UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 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 the United States Department of Health and Human Services, HEALTH RESOURCES AND SERVICES ADMINISTRATION, DIANA ESPOSITO, in her official capacity as Acting Administrative of the Health Resources and Services Administration, Defendants.	Civil Action No. 3:21-cv-634 *AMICUS CURIAE* BRIEF OF NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC. IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

BRIEF OF *AMICUS CURIAE*
NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.
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INTRODUCTION AND SUMMARY OF ARGUMENT

The outcome of this case turns on a straightforward question of statutory interpretation:

> Does the 340B statute grant the Secretary of the U.S. Department of Health and Human Services ("HHS") authority to force pharmaceutical manufacturers to transfer their drugs at deeply discounted prices to for-profit commercial pharmacies?

The answer to that question is clearly no. Nothing in the 340B statute grants HHS authority to impose that obligation and, as a result, HHS's attempt to do so is *ultra vires*. *See City of Arlington v. FCC*, 569 U.S. 290, 297–98 (2013) (when an agency acts "beyond what Congress has permitted it to do," its actions are "ultra vires").

Because Congress has never authorized HHS to force manufacturers to transfer 340B-discounted drugs to commercial pharmacies, it necessarily follows that agency officials also have no authority to impose that obligation through an administrative dispute-resolution ("ADR") process. The 340B statute directs HHS to appoint panels of agency employees to resolve basic disputes that arise when a covered entity believes it has not paid the proper discounted price, or when an audit shows that a covered entity has generated illegal duplicate discounts or sold 340B drugs to non-patients. *See* 42 U.S.C. § 256b(d)(3). HHS's ADR rule sweeps far more broadly than what the statute permits. *See 340B Drug Pricing Program: Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10). Nothing in the 340B statute authorizes ADR panels

to engage in legislative policymaking. And, in all events, HHS may not use the ADR process to reshape the 340B program by directing ADR panels to impose substantive obligations on manufacturers that extend beyond what Congress intended.

In its attempt to rewrite the 340B statute, HHS has engaged in an elaborate shell game. In response to manufacturer initiatives seeking to limit contract pharmacy abuses, the agency hastily promulgated its ADR rule without complying with proper notice and comment procedures and without responding to objections that the process was biased against manufacturers. *See* Sanofi Am. Compl. ¶¶ 9; 49-54; 108; and 112. It then issued an "advisory opinion" — its December 30, 2020 decision — announcing the agency's final, definitive position that the 340B statute requires manufacturers to transfer (or facilitate the transfer of) discounted drugs to commercial pharmacies. *See* HHS, Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (Dec. 30, 2020). Although HHS's position is contrary to the statute, the agency's decision binds the agency employees that serve on the ADR panels, meaning that the outcome of any administrative proceeding is preordained with respect to the contract-pharmacy issue.

HHS is now trying to use its ADR rule to insulate its December 30 decision from meaningful judicial review, seeking to force manufacturers to go through a one-sided adjudicatory process that exposes them to substantial civil penalties. In purporting to empower the ADR panels to impose extra-statutory requirements, the

agency's ADR rule violates the Constitution. As Sanofi explains, the panel members are not appointed by the President or confirmed by the Senate; they are only removable for cause; and their decisions are not subject to review or alteration by superior officers. *See* 42 C.F.R. §§ 10.20(a)(1)(ii), 10.24. Moreover, by directing the panels to issue judgments for money damages and equitable relief, *see id.* § 10.21(a), the ADR rule authorizes the panels to exercise a core judicial function — adjudicating private rights — that the Constitution reserves for Article III courts.

The Court should grant Sanofi's motion for a preliminary injunction to maintain the *status quo* until this Court is able to resolve this case on its merits. Sanofi is very likely to prevail because (1) no permissible interpretation of the statute supports HHS's position, and (2) the ADR rule is constitutionally infirm. An injunction is necessary to protect Sanofi from the irreparable harm that would result if it were forced into a gerrymandered ADR process that exceeds HHS's lawful authority and violates constitutional requirements.

