IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 3:21-CV-634

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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

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

Sanofi's ultimate goal in this suit is manifestly clear in its complaint: It seeks to have this Court sanction Sanofi's rewrite of its statutory obligations in a way that would drastically restrict many providers' access to 340B-discounted drugs (and, in so doing, boost Sanofi's profits). In this emergency motion, however, Sanofi seeks to advance that goal by blocking implementation of a new rule that establishes a straightforward, statutorily mandated administrative dispute-resolution

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

There is no cause for this Court to do so. As demonstrated herein, Sanofi is unlikely to succeed on the merits of its challenge to the rule: decision-makers are supervised by, and can be removed at will by, the HHS Secretary, and thus constitute inferior officers; Sanofi's Article III challenge rests on false premises regarding the ADR Board's powers and the claims it may hear; and Sanofi faces no irreparable harm in "being haled before" the dispute-resolution mechanism Congress envisioned. Moreover, the public interest firmly lies in allowing the agency charged with oversight of the 340B Program to resolve, in the first instance, whether the recent manufacturer restrictions are lawful, thereby providing clarity for both covered entities and drug makers. Sanofi's emergency motion should be denied.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of Health and Human Services ("HHS"), through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report), and also may benefit uninsured and underinsured patients, when covered entities opt to pass along the discounts by helping patients afford costly medications. Congress expressly conditioned drug manufacturers' access to an incredibly valuable federal benefit—coverage of their products under

Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). Pharmaceutical companies thus may opt out of providing discounted drugs to safety-net healthcare providers and their low-income patients, but then lose access to "a significant portion of manufacturers' annual revenues" through drug coverage in federal health-insurance programs. *See* Am. Compl. ("Compl.") at ¶ 24, ECF No. 17.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

dysfunction. *See Eli Lilly v. HHS*, No. 21-cv-81 (S.D. Ind.), Compl. ¶ 78. But that relatively modest restriction opened the floodgates to further disruptions of the 340B Program: Only one month later, Eli Lilly extended its new contract-pharmacy restrictions to *all* its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Ex. G, and other pharmaceutical companies promptly following suit. For its part, Sanofi announced that it would begin *requiring* covered entities to register through a third-party platform and provide detailed claims data on patients' prescriptions in order to continue purchasing its drugs for shipment to contract pharmacies, purportedly to allow Sanofi to police instances of duplicate discounts. *See* Compl. Ex. 1. Not only did Sanofi not seek involvement, approval, or review of its new restriction by HHS, it wrote to then-HHS Secretary Azar confirming that "covered entities will need to register with [its third-party platform] and submit claims-level-detail on all 340B contract pharmacy utilization *in order to be eligible for* 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy." *Id.* Ex. 2 at 2-3 (emphasis added). Sanofi's letter confirmed its intent of targeting prescriptions written by covered entities but filled at outside dispensers, informing the agency that, "if a covered entity refuses to provide the claims data described above, *we will restrict the entity's use of contract pharmacy arrangements*," although the limited number of safety-net providers with the means to operate their own, in-house pharmacy "will remain eligible to purchase at 340B prices for shipment to their own facilities." *Id.* at 3 (emphasis added).

Although HRSA published on its official 340B website Eli Lilly's original notice restricting access to Cialis, HRSA refused to post that drug maker's later notice expanding the 340B restrictions or those of other companies, including Sanofi. HRSA then told an industry reporter that the agency "is considering whether manufacturer policies … violate the 340B statute and whether sanctions may apply," including, "but not limited to, civil monetary penalties."[1] HRSA further warned that

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

"manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies"; the agency thus "continues to strongly encourage all manufacturers to sell 340B priced drugs … directly and through contract pharmacy arrangements."

After Eli Lilly and Sanofi acted, other large, global pharmaceutical companies imposed their own unilateral restrictions on covered entities' access to discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, and Novartis and Novo Nordisk imposed their own, separate restrictions soon thereafter. *See AstraZeneca Pharmaceuticals v. Azar*, No. 21-cv-27-LPS, ECF No. 13, Am. Compl. Exs. A, C (D. Del.); Novartis 340B Policy Changes, https://www.novartis.us/news/statements/new-policy-related-340b-program; *Novo Nordisk v. Azar*, No. 21-cv-806-FLW-LHG, ECF No. 1, Compl. ¶¶ 56-58 (D.N.J.).

As public outcry grew, a bipartisan group of Attorneys General representing 28 states plus the District of Columbia wrote a strongly worded letter urging the Secretary "to address drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities, such as community health centers," "by making immediate determinations that manufacturers' actions violate the terms of their participation in the Medicare Part B and Medicaid Programs," Compl. Ex. 9. The Attorneys General explained that, "[e]ach day that drug manufacturers violate their statutory obligations, vulnerable patients and their healthcare centers are deprived of the essential healthcare resources that Congress intended to provide" and that the companies "are, without justification, flouting discounted pricing requirements for low-income patients and/or unreasonably conditioning 340B pricing on data demands"—moves the authors characterized as "especially egregious" "[d]uring a national public health crisis." *Id.* A bipartisan group of 246 U.S. Representatives sent a similar letter, explaining that 340B always has had "strong bipartisan support," that "no provisions in the statute [] allow manufacturers to set conditions or otherwise impede a provider's ability" to purchase discounted drugs, and that the manufacturers' restrictions "are in violation of the statutory requirements" and

"establish a dangerous precedent."[2] Sanofi has since relented slightly; effective March 2021, Sanofi will permit covered entities lacking an in-house pharmacy to access 340B pricing through a single, designated contract pharmacy even if they decline to provide detailed claims data on each prescription, or through multiple pharmacies if they comply with Sanofi's informational demands. Notice of Mot. for Prelim. Inj. 8, ECF No. 19 ("Mot.").

The pharmaceutical manufacturers' abruptly announced, unilateral restrictions on 340B access caused upheaval due to covered entities' longstanding reliance on contract-pharmacy arrangements, prompting various safety-net providers to urge HHS to take action by filing emergency motions *against the agency* seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO and Prelim. Inj., *Ryan White Health Clinics for 340B Access v. Azar*, No. 20-cv-2906-KBJ (D.D.C. Nov. 23, 2020)), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020), ECF No. 7. HHS moved to dismiss those suits for lack of jurisdiction while confirming that its investigation of the manufacturers' actions is ongoing. Just last week, one court granted HHS's motion to dismiss, confirming that the legality of drug makers' new 340B restrictions must be decided, in the first instance, by the agency. "Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process" and, though "[t]he judiciary has a prescribed role in this process," "its role comes *only after* the parties have participated in this ADR process." *See Am. Hosp. Ass'n v. Dep't of Health & Human Servs.,* No. 4:20-cv-08806-YGR, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) (refusing to "short-circuit the foundational regime that Congress has enacted in the 340B Program").

