Court from implementing or enforcing against Plaintiffs the Administrative Dispute Resolution Regulations published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§ 10.20–24. Consistent with the Seventh Circuit's holding in *MillerCoors LLC v. Anheuser-Busch Companies, LLC*, Nos.

19-2200, 19-2713 & 19-2782, 2019 WL 5280872, at *1 (7th Cir. Oct. 18, 2019), this injunction shall be set forth in a separate Order without reference to any other document.

IT IS SO ORDERED.

Date: 3/16/2021

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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