A preliminary injunction is also in the public interest. There is a strong public interest in preventing administrative overreach and protecting the rule of law. The drugs that manufacturers produce are their own drugs; they do not belong to either HHS or the covered entities that are permitted to purchase them at discounted prices for the benefit of vulnerable patients. Manufacturers are entitled to control their own property unless and until Congress imposes restrictions through duly enacted

legislation. The fact that HHS has allowed hospitals and commercial pharmacies to exploit the 340B program does not create an enforceable obligation on manufacturers to accede to their demands.

Preventing HHS from interfering with manufacturers' rights to prevent transfers to commercial pharmacies is also essential to protecting the integrity of the 340B program. Reports show that large commercial pharmacies have been syphoning off hundreds of millions of dollars a year in profits from the sale of manufacturers' drugs and are projected to profit by $3.3 billion in 2020. *See* Eric Percher, et al., Nephron Research, The 340B Program Reaches a Tipping Point: Sizing Profit Flows & Potential Disruption, at 3, 30–31 (2020). The use of contract pharmacies is also dramatically increasing the risk of duplicate discounts, which are prohibited under the statute. *See* Sanofi Am. Compl. ¶¶ 29, 37, 39–40. Moreover, while commercial pharmacies reap windfalls, this massive expansion in the 340B program is not benefitting the vulnerable patients the program is supposed to serve. *See* Adam J. Fein, *The Federal Program That Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program" while patients "don't benefit").

The Court should grant a preliminary injunction.

ARGUMENT

I. HHS Has No Authority to Require Manufacturers to Transfer Discounted Drugs to For-Profit Commercial Pharmacies.

HHS's decision — that manufacturers are required to transfer or facilitate the transfer of their drugs to for-profit commercial pharmacies — exceeds its lawful authority and has no support in the 340B statute. The statute requires only that manufacturers "offer" their drugs to covered entities "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).

A. Nothing in the 340B Statute Permits HHS to Force Manufacturers to Transfer Their Drugs to Commercial Pharmacies.

In 2020, certain manufacturers (including Novo and Sanofi) exercised their rights to implement integrity initiatives that limit when they will honor requests that 340B-discounted drugs be transferred to for-profit commercial pharmacies. *See* Sanofi Am. Compl. ¶¶ 5, 41. Those initiatives took care to emphasize that the manufacturers would continue to comply fully with their statutory obligations by offering their outpatient drugs at 340B-discounted prices to all eligible covered entities, but that they were no longer willing to transfer the drugs to third parties that are not statutorily eligible. Those initiatives followed years of trying to convince HHS to satisfy its statutory obligations to safeguard the 340B program's integrity, *see* 42 U.S.C. § 256b(d)(2), and to protect against the pervasive problems of duplicate discounts and diversion to non-patients, *see id.* § 256b(a)(5)(A), (B); *see*

also GAO, GAO-20-108, 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, at 5 (2019); H. Comm. on Energy & Commerce, *Review of the 340B Drug Pricing Program*, 114th Cong. (Jan. 11, 2018).

HHS's well-documented failure to protect the 340B program's integrity, and its non-binding 2010 guidance purporting to allow covered entities to contract with an unlimited number of commercial pharmacies, have exacerbated these problems and, in recent years, resulted in extraordinary growth in the 340B program. *See* Aaron Vandervelde et al., Berkeley Research Grp., LLC, For-Profit Pharmacy Participation in the 340B Program, at 4 (2020) (finding that the 340B program has grown by more than 4,000% since HHS permitted covered entities to contract with an unlimited number of pharmacies). This growth has not benefitted patients — indeed, patient charitable care has decreased. Meanwhile, covered entities and large commercial pharmacies have enjoyed a windfall in profits from the sale of manufacturers' drugs. *See* Letter from Adam J. Fein, Drug Channels Inst., to Hon. Lamar Alexander and Hon. Greg Walden (Oct. 30, 2020). Billions of dollars of drugs that belong to manufacturers are not being used for the benefit of patients but are instead being captured for the benefit of commercial interests. *See* Percher, The 340B Program Reaches a Tipping Point, *supra*, at 3 and 30–31.