In response to the growing public outcry, HHS's General Counsel issued an Advisory Opinion on December 30, 2020, confirming his view—in accord with the agency's longstanding guidance—"that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to

[2] Letter to Sec. Azar, *available at* https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf .

charge the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("AO") at 1.[3] The AO explained that the 340B statute requires manufacturers, in exchange for access to Medicaid and Medicare Part B, to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the distribution or dispensing arrangements selected by the covered entity. *Id.* at 2. And contract-pharmacy arrangements unequivocally involve purchase by a covered entity, the General Counsel explained, regardless whether "[t]he situs of delivery[] be [] the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Id.* at 3. Moreover, the opinion continues, covered entities have relied on contract pharmacies for decades—and that system is wholly compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," *i.e.*, "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. A restriction limiting 340B discounts in the manner now imposed by drug makers would produce "a bizarre result," "inconsistent with the purpose of the Program and common sense." *Id.* The General Counsel confirmed that this interpretation is compelled by the statute itself; no rulemaking is required, and no expansion of the 340B Program has been effectuated, because Congress did not permit drug makers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. AO at 2-4.

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

The pharmaceutical companies' concerted actions to upend the 340B status quo have continued in litigation. Three drug makers, including Sanofi, filed suit on the same day challenging the General Counsel's Advisory Opinion. *Sanofi*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), ECF No. 1; *Eli Lilly*, No. 1:21-cv-81-SEB-MJD (Jan. 12, 2021), ECF No. 1; *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1. Motions for extraordinary injunctive relief are now pending in all

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

three actions. *Sanofi-Aventis*, ECF No. 19; *Lilly*, ECF No. 18; *AstraZeneca*, ECF No 14. Two additional, similar suits were filed shortly thereafter. *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

As for this action, notwithstanding the advisory nature of the General Counsel's opinion and the fact that it reiterated guidance the agency long ago had issued (and with which Sanofi had complied, without challenge, for ten years), Sanofi now asks this Court to declare the advice unlawful and to bless Sanofi's intention not "*to provide discounted covered outpatient drugs to contract pharmacies*." Compl., Prayer for Relief No. 4, ECF No. 1 (emphasis added). In other words, Sanofi asks this Court to sanction a substantially more-sweeping change to the 340B Program than the disruptive restrictions Sanofi and its peers already have imposed.

Three weeks after filing this suit, Sanofi amended its complaint to add new claims related to the ADR Rule issued last December. *See* Am. Compl., ECF No. 17. That same day, Sanofi filed a motion for extraordinary injunctive relief, challenging the Rule on constitutional grounds. Sanofi contends that the ADR Board violates the Constitution's Appointments Clause and that it unlawfully impinges on the province of Article III courts. *See* Mot. 17-27.

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary and drastic remedy." *Munaf v. Geren*, 553 U.S. 674, 689 (2008) (citation omitted). It is "never awarded as of right," *id.* at 690, and "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion," *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted). To obtain a preliminary injunction, the plaintiff must first "show both a likelihood of success on the merits and a probability of irreparable harm." *Ass'n of N.J. Rifle & Pistol Clubs Inc. v. Att'y Gen. N.J.*, 974 F.3d 237, 245 (3d Cir. 2020) (internal quotation marks and citation omitted). A failure to demonstrate either element "must necessarily result in the denial of a preliminary injunction." *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989) (citation omitted). However, if these two "gateway factors are met," *Reilly v. City of Harrisburg*, 858 F.3d

173, 179 (3d Cir. 2017), a court should then "consider the effect of the issuance of a preliminary injunction on other interested persons and the public interest," *Ass'n of N.J. Rifle & Pistol Clubs Inc.*, 974 F.3d at 245 (citation omitted). It is in the court's "sound discretion" to determine whether "all four factors, taken together, balance in favor of granting the requested preliminary relief." *Reilly*, 858 F.3d at 179.

ARGUMENT

Sanofi and its peers are engaged in a brazen attempt to effect a unilateral sea change in the settled operation of the 340B Program. Congress devised the program to provide affordable medications and much-needed revenue to vulnerable patients and safety-net healthcare providers, and expressly conditioned a valuable federal benefit, coverage of drug manufacturers' products in the nation's largest health-insurance programs, on the companies' agreement to provide deep discounts on *purchases by* covered entities. Now a cohort of highly profitable, massive pharmaceutical companies seek to litigate out of the obligation to comply with their end of the bargain, by creating from whole cloth novel restrictions on covered entities' access to 340B discounts, including limitations on the delivery site or dispensing mechanism employed by the covered entity, and onerous reporting requirements with no basis in statute or regulation. These abruptly imposed restrictions have caused upheaval by severely curtailing access to the discounts to which covered entities are entitled. Any doubt as to Sanofi's intent is dispelled by its request that the Court declare "that Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies"—a request which ignores the covered entities' twenty-five-year reliance on contract-pharmacy agreements *and* fundamentally mischaracterizes the transactions at issue by pretending it is the pharmacies, not covered entities, that purchase Sanofi's discounted drugs.[4]

Regardless, neither the legality nor the wisdom of contract-pharmacy arrangements is now before the Court. In its motion Sanofi instead seeks to block implementation of a straightforward administrative dispute-resolution mechanism, mandated by Congress and modeled after numerous

[4] *See* Compl., Prayer for Relief No. 4.

existing agency systems, that Sanofi fears will issue an adverse decision on its unilaterally imposed contract-pharmacy restrictions. There is no cause for this Court to do so because Sanofi's constitutional challenges fundamentally misrepresent the Rule and the powers it grants to Board members. Moreover, Sanofi faces no irreparable harm in being "haled before" the dispute-resolution mechanism Congress mandated, and cannot overcome the fact that the public interest firmly lies in allowing HHS to resolve, in the first instance, whether Sanofi's contract-pharmacy restrictions are lawful.

I. SANOFI CANNOT SUCCEED ON THE MERITS

A. ADR Board Members Are Inferior Officers

Sanofi's argument that the ADR Rule creates principal officers in contravention of the Appointments Clause, U.S. Const. art. II, § 2, cl. 2, contorts the Rule's plain language and ignores precedent holding that similar schemes create inferior, not principal, officers. Sanofi insists that the ADR Board operates without "oversight or review by any superior Executive Branch officer," with members who "are not even removable except for cause," Mot. 21, 23, but neither premise finds support in the plain text of the Rule. Although the Rule does not create an internal agency appeals process, there are no restrictions on the Secretary's oversight and supervision of the Board. The Secretary appoints ADR Board members and delegates to them responsibility for issuing final decisions, and the Secretary retains the ability to revoke that delegation at any time, to issue binding regulations that constrain the Board members, and may remove a Board member at will, at any time. Under established precedent, Board members thus serve as inferior officers who may be appointed by the Secretary.

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

Although the Supreme Court has "not set forth an exclusive criterion for distinguishing between principal and inferior officers," it has explained that, "[g]enerally speaking, the term 'inferior officer' connotes a relationship with some higher ranking officer or officers below the President: Whether one is an 'inferior' officer depends on *whether he has a superior*." *Edmond v. United States*, 520 U.S. 651, 661-62 (1997) (emphasis added). The focus is not merely on whether the officer has some "superior" who "formally maintain[s] a higher rank," but on whether the officer is one "whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.* at 662-63. *Edmond* involved a challenge to military judges of the Coast Guard Court of Criminal Appeals—officers that exercised significant discretion and responsibility, including the authority to resolve constitutional challenges, review death sentences, and independently weigh evidence to determine guilt and sentence. *Id.* at 662. In deeming the judges inferior officers, the Court emphasized that "the line between principal and inferior officers" turns on supervision by a higher authority, not on the "exercise of significant authority," which is the hallmark of *any* officer. *Id.* at 662-66. And because a higher authority could remove a military judge "without cause"—"a powerful tool for control"—and also "exercise[] administrative oversight," including the ability to "prescribe uniform rules of procedure" and "formulate policies and procedure," the judges were subject to sufficient supervision to qualify as inferior officers. *Id.* at 664. This conclusion was not altered by the fact that the supervising principal officer "may not attempt to influence (by threat of removal or otherwise) the outcome of individual proceedings." *Id.*[5]

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

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

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

Applying these principles, the Third Circuit held that members of HHS's Appeals Board, which were empowered to review "*a ruling by the Secretary of HHS*," constituted inferior officers properly appointed by the Secretary. *Commonwealth of Pennsylvania v. HHS*, 80 F.3d 796, 798 (3rd Cir. 1996) (emphasis added). The Appeals Board at issue in *Pennsylvania* had been created by the Secretary through regulation (and later granted additional authority by Congress through statute) to resolve disputes between the Secretary and states arising under a complicated regulatory scheme related to child support. *Id.* at 800. Board members were appointed by the Secretary, and Board rulings constituted final agency action reviewable only in district court. *Id.* at 800-01. Pennsylvania argued board members must be principal officers in light of: (1) the broad "scope of the Board members' authority"; (2) the Board's statutory jurisdiction, which placed "much of the Board's jurisdiction … beyond the reach of the Secretary"; and (3) that "Board members will serve indefinitely unless removed for misconduct." *Id.* at 802. The Third Circuit agreed with the government that Board members were inferior, not principal, officers because the Board was bound by the Secretary's regulations, "*i.e.*, it applies, rather than makes, agency policy"; because its review was restricted to certain categories of disputes "limited by regulation"; because the Secretary could remove board members; and because the Secretary "retains discretion to terminate or reassign all but a few of the Appeals Board's functions." *Id.* at 803. "[P]erhaps most significantly," the court continued, "the Secretary could altogether eliminate the powers of the Board that are at issue here." *Id.*; *see also id.* at 804 (confirming "it is difficult to imagine how Appeals Board members could be principal officers" under controlling Supreme Court

authorities). Importantly, this conclusion was in no way displaced by the fact that Appeals Board rulings were reviewable only in district court under the APA.

Pennsylvania is far from unique; persuasive appellate authorities have reached similar conclusions, and demonstrate the different ways in which an inferior officer's work may be "directed and supervised at some level," *Edmond*, 520 U.S. at 662-63, by superior officers. For example, the D.C. Circuit held that the judges of the Copyright Royalty Board are inferior officers, so long as they have no statutory restrictions on removal, even though their decisions are not "directly reversible" by any other Executive Branch officer. *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1338-41 (D.C. Cir. 2012). After severing a statutory removal restriction, the court explained: "With unfettered removal power, the Librarian [of Congress] will have the direct ability to 'direct,' 'supervise,' and exert some 'control' over the Judges' decisions"—even though individual decisions "will still not be directly reversible" by any higher official. *Id.* at 1341. As with *Edmond*, although the judges exercised "broad discretion" to decide the cases before them, a principal officer provided general supervision through the ability to approve the judges' procedural regulations, issue ethical rules, and "oversee[] various logistical aspects of their duties," including the provision of administrative resources. *Id.* at 1338. Yet even absent any mechanism for the supervising principal officer "to play an influential role in the [judges'] substantive decisions," and that the judges "issue decisions that are final for the executive branch, subject to reversal or change only when challenged in an Article III court," the court of appeals was "confident that … the [judges] will be inferior rather than principal officers" absent any statutory removal restriction. *Id.* at 1338, 1340, 1341.

Indeed, the D.C. Circuit reaffirmed *Intercollegiate Broadcasting* just this month, and specifically rejected the argument that "an inferior officer's decisions must be subject to review by a principal officer." *Fleming v. USDA*, No. 17-1246, slip op. at 18-19 (D.C. Cir. Feb. 16, 2021). In light of "substantial oversight by the Secretary," including through promulgation of "procedural and substantive regulations," the court had "little difficulty classifying the Department[of Agriculture's] ALJs as inferior officers." *Id.*

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

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

Sanofi's arguments to the contrary are *irreconcilable* with binding circuit precedent. The Appeals Board members at issue in *Pennsylvania* operated with significantly greater independence than ADR

Board members here—indeed, they reviewed *decisions of the Secretary*—and, as here, issued binding decisions reviewable only in district court, yet the Third Circuit found it "difficult to imagine" they could be anything other than inferior officers. 80 F.3d at 798, 804. Sanofi attempts to skirt this conclusion by referencing *Pennsylvania* with a "cf." citation and plucking language from context. Mot. 21-22 (referencing statement that Appeals Board "powers were 'strictly limited by the statute and implementing regulations'" and "were subject to oversight of a Senate-confirmed official"). But that begrudging acknowledgement of controlling authority ignores the Third Circuit's reasoning: The Board's powers were "limited" in that it could review only certain types of cases and was required to "appl[y], rather than make[], agency policy," 80 F.3d at 803, and the "oversight" related to the Secretary's removal power and ability to withdraw some of the board's delegated authority. Those factors are equally present here, *except* that the Secretary may remove ADR Board members at will, rather than only for-cause.