In response to manufacturer initiatives limiting distribution to contract pharmacies, HHS issued a final decision on December 30, 2020, in the form of an "advisory opinion" by HHS's General Counsel. Reflecting the agency's definitive position, the decision announces that manufacturers must transfer their drugs to commercial pharmacies.

> [W]e conclude that to the extent that 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.

Decision, at 1. The decision also takes the position that the statute strips manufacturers of their basic property rights. In HHS's view, manufacturers concerned with abuses have no ability to control who receives their drugs or to impose any conditions on transferring the drugs to third parties; instead, manufacturers must do what covered entities tell them. Manufacturers' only recourse is to conduct audits and then submit claims to the ADR process. *Id.* at 5.

These conclusions have no support in the statute. The statute's plain text requires each manufacturer to enter into a pharmaceutical pricing agreement with HHS and, under that agreement, to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). That is the sum total of the statute's language regarding manufacturers' obligation to offer drugs

at discounted prices. Neither the statute nor the agreement says anything about commercial pharmacies.

Manufacturers can thus comply with the statute's commands by offering covered entities 340B-covered drugs at discounted prices, while simultaneously refusing requests to transfer the drugs to for-profit commercial pharmacies. That conclusion is confirmed by basic principles of statutory construction.

First, the statute defines which entities qualify as covered entities entitled to obtain access to manufacturers' drugs. *See* 42 U.S.C. § 256b(a)(4). The term includes only those hospitals, clinics, and health care providers that predominantly serve low-income and uninsured patients. *See* Sanofi Am. Compl. ¶ 2. There is no dispute that for-profit commercial pharmacies are not "covered entities." And because commercial pharmacies are neither covered entities nor patients of covered entities, they have no statutory right to participate in the program or to gain access to manufacturers' 340B-discounted drugs.

Second, the statute expressly prohibits covered entities from transferring 340B drugs to third parties, stating that "a covered entity shall not resell or otherwise transfer" 340B drugs to any "person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Because covered entities are prohibited from transferring the drugs to third parties, they cannot circumvent that restriction by forcing manufacturers to transfer the drugs for them. *See Altamont Gas Transmission Co. v. FERC*, 92 F.3d

1239, 1248 (D.C. Cir. 1996) (recognizing principle that agency may not "attempt[] to do indirectly what it could not do directly").

While HHS has indicated in non-binding guidance that it does not consider the transfer of 340B drugs to commercial pharmacies to violate the statute, that exercise of enforcement discretion does not mean that the agency has authority to force manufacturers to accede forever to covered entities' demands. Nor can it change manufacturers' statutory obligations. By definition, a guidance document "lack[s] the force of law" and cannot create substantive rights and obligations, as HHS has previously recognized. *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also* Tom Mirga, *HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020). Accordingly, while manufacturers have tried for many years to accommodate covered entity requests, the continued expansion in the 340B program, combined with HHS's failure to police abuses, has made the situation untenable.

Third, forcing manufacturers to transfer their drugs to for-profit commercial pharmacies entails such a massive expansion of the 340B program — allowing pharmacies to obtain billions in profits — that it would be improper to assume that Congress intended that result absent particularly clear statutory language. *See Gonzales v. Oregon*, 546 U.S. 243, 267 (2006). As noted above, the statute requires only that manufacturers offer their drugs to covered entities at a discounted price.

42 U.S.C. § 256b(a). That would be an uncommonly "cryptic" and obscure way for Congress to delegate authority to HHS to impose an additional obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000); *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions").

Fourth, the conclusion that Congress did not authorize HHS to impose such a fundamental change in the 340B program is reinforced by the principle that statutes should be interpreted to avoid serious constitutional concerns. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). The 340B program raises concerns under the Takings Clause because, instead of relying on general tax revenues, the program is funded entirely by drug manufacturers. *See Armstrong v. United States*, 364 U.S. 40, 49 (1960) (one purpose of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole"). It operates as a classic take-and-transfer scheme, requiring manufacturers to provide their drugs to covered entities at confiscatory prices, and then permitting covered entities to sell the drugs or seek reimbursement for the drugs at market prices. *See Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("It is against all reason and justice" to presume that the legislature has been entrusted with the power to

enact "a law that takes property from A and gives it to B"); *Horne v. Dep't of Agric.*, 576 U.S. 350 (2015); *see also FPC v. Hope Nat. Gas Co.*, 320 U.S. 591 (1944) (explaining that even public utilities are protected from confiscatory rates).