Rather than provide any cogent response, Sanofi misconstrues the Rule and misapplies both the supervision and removal prongs of the Appointments Clause analysis. As to supervision, Sanofi ignores all the relevant, powerful tools for control that the Secretary may exercise, instead insisting that "ADR panelists are principal officers because their decisions are not subject to oversight or review by any superior Executive Branch officer." Mot. 21. That assertion lacks merit for numerous reasons: the Supreme Court has never held that an inferior adjudicative officer's decisions *must* be reviewed, individually, by a principal officer; the Court's reasoning in *Edmond* and *Free Enterprise Fund* emphasizes other means of "supervision" than direct review of an officer's decisions; and the Third Circuit in *Pennsylvania* confirmed that a similar adjudicatory board within HHS was comprised of inferior officers even though its decisions also were not subject to direct review by a superior officer. And outside this circuit, persuasive, directly on-point appellate authorities squarely have rejected Sanofi's contention. For example, the lack of direct, intra-agency review was true of the judges in *Intercollegiate Broadcasting* too, yet the court of appeals was "confident" in deeming them inferior officers. 684 F.3d at 1341. At

bottom, the absence of an internal review mechanism does not prevent the Secretary from supervising Board members—nor does it render them principal officers.[6]

Sanofi's argument as to the removal prong rests on a flatly false premise. Sanofi wholly ignores the fact that the Rule does not purport to place *any* restrictions on Board members' removal, yet nonetheless argues that for-cause removal protection renders them principal officers. Mot. 22-23. But no protection from removal applies; the statute contains no restriction on the Secretary's removal of Board members, 42 U.S.C. § 256b(d)(3)(A)-(B), and the regulation likewise does not suggest any restriction on the Secretary's ability to remove members at will (and a regulatory for-cause provision would *have no impact* on the Secretary's power regardless, *In re Grand Jury*, *supra*). Sanofi's insistence that Board members "answer to no superior Executive Branch officer but the President," Mot. 21, contravenes "[t]he general and long-standing rule [] that, in the face of statutory silence, the power of removal presumptively is incident to the power of appointment." *Kalaris v. Donovan*, 697 F.2d 376, 389 (D.C. Cir. 1983); *see also Free Enterprise Fund*, 561 U.S. at 509 ("Under the traditional default rule, removal is incident to the power of appointment.").

Sanofi attempts to elide this lack of constraint by pointing to a provision delegating *to the HRSA Administrator* the power to remove a member from a particular panel "for cause," including for a conflict of interest. Mot. 22-23; 42 C.F.R. § 10.20(a)(1)(ii), (2). In other words, Sanofi engages in subterfuge by discussing only the circumstances in which a panelist is removed *from a particular assignment* for cause, including conflicts, and falsely equating that standard with removal *from the Board* altogether—*i.e.*, the relevant consideration for constitutional purposes. This attempt fails; the

[6] Sanofi's reliance on *Association of American Railroads v. U.S. Department of Transportation* is misplaced. 821 F.3d 19 (D.C. Cir. 2016). The arbitrators in question there were not deemed principal officers solely because their decisions lacked secondary review before constituting final agency action. Mot. 21. Rather, "[n]owhere d[id] [the statute] suggest the arbitrator 'is directed and supervised at some level by others'"; indeed, the arbitrators lacked *any* supervision, whatsoever, by any official. *Id.* at 39 (citation omitted). That level of independence is fundamentally different from the ADR Rule, which leaves Board members subject to supervision by the Secretary in numerous ways, discussed above. Moreover, it is telling that Sanofi places heavy reliance on the D.C. Circuit's opinion in *Association of American Railroads* while wholly ignoring that circuit's holding in *Intercollegiate Broadcasting* that an agency adjudicator's decisions *need not* be subject to internal review to establish the "supervision" required of inferior officers.

delegation of partial authority to take ADR Board members from a particular panel merely allows the HRSA Administrator to share in the supervision of the ADR process; it in no way constrains the Secretary's ability to remove an individual from a panel, or from the Board, at will—with or without a conflict of interest.[7] Tellingly, every mention of removal in Sanofi's brief references *panel assignments*, not the entirely distinct issue of removal *from the Board*. Mot. 2, 11, 12, 17, 22, 23. Put simply, ADR Board members do not operate "subject to no [] control," Mot. 22, because the Secretary may rescind his delegation of authority at any time by removing a Board member for any reason. This "powerful tool for control," *Edmond*, 520 U.S. at 664, demonstrates that members serve as inferior officers.

Nor does the statutory directive that the "decision-making official or decision-making body" selected by the Secretary "be responsible for reviewing and finally resolving claims," 42 U.S.C. § 256b(d)(3)(B)(i), mean that "the Secretary cannot abridge their authority," as Sanofi posits. Mot. 22. That reference to finality dovetails with the adjacent directive that "[t]he administrative resolution of a claim or claims … 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). In other words, the statute sets out a straightforward delegation for the new dispute-resolution mechanism to issue final agency actions, subject to review under the APA, as is quite common among agency adjudicatory bodies. *See infra* § I.B. There is no support for Sanofi's contention that this places Board members outside the Secretary's "control" or prevents him from "abridg[ing] their authority." Mot. 22. The statute merely requires the Secretary to designate *some* entity with authority to resolve claims. The Secretary still can revise the regulation (and with it the Board's structure, procedure, or operating guidelines) or rescind it altogether and, at his discretion, create a new ADR process or designate *himself* the "decision-making official … within the Department … to be responsible for reviewing and finally resolving claims." 42 U.S.C. § 256b(d)(3)(B)(i).

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

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

Sanofi's challenge fails because Board members are inferior officers whose work is "directed and supervised at some level" by the Secretary, a principal officer appointed by the President with Senate confirmation. *Edmond*, 520 U.S. at 663. Like the Appeals Board members in *Pennsylvania*, 80 F.3d at 801-04, ADR Board members issue final agency decisions subject to APA review in district court, yet remain subject to the Secretary's general supervision. Like the officers in *Intercollegiate Broadcasting*, 684 F.3d at 1341, and *Free Enterprise Fund*, 561 U.S. at 510, Board members are freely removable at will. Like the Special Counsel in *In re Grand Jury Investigation*, 916 F.3d at 1052-53, the Secretary could revoke or modify the ADR Rule—and thus the members' authorizing regulations—at any time. And like the inferior officers in *Edmond*, 520 U.S. at 664, Board members must follow their superior's rules of procedure and substantive policy, and members may be removed from any particular assignment. The Secretary retains plenary authority to revise the Rule and, in so doing, modify the workings of the Board. Board members thus have received a proper appointment as inferior officers from the Secretary of HHS as the Head of a Department.

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

As with its Article II challenge, Sanofi's Article III argument rests on a wildly inaccurate portrayal of the Board's remedial powers and of the claims it is empowered to hear. Far from

empowering "unaccountable bureaucrats [to] resolve private disputes" in a "faux judicial process," Mot. 1, the ADR Rule creates a straightforward mechanism for the agency to determine compliance with a statutory scheme Congress entrusted to HHS—precisely the type of administrative adjudication that courts have blessed for much of the past century. The Rule creates no Article III concerns.

As an initial matter, Sanofi falsely claims that the Board is empowered to "issue final judgments for … equitable relief in order to resolve disputes between private parties over … the price of a drug." Mot. 3. This assertion is nonsensical because, under the 340B statute, the price of Sanofi's medications when purchased by a covered entity is mandated by statute, and Sanofi must comply with its obligation to fulfill orders *placed by covered entities* at no more than that ceiling price if it wishes to retain access to Medicaid and Medicare Part B. The Board determines compliance by both covered entities and manufacturers with statutory requirements—it does not set prices or command the conveyance of private property.

Moreover, the ADR Rule facially disproves Sanofi's argument as to the Board's powers. *See* Mot. 23 (claiming that panels may "enter[] injunctive relief commanding the conveyance of property and awarding money damages"). Although ADR Panels are empowered to issue a final agency decision, those decisions are *not* self-effectuating. Panel decisions must be "submit[ted] … to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e). Indeed, in response to comments, some of which expressed "concern[]" that the proposed rule *lacked* a specific enforcement mechanism, the agency rejected calls for more-specific provisions by explaining that ADR panels "may make recommendations to HRSA for sanctions, including referrals to the HHS Office of Inspector General for its consideration of civil monetary penalties," and that the absence of specific enforcement mechanisms in the Rule is designed "to permit HHS maximum flexibility in determining what is appropriate" when a panel determines a violation has occurred. *See* 85 Fed. Reg. at 80,642. Sanofi's clamoring that the Rule "empower[s] ADR panels to require manufacturers like Sanofi to transfer their property to contract pharmacies … and giv[es] those panels *the power to enforce their decisions* through orders conveying money damages and prescribing injunctive relief," Mot. 27 (emphasis added), ignores the Rule's plain text requiring panels

to submit decisions *to HRSA* "for appropriate action," 42 C.F.R. § 10.24(e), not to mention the absence of *any* "power to enforce their decisions," Mot. 27.

Sanofi's complaints about potential "equitable relief" further misconstrue the Rule; contrary to its portrayal, *e.g.*, Mot. 26, the Rule does not purport to authorize panels to issue sweeping injunctions. Rather, the "equitable relief" referred to in the Rule establishes a jurisdictional floor on the claims heard by a panel, to exclude *de minimis* claims. 42 C.F.R. § 10.21 (a), (b) (granting jurisdiction "to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000" within twelve months); 85 Fed. Reg. at 80,633 (explaining that provision is designed to exclude *de minimis* claims). Read in context, the "equitable relief" contemplated in the Rule means an order determining whether a manufacturer or covered entity has violated the statute—not a self-executing, judicial-style remedy. The 340B statute clearly contemplates that the new ADR process will resolve questions of program compliance, and that is all the Rule purports to authorize, since panel decisions must be referred to HRSA for enforcement. Nowhere does the Rule allow panels to grant a sweeping "injunction," under penalty of contempt, as can be issued by an Article III court. Rather, the "equitable relief" issued by a panel would declare specified conduct to be unlawful—the equivalent of a cease-and-desist order, which can be obeyed or appealed—not a self-executing injunction.

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

reinstatement, with back pay, and Commodity Futures Trading Commission can order fines "of the higher of $100,000 or the gain of the wrongdoer" plus restitution).

Sanofi's complaints about the ADR Board's authority to conduct proceedings are easily dispatched. Sanofi urges this Court to find an Article III problem based on panels' "authority to issue money judgments, to impose sanctions, to issue equitable remedies, including injunctions compelling the disposition of property, to take evidence and hear testimony, and to issue precedential and binding decisions." Mot. 26. Again, the assertions regarding remedies are false. And the adoption of court-like procedures makes no difference, because the Supreme "Court has never adopted a 'looks-like' test to determine if an adjudication has improperly occurred outside of an Article III court," since "[t]he fact that an agency uses court-like procedures does not necessarily mean it is exercising the judicial power." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1378 (2018) (rejecting argument that non-judicial patent adjudication "violates Article III because it shares 'every salient characteristic associated with the exercise of the judicial power," including "motion practice …; discovery, depositions, and cross-examination of witnesses; introduction of evidence and objections based on the Federal Rules of Evidence; and an adversarial hearing before the Board") (citation omitted). In short, the procedures adopted by the ADR Rule mirror those found, and upheld, in other agency adjudications.

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

offended by adjudication of public rights outside the judiciary because, when Congress creates new rights (such as through a novel, comprehensive regulatory scheme), it has broad latitude to grant jurisdiction to federal courts or assign adjudication in another branch.

Public rights capable of resolution before an administrative agency are not limited, as Sanofi contends, to rights collectively "held by the entire community or involving disputes between the government and a private party." Mot. 24. On the contrary, the Supreme Court long ago "rejected the limitation of the public rights exception to actions involving the Government as a party," instead explaining that it encompasses "cases in which the claim at issue derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority." *Stern*, 564 U.S. at 490-91 ("[W]hat makes a right 'public' rather than private is that the right is integrally related to particular Federal Government action."). Thus it matters not that the dispute may arise between private parties; it is the character of the *right* at issue—one specially created by Congress—that renders it amenable to non-judicial resolution. In fact, the argument Sanofi presses here has been explicitly rejected by the Supreme Court. After canvassing various agency adjudicative schemes, all of which "surely determine liabilities of individuals," the Court explained that, "[i]f the identity of the parties alone determined the requirements of Article III … the constitutionality of many quasi-adjudicative activities carried on by administrative agencies involving claims between individuals would be thrown into doubt." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 587, 589 (1985); *see also id.* 571-75, 584 (upholding binding arbitration to resolve disputes between private companies because "[a]ny right to compensation … results from [the statute] and does not depend on or replace a right to such compensation" under state or common law). These principles recently were reaffirmed in *Oil States*, which upheld a procedure whereby an administrative board, through adversarial proceedings between private parties, determines the validity of patent rights. The Court's conclusion was not displaced by the fact that patents might be "property for purposes of the Due Process Clause or the Takings Clause." 138 S. Ct. at 1379. As the Third Circuit succinctly has summarized, "public rights" post-*Union Carbide* are those "involv[ing]

rights that [a]re an integral part of a public regulatory scheme, assigned to an administrative agency." *Beard v. Braunstein*, 914 F.2d 434, 441 (3rd Cir. 1990).