These serious constitutional concerns explain why the 340B statute requires a close nexus between its only legitimate public purpose — helping vulnerable patients — and the enumerated entities entitled to gain access to manufacturers' drugs at deeply discounted prices. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987) (noting that when government imposes a regulatory exaction as a condition of receiving a government benefit, the exaction must have a sufficient nexus to a legitimate public purpose). The statute's careful limits on which entities may participate in the program, and the restriction on transfers to non-patients, are essential to keeping the statute within constitutional bounds. In contrast, forcing manufacturers as a condition of participating in the program to transfer their drugs at confiscatory prices to commercial pharmacies is a bridge too far. If the statute imposed that requirement, it would work an impermissible A-to-B private taking.

B. HHS's Justifications Are Impermissible and Contrary to Law.

HHS asserts that manufacturers are required to transfer their drugs to commercial pharmacies because "[a]ll that is required is that the discounted drug be 'purchased by' a covered entity," and "neither the agency nor a private actor is authorized by section 340B to add requirements to the statute." Decision, at 2. But

manufacturers are not adding requirements to the statute; they are merely exercising private rights that they hold as owners of the drugs they produce.

HHS misreads the 340B statute by focusing narrowly on the word "purchase." Contrary to HHS's suggestion, the statute does not give covered entities a right to "purchase" drugs on whatever terms they desire. The statute dictates only one term of the sale — the drugs must be offered at the discounted price. As long as that requirement is met, manufacturers are free to impose any other reasonable restrictions on the sale of their drugs. It is HHS, not any manufacturer, that is seeking to rewrite the statute to impose requirements that Congress has not imposed. *See id* (citing cases for the proposition that courts should not add requirements to statutes beyond what Congress has directed).

HHS's December 30 decision contends that the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.* at 3. That attempt at rhetorical flourish only highlights how far HHS has departed from the statutory text. In common parlance, no one would reasonably conclude that an obligation to *offer* a product at a discounted price also imposes a requirement to *deliver* the product to wherever the purchaser may request. When a supermarket offers a discounted price on a product to anyone who cuts a coupon from their local paper, that does not give the coupon holder a right to demand *delivery* to their preferred location, much less that the product be delivered to *someone else*. The

right granted by the coupon is limited to coupon holder's right to purchase at the discounted price; it does not impose other restrictions on the supermarket or grant other rights for the benefit of third parties.

So too here. If covered entities were to insist that manufacturers ship their drugs to the moon, manufacturers would rightfully object that nothing in the statute imposes such a far-reaching obligation. The same logic applies to commercial pharmacies. As noted above, manufacturers are continuing to offer 340B-discounted drugs to covered entities at the mandated price, which is all that the statute requires.

HHS also contends that forcing manufacturers to transfer drugs to for-profit commercial pharmacies is analogous to a covered entity using a courier service. *See id*. at 7. But that only underscores that HHS is ignoring the abuses that have resulted from allowing contract pharmacies to participate in the 340B program. First, unlike a hypothetical courier, commercial pharmacies are not receiving a bona fide fee for services provided; instead, they are sharing in the profits (the "spread") resulting from purchasing manufacturers' drugs at deeply discounted prices and then selling them at market prices. Second, contract pharmacies — unlike couriers — sell the discounted drugs and, in doing so, often contribute to covered entities' failure to share discounts with vulnerable patients. Third, the use of contract pharmacies has dramatically increased the problems of prohibited duplicate discounts and sales to non-patients. If couriers were to raise the same problems as contract pharmacies,

HHS would be obligated to address the abuses. And manufacturers would have no obligation to participate.

In short, HHS's decision is unreasoned, unreasonable, and contrary to plain statutory text. The agency's December 30 decision will undoubtedly influence and bias the outcome of the HHS-led ADR proceedings to the detriment of manufacturers. Because HHS has no authority to read new requirements into the statute, Sanofi and other manufacturers are entitled to relief striking down the agency's December 30 decision. In the meantime, for reasons explained below, this Court should grant a preliminary injunction to prevent HHS from attempting to impose its preferred extra-requirements through an unconstitutional ADR process.