Sanofi's assertion that the Rule violates Article III by allowing non-judicial adjudication of private rights, Mot. 23-27, rests on a warped interpretation of the disputes presented to the Board. The ADR process does not decide "private contract and property rights," nor does Sanofi's "underlying right to compensation in the absence of 340B" have any relevance, since Sanofi has opted in to the 340B Program and must comply with its obligation to sell discounted drugs to covered entities. *Id.* at 25. The ADR process, like other administrative determinations of public rights, *supra*, determines only the question whether parties have complied with the statutory provisions enacted by Congress. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.3. The panels cannot determine "the price of a drug," Mot. 3; the statutory ceiling price accomplishes that task. The panels do not decide to whom Sanofi must offer discounted drugs; the 340B statute determines this, too. The ADR panels, contrary to Sanofi's portrayal, do not have independent authority to order the disgorgement of private property—only to decide compliance with the statutory regime.[8] And the statutory disputes ADR panels resolve emphatically are not "traditional actions at common law," *Stern*, 564 U.S. at 484, since they are entirely creatures of the 340B Program. No covered entity could sue a manufacturer for "overcharging," and no manufacturer could sue a covered entity for "duplicate discounting" or "diversion," in federal court.[9] As demonstrated above, the Supreme Court repeatedly has upheld

[8] In its Background section, Sanofi correctly admits that panels are granted "jurisdiction to resolve claims … based on the determination of whether the parties violated Section 340B through overcharging, diversion, or duplicate discounting." Mot. 12. The determination of compliance with those 340B statutory requirements—the only type of claim the Rule empowers ADR Panels to hear—is precisely the type of regulatory claim commonly heard by administrative agencies, as discussed herein, and bears no resemblance to common-law "contract and property rights," Mot. 25.

[9] Sanofi attempts to distract from this inescapable conclusion by misconstruing the claim now pending before the Board as seeking resolution of "whether Sanofi must provide its property to a third party (a contract pharmacy) at a discounted price over Sanofi's objection." Mot. 25. But an ADR Panel will be tasked with determining only whether Sanofi's "integrity initiative" violates its obligations to covered entities. And manufacturers plainly do *not* provide discounts "to contract pharmacies." Rather, for decades drug companies simply have fulfilled orders from covered entities that are *shipped* to pharmacies. *See, e.g.*, Compl. ¶ 41 (admitting that "integrity initiative" places conditions on when Sanofi

administrative adjudication of statutory, public rights notwithstanding that the disputes arose between private parties and resulted in the exchange of property. The ADR Rule does not concern private rights any more than the administrative adjudications sanctioned in, *e.g.*, *Union Carbide*, 473 U.S. at 587-89.

Sanofi bizarrely insists that the "rights the ADR panel will determine do not 'derive from a federal regulatory scheme'" on the very page it admits that "a covered entity's entitlement to a discount is established by a federal statute." Mot. 25 (referencing *Stern*, 564 U.S. at 488). This contention is preposterous. Congress created the 340B Program, thereby granting covered entities the statutory *right* to discounted medications, and pharmaceutical manufacturers, like Sanofi, the statutory *right* to access incredibly valuable revenue streams (Medicaid and Medicare Part B) in exchange for providing its property in the form of discounted drugs. The rights of both covered entities and manufacturers under this scheme are quintessential public rights, created by a comprehensive and well-established regulatory system, and of precisely the same character as the administrative proceedings cited approvingly in *Union Carbide*. *See* 473 U.S. at 587-89. Sanofi can opt out of the 340B Program and lose the right to access to Medicaid and Medicare Part B, but it cannot enjoy those rights while shirking its obligations under 340B. The ADR Board cannot hear freestanding common-law "contract and property" disputes, Mot. 25, only determinations "whether the parties violated Section 340B through overcharging, diversion, or duplicate discounting" (as Sanofi admits, Mot. 12). "The category of public rights may include seemingly private rights, if they are closely integrated into a public regulatory scheme assigned to an administrative agency." *Billing v. Ravin, Greenberg & Zackin, P.A.*, 22 F.3d 1242, 1246 (3rd Cir. 1994) (citation omitted); *see also Kalaris*, 697 F.2d at 388 ("The law is emphatically clear that when Congress creates a substantive federal right, it possesses substantial discretion to prescribe the manner in which that right may be adjudicated."); *id.* at 400 (upholding administrative resolution of workers' compensation claims, noting "the scores of administrative boards and tribunals in the Executive Branch that currently adjudicate claims to federal statutory rights").

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will "*ship discounted drugs to [] contract pharmacies*") (emphasis added). It is Sanofi and its peers that seek to upend an established system.

Sanofi's argument that the Board's "powers exceed the scope of administrative review schemes the Supreme Court has approved," relies on wholly inapposite caselaw. Mot . 26. Both *CFTC v. Schor*, 478 U.S. 833, 851 (1986), and *Stern*, 564 U.S. at 500, considered whether state common-law counterclaims (*i.e.*, core private rights) could be adjudicated in non-Article III bodies serving as "adjuncts of Article III courts," *id.* at 487. The so-called "adjunct" doctrine is relevant only where traditional *private* rights are being adjudicated, whereas here the matters heard by the Board concern only public rights. *See Schor*, 478 U.S. at 853 (upholding agency adjudication of "'private' right for which state law provides the rule of decision"); *Crowell v. Benson*, 285 U.S. 22, 46 (1932) (upholding administrative scheme that displaced traditional common-law claim and created "expert[] and inexpensive method for dealing with a class of questions of fact … peculiarly suited to … determination by an administrative agency"); *Kalaris*, 697 F.2d at 386 ("Article III does not require Article III judges to perform every stage of adjudication where 'private rights' are at stake."). The adjunct doctrine does not provide the rule of decision here because the ADR Board resolves disputes arising wholly under the 340B statute. *Oil States*, 138 S. Ct. at 1378.