II. Because HHS Has No Authority to Require Manufacturers to Transfer Their Drugs to Commercial Pharmacies, It Also Has No Authority to Impose That Requirement Through an Unconstitutional Administrative Dispute Resolution Process.

Sanofi is likely — if not certain — to prevail on its challenge to HHS's unlawful December 30 decision, and it should not be forced into an unconstitutional ADR process. Because HHS lacks statutory authority to require manufacturers to transfer their drugs to commercial pharmacies, it also lacks authority to set up an ADR process for its employees to impose that requirement through the guise of resolving disputes. An injunction is appropriate to maintain the status quo, to protect the Court's jurisdiction, and to avoid irreparable harm.

There can be no meaningful dispute that HHS's December 30 decision is a final rule that reflects the consummation of the agency's decision-making process. *See* 5 U.S.C. § 551(4) (defining a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"). Because the decision subjects Sanofi to potential money damages and substantial civil monetary penalties, there is no requirement that Sanofi wait for agency proceedings to conclude before seeking judicial relief. *See U.S. Army Corps. of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815–16 (2016); *Sackett v. EPA*, 566 U.S. 120, 126–27 (2012). That is especially true because the agency's December 30 decision is binding on the government employees appointed to the ADR panels, which means that the outcome of any ADR proceedings is both preordained and biased against manufacturers. *See D.E. v. Cent. Dauphin Sch. Dist.*, 765 F.3d 260, 275 (3d Cir. 2014) (recognizing that exhaustion of administrative process is not required when (1) it would be futile, (2) the issue presented is a purely legal question, (3) the agency cannot grant relief, or (4) it would cause severe or irreparable harm). As envisioned by HHS, the December 30 decision effectively resolves all liability issues and turns the ADR proceedings into a trial on damages.

HHS's attempt to rewrite the statute and then hide behind an unconstitutional ADR process is precisely the type of agency "shenanigans" that courts are obligated to correct. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (courts have

authority to correct agency "shenanigans" even in the context of a judicial review bar); *Cuozzo Speed Techns. v. Lee*, 136 S. Ct. 2131, 2142 (2016) (same). It bears emphasis that the ADR process has never before been used to resolve disputes and was created only late last year. Indeed, having missed the statutory deadline to establish an ADR process by more than 10 years, HHS rushed to promulgate a defective proposed rule that it had previously formally withdrawn, changed the rule without following proper notice-and-comment procedures, and failed to respond to meaningful objections, including objections that the rule sets out a one-side process that does not lead to the fair adjudication of disputes. *See* Sanofi Am. Compl. ¶¶ 9; 49-54; 107-108. It cut those corners in direct response to manufacturer initiatives seeking to curtail contract pharmacy abuses, setting up its unlawful attempt to transform non-binding guidance permitting covered entities to contract with commercial pharmacies into a new binding legal obligation on manufacturers.

None of this should be tolerated. An injunction is warranted to protect this Court's jurisdiction and the integrity of the judicial process. *See Urban v. United Nations*, 768 F.2d 1497, 1500 (D.C. Cir. 1985) (per curiam) (courts "may employ injunctive remedies to protect the integrity of the courts and the orderly and expeditious administration of justice"). An injunction is also required to prevent the irreparable harm that would result from forcing Sanofi into an unconstitutional process. As Sanofi's brief explains, in attempting to empower ADR panels to

impose new obligations on manufacturers — going far beyond the statutory mandate — HHS has violated Article II and Article III of the Constitution.

First, the ADR rule is invalid because the panels are delegated authority to function as principal officers of the United States, but they are not appointed by the President or confirmed by the Senate. *See Lucia v. SEC*, 138 S. Ct. 2044, 2053–55 (2018). HHS has directed the ADR panels to exercise significant legislative authority — to wield the tools of federal trial judges to force manufacturers to transfer their drugs at discounted prices to commercial pharmacies. In doing so, the panels are acting as *principal* officers of the United States. The panel's decisions are the "final" word of the Executive Branch, and they are "precedential and binding on the parties." 42 C.F.R. § 10.24(d). Under the ADR rule, ADR panel decisions cannot be undone by the Secretary, and only "a court of competent jurisdiction" can set them aside. *Id*. Moreover, individuals serving as ADR panelists can be removed only "for cause" under the terms of the ADR rule. *See* 42 C.F.R. § 10.20(a)(1)(ii).

This power to make final, binding decisions on a significant question of legislative policy, with no oversight by superior officers, renders the ADR panels subject to the Article II requirements of the Appointments Clause. *See Free Enter. Fund v. Pub. Accounting & Oversight Bd.*, 561 U.S. 477, 486, 510 (2010) (holding that PCAOB members are inferior officers because the SEC's "oversight authority"

included the ability to "approv[e] and alter[]" decisions). Because the ADR panels do not meet those requirements, they are unconstitutional.

Second, the ADR rule is invalid under Article III because it empowers the panels to adjudicate *private rights*, including authorizing them to enter injunctive relief, command the conveyance of property, and award money damages. *See* Sanofi Br. 23–24. As Sanofi explains, the ADR rule intrudes on the prerogatives of the judiciary because the adjudication of private rights, such as the right to hold and transfer private property, "lie[s] at the core of the historically recognized judicial power." *Id.* at 24 (quoting *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 70 (1982) (plurality op.)).

Whether Sanofi has an obligation to transfer its property to third parties is a matter that, by its very nature, is "the subject of a suit at the common law." *Den ex dem. Murray v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1855). Indeed, under the terms of the ADR rule, covered entities seeking to require manufacturers to transfer 340B-discounted drugs to commercial pharmacies are authorized to file "an action for monetary damages," and the ADR panels are permitted to award "equitable relief." 42 C.F.R. § 10.21. Money damages and equitable relief are quintessential forms of judicial remedies. Moreover, ADR panels are expected to issue binding determinations "regarding 'the liability of [one party] to [another] under the law as defined." *Oil States Energy Servs. LLC v.*

Geene's Energy Grp., LLC, 138 S. Ct. 1365, 1378 (2018) (quoting *Crowell v. Benson*, 285 U.S. 22, 51 (1932)). That is undoubtedly why the ADR rule acknowledges that the panels are "akin to an arbitration panel focusing on complex commercial arrangements between private actors, where Federal funds may not be directly involved." 85 Fed. Reg. at 80,635.

HHS has suggested that the ADR panels fall within the *public rights* exception to Article III, relying on the principle that when Congress creates a new *public right*, Congress has "latitude to assign adjudication" of that right to entities other than Article III courts. *Oil States*, 138 S. Ct. at 1373. But whether manufacturers are liable to covered entities for money damages is not a question of public rights. The public rights exception does not apply for the same reason that HHS's advisory opinion exceeds its lawful authority: Congress has never created a statutory right for either HHS or covered entities to require manufacturers to transfer their drugs at discounted prices to commercial pharmacies. In addition, Congress only authorized HHS to establish an administrative process for resolving claims by covered entities that they paid too much for 340B-discounted drugs. The contract pharmacies issues do not "derive[]" from any "federal regulatory scheme" and do not result from any statutory provision. *Stern v. Marshall*, 564 U.S. 462, 490 (2011).

* * *

HHS has not and cannot identify any provision in the 340B statute that requires manufacturers to transfer their 340B-discounted drugs to commercial pharmacies. That should be the beginning and end of this case. Because Congress has never granted HHS authority to impose that obligation on manufacturers, the agency also has no authority to empower ADR panels to impose that obligation in the guise of resolving disputes. HHS's attempt to rewrite the law and evade judicial review though a one-sided and unconstitutional administrative process is improper. This Court should grant an injunction to preserve the *status quo* and prevent HHS from moving forward with ADR proceedings until it is able to resolve the important statutory and constitutional questions raised in this case.

CONCLUSION

The Court should grant a preliminary injunction.

Respectfully submitted,

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Dated: February 25, 2021