Sanofi's complaint that it has "not consented to this scheme," Mot. 27, is specious. First, its assertion that "[s]ubmitting to ADR panels … as a condition of Medicare participation is hardly a voluntary choice," is conclusory and essentially admits that Sanofi seeks all the benefits of the scheme Congress devised with no strings attached. *Id.* (It also ignores the fact that Congress mandated creation of the ADR process *in 2010*, so Sanofi has been on notice.) On the contrary, Sanofi *is* free to opt out of 340B and Medicaid and Medicare at any time—but it may not continue to enjoy the benefit Congress granted while refusing to "submit[]" to the body directed to resolve disputes arising under the regulatory scheme. Moreover, Sanofi's consent is wholly irrelevant because the Board hears only public rights disputes and thus need not serve as an "adjunct" of the district court. *Stern*, 564 U.S. at 493. Nor does it matter whether Sanofi has "consented to the conclusion" it believes "the ADR panels will ultimately reach," Mot. 27, since the panels will merely be interpreting the statutory language and, if Sanofi disagrees with their ultimate conclusion, it is free to seek review of that interpretation in district court.

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

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

II. SANOFI HAS NOT ESTABLISHED IRREPARABLE HARM

A. ALLEGED VIOLATIONS OF STRUCTURAL CONSTITUTIONAL PROVISIONS ARE INSUFFICIENT TO SUPPORT A PRELIMINARY INJUNCTION

Sanofi claims that it will suffer irreparable harm in the absence of preliminary relief simply by having to submit to administrative proceedings that "violat[e] the Constitution's structural protections." Mot. 27–29. As explained above, however, the ADR Rule is lawful and constitutional. *See supra* §§ I.A, B. This alone defeats Sanofi's claim of irreparable harm. But even setting the merits aside, Sanofi has not alleged the type of deprivation contemplated by the bulk of authorities it cites—*i.e.*, the deprivation of an individual constitutional right. *See United Church of the Med. Ctr. v. Med. Ctr.*

Comm'n, 689 F.2d 693, 701 (7th Cir. 1982) (involving the alleged deprivation of the individual right to due process); *Valley v. Rapides Parish Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (same); *Hammond v. Baldwin*, 866 F.2d 172, 175–78 (6th Cir. 1989) (same); *Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cty.*, 893 F. Supp. 301, 307 (D.N.J. 1995) (involving alleged violations of individual rights conferred by the dormant Commerce Clause).[10]

Sanofi seeks preliminary relief on the basis of structural constitutional claims involving Article II's Appointments Clause and Article III's vesting of judicial authority. *See* Mot. 18–27. But an alleged violation of "a structural provision of the Constitution that does not confer personal rights" cannot itself support a finding of irreparable harm. *Weisshaus v. Cuomo*, 20-cv-5826 (BMC), 2021 WL 103481, at *5 (E.D.N.Y. Jan. 11, 2021). "[W]hile a violation of constitutional rights can constitute *per se* irreparable harm, *per se* irreparable harm is caused only by violations of 'personal' constitutional rights[,] to be distinguished from provisions of the Constitution that serve 'structural' purposes . . . ." *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 545 F. Supp. 2d 363, 367 (S.D.N.Y. 2008) (alterations adopted and citation omitted), *rev'd on other grounds*, 556 F.3d 114 (2d Cir. 2009); *accord Pub. Serv. Co. of N.H. v. Town of W. Newbury*, 835 F.2d 380, 382 (1st Cir. 1987); *Am. Petroleum Inst. v. Jorling*, 710 F. Supp. 421, 431 (N.D.N.Y. 1989); *Live 365, Inc. v. Copyright Royalty Bd.*, 698 F. Supp. 2d 25, 45 (D.D.C. 2010); *Pro. Towing & Recovery Operators of Ill. v. Box*, No. 08 c 4096, 2008 WL 52211192, at *12–13 (N.D. Ill. Dec. 11, 2008); *see also Hohe v. Casey*, 868 F.2d 69, 73 (3d Cir. 1989) ("Constitutional harm is not necessarily synonymous with the irreparable harm necessary for issuance of a preliminary injunction.").[11] Because Sanofi has not even alleged, let alone demonstrated, that it will be deprived of

[10] The dormant Commerce Clause is not a mere structural provision of the Constitution, but confers individual rights. *See Oxford Assocs. v. Waste Sys. Auth. of E. Montgomery Cty.*, 271 F.3d 140, 146 (3d Cir. 2001); *accord City of Hugo v. Nichols*, 656 F.3d 1251, 1257 (10th Cir. 2011) ("The dormant Commerce Clause . . . itself provides substantive rights.").

[11] Sanofi cites but a single case finding irreparable harm based on an alleged violation of a structural constitutional provision. Mot. 29 (citing *Ironridge Glob. IV, Ltd. v. SEC*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015)). But this outlier—which provides no reasoning and cites no relevant precedent for its decision—cannot stand against the weight of contrary authority.

a specific personal constitutional right, it cannot rely on that nonexistent constitutional injury to establish irreparable harm.

Finally, Sanofi's reliance on *Cirko ex rel. Cirko v. Commissioner of Social Security*, 948 F.3d 148 (3d Cir. 2020), is completely misplaced. The court in *Cirko* was concerned with whether Appointments Clause challenges brought in federal court are subject to an exhaustion requirement, *id.* at 153, not whether an alleged Appointments Clause violation is sufficient to establish irreparable harm for the purpose of granting preliminary relief, *see Illinois v. Lidster*, 540 U.S. 419, 424 (2004) ("Language in judicial opinions" must be read "as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering."). And contrary to what Sanofi may suggest, the court in *Cirko* did not hold that an individual is presumptively deprived of its liberty interests whenever structural constitutional provisions are transgressed. *See* Mot. 27–29.[12]

B. Injuries That May Arise From an Adverse ADR Decision Are Too Remote and Too Speculative to Establish Irreparable Harm

Sanofi argues further that it will suffer irreparable harm in the form of civil monetary penalties or other damages incurred as a result of an adverse decision if one is issued at the conclusion of the ADR proceedings. Mot. 29–31. The mere "possibility of [these] remote future injur[ies]" cannot justify preliminary relief, however. *See Cont'l Grp., Inc. v. Amoco Chems. Corp.*, 614 F.2d 351, 359 (3d Cir. 1980) (citation omitted); *accord Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91 (3d Cir. 1992) ("[A] showing of irreparable harm is insufficient if the harm will occur only in the indefinite future."). Rather, a preliminary injunction "may be unleashed only against conditions generating a *presently existing actual threat*." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 487 (3d Cir. 2000) (emphasis added and citation

[12] Rather, the court's reliance on *Landry v. Fed. Deposit Ins. Corp.*, 204 F.3d 1125 (D.C. Cir. 2000), appears to demonstrate that the "harm" that will be "presumed" from an Appointments Clause violation, *Cirko*, 948 F.3d at 154, relates to the "causal link between the [constitutional] error and the authority's *adverse decision*," *Landry*, 204 F.3d at 1131 (emphasis added); *see also Cirko*, 948 F.3d at 154 (noting the difficulty in showing that an Appointments Clause violation "played a causal role in [the plaintiff's] loss"—*i.e.*, the plaintiff's adverse ruling (quoting *Landry*, 204 F.3d at 1131)).

omitted). Sanofi's fear that it "*may in the future* suffer significant financial and other injury as a result of ADR panel decisions," Mot. 28–29 (emphasis added), is both too remote and too conjectural to satisfy Sanofi's burden of making a "clear showing of immediate irreparable injury." *See Cont'l Grp., Inc.*, 614 F.2d at 359 (citation omitted).[13]

Moreover, Sanofi's claim of irreparable harm rests on its groundless suggestion that an adverse ADR decision is "effectively preordained" given the conclusions reached in the AO. *See* Mot. 30. But "the risk of irreparable harm" sufficient to justify preliminary relief "must not be [so] speculative." *Adams*, 204 F.3d at 488. By its terms, the AO is not binding on an ADR panel, as it simply outlined the views of the Office of the General Counsel. AO at 8. Additionally, the AO interpreted the 340B statutory requirements as a "general" matter, and did "not opine on the legality of any specific contract-pharmacy model," including Sanofi's. AO at 8 n.9. Sanofi has simply no basis upon which to surmise how an ADR panel might view the relevant law and facts at issue in any future proceedings related to Sanofi's contract-pharmacy policy. Therefore, Sanofi's speculation in this regard cannot support an injunction. *See Adams*, 204 F.3d at 488.

Finally, even Sanofi acknowledges (rightly) that, if it suffers any injury as a result of an adverse ADR decision, "it could separately challenge the merits of th[at] decision[]" in federal court. Mot. 28–29; *see also* 85 Fed. Reg. 80,641, 42 C.F.R. § 10.24(d). The availability of an adequate remedy at law "belies [Sanofi's] claim of irreparable injury." *Instant Air Freight Co.*, 882 F.2d at 801; *accord Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 n.3 (3d Cir. 1988); *see also Goadby v. Phila. Elec. Co.*, 639 F.2d 117, 122 (3d Cir. 1981) ("[W]e perceive an even more fundamental error in the district court's determination. It ignored the basic tenet of equity jurisprudence: if an adequate remedy at law exists, equitable relief will not be granted.").

[13] Sanofi appears to vaguely contend that "damages . . . incur[red] in defending itself before the ADR panel" also constitutes irreparable harm. Mot. 31. Such an argument has long been foreclosed, however. *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980) ("Mere litigation expense, even substantial and unrecoupable cost, does not constitute irreparable injury."); *accord Bethlehem Steel Corp. v. EPA*, 669 F.2d 903, 911 (3d Cir. 1982) ("The only cost sustained by the company . . . would be for litigation expenses, and it is well-settled that they do not constitute irreparable injury.").

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

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). "[T]here is inherent harm to an agency in preventing it from enforcing regulations that Congress found [to be] in the public interest to direct that agency to develop." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *Seaside Civic League, Inc. v. U.S. Dep't of Housing & Urban Dev.*, 2014 WL 2192052, at *3 (N.D. Cal. 2014). Here, Congress required HHS to promulgate regulations "establishing and implementing a binding ADR process for certain disputes arising under the 340B Program." 85 Fed. Reg. 80,633. HHS has done so, and any injunction prohibiting the enforcement of these statutorily required regulations would cause injury to the agency and to the public interest.

This is particularly so when it is *Sanofi* that has upended the status quo by abandoning its decades-long practice (and the agency's longstanding guidance) of fulfilling orders placed by covered entities using contract pharmacies, causing significant uncertainty for safety-net healthcare providers serving low-income patients amidst a global pandemic. The public interest strongly militates against delaying the agency's efforts to resolve this uncertainty through the statutorily mandated administrative process intended for such disputes. *See Spencer v. Dist. of Columbia*, 416 F. Supp. 2d 5, 13 (D.D.C. 2006) (denying request for injunction when administrative process was available and injunction "would represent a major disruption of a carefully crafted legislative scheme"). The need for prompt resolution of the contract-pharmacy dispute before the agency is heightened by the fact that covered entities and manufacturers cannot sue to enforce 340B Program requirements, *Astra*, 563 U.S. at 117-21, and must resolve their disputes in the ADR process, *see Am. Hosp. Ass'n*, 2021 WL 616323, at *6.

Finally, although it is generally true that the public interest is not served by enforcement of an unconstitutional law, *see* Mot. 32, Sanofi has not asserted a violation of individual constitutional rights, *see supra* §§ I.A, B. And because its constitutional claims are meritless in any event, any alleged constitutional violations are irrelevant to this inquiry.

IV. ANY INJUNCTIVE RELIEF SHOULD BE LIMITED

Although preliminary relief is unjustified here, at a minimum, any injunction should be no broader than necessary to redress Sanofi's alleged injuries. Because a federal court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it," any remedy ordered by a court must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established"—*i.e.*, "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933–34 (2018) (citation omitted). Equitable principles likewise require that an injunction "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr. Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to "preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

By requesting that HHS be enjoined from "implementing, enforcing, or otherwise giving effect" to the ADR Rule "*in any administrative proceeding*," Prop. Order Granting Mot. for Prelim. Inj., ECF No. 19-13 (emphasis added), Sanofi seeks relief far beyond any injury to itself, which would flout basic equitable principles. Indeed, Sanofi does not even attempt to show how a far-ranging injunction that would forestall the operation of the ADR Rule in proceedings wholly unrelated to Sanofi would be necessary to redress its alleged injuries. Absent such a showing, the Court lacks jurisdiction to grant Sanofi's requested relief.

CONCLUSION

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

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Respectfully submitted,

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