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 Administrator of the Health Resources and Services Administration,

Defendants.

Civil Action No. 3:21-cv-634

Oral argument requested

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") respectfully requests a preliminary injunction to prevent the U.S. Department of Health & Human Services ("HHS") from establishing an administrative process in which unaccountable bureaucrats will resolve private disputes by issuing binding judgments, awarding money damages, and issuing injunctions—all without the defendants' consent. One complaint has already been filed against Sanofi in this faux judicial process. Others are sure to soon follow. Worse still, HHS has already issued an "advisory opinion" making it a foregone conclusion that Sanofi will lose. None of this is remotely proper under Article II and Article III of the Constitution. This Court should preliminarily enjoin HHS's new rule establishing this unconstitutional process.

This case concerns what is known as the 340B Program, through which Congress requires drug manufacturers like Sanofi to discount the price of drugs purchased by certain health care providers known as "covered entities." 42 U.S.C. § 256b ("Section 340B"). In two related midnight regulations issued at the end of the Trump Administration, HHS (1) established an unconstitutional administrative process for resolving private disputes between manufacturers and covered entities over drug prices, and (2) ruled in favor of covered entities on a hotly contested legal issue about manufacturers' obligations under Section 340B. The two rules work in

tandem to provide an administrative forum and the rule of decision for resolving these disputes.

Although Sanofi's amended complaint challenges both new rules, Sanofi seeks to preliminarily enjoin only the first rule—the Administrative Dispute Resolution ("ADR") Rule, which established the unconstitutionally structured administrative process. In the ADR Rule, HHS established procedures allowing covered entities to submit claims alleging that drug manufacturers have overcharged for their drugs or placed limitations on the purchase of 340B-priced drugs. The ADR Rule empowers panels ("ADR Panels") of HHS employees to wield full judicial authority to resolve these claims. For example, the ADR process will operate under the Federal Rules of Civil Procedure and Evidence, an ADR Panel can award money damages and equitable relief, and all ADR decisions will be final, binding, and precedential.

Sanofi is likely to prevail on the merits of its claims that the ADR Rule is unconstitutional for two reasons. First, the ADR Rule violates Article II of the Constitution because the members of the ADR Panels are principal officers under the Appointments Clause—which means they must be appointed by the President and confirmed by the Senate. But the ADR Rule calls for neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal restrictions and thus not even politically accountable. There is no

Senate-confirmed agency employee with authority to review each ADR Panel's judgment.

Second, the ADR Rule violates Article III of the Constitution by granting these unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes between private parties over private rights—namely, the price of a drug. The Constitution reserves this authority to Article III courts.

Sanofi also faces imminent irreparable harm absent a preliminary injunction. It is well-established that being haled before an unconstitutional tribunal is irreparable harm. That is exactly what Sanofi now faces. Since the ADR Rule became effective on January 13, 2021, covered entities have already filed claims against Sanofi asking HHS to take action against Sanofi—including by moving for a preliminary injunction. Many others entities have threatened to file similar claims against Sanofi. And the outcome of these claims is not in doubt, because HHS has already decided that drug manufacturers like Sanofi are acting in a manner that violates Section 340B.

The equities weigh in favor of granting a preliminary injunction, too. The government will not be harmed by its inability to enforce an unconstitutional rule. In the meantime, Sanofi continues to offer discounted drug prices to all covered entities, consistent with its obligations under Section 340B.

BACKGROUND

I. The 340B Program

Established in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, the 340B Program seeks to assist the needy by reducing pharmaceutical costs for "public hospitals and community health centers, many of which provide safety-net services to the poor." HHS Office of the General Counsel, Advisory Opinion 20-06: On Contract Pharmacies Under the 340B Program ("Advisory Opinion"), at 1 (Dec. 30, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf. In particular, drug manufacturers participating in the 340B Program must offer steep discounts on certain drugs to a statutory list of "covered entities," such as children's hospitals and rural hospitals. *See* 42 U.S.C. § 256b(a)(1), (4)(A)–(O). Although manufacturers are not formally required to participate in the 340B Program, they have little choice but to do so, because otherwise they would be barred from participating in Medicaid and Medicare Part B—which contribute a major portion of manufacturers' annual revenues. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

Manufacturers enter the 340B Program by signing a form contract with the government known as a pharmaceutical pricing agreement ("PPA"). Such agreements "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below" discounted prices calculated according to a prescribed

statutory formula. 42 U.S.C. § 256b(a)(1). If a manufacturer does not comply with its 340B obligations, the government may institute enforcement actions, seek civil monetary penalties, and even terminate the PPA—and with it the manufacturer's ability to participate in Medicaid and Medicare Part B. *See id.* §§ 256b(d)(1)(B)(vi), 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–13 (Dec. 12, 1996).

To prevent waste and abuse in the 340B Program, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A). Section 340B also prohibits "diversion," which occurs when covered entities resell or transfer discounted drugs to persons other than their patients. *See id.* § 256b(a)(5)(B). In addition, to ensure that the 340B Program serves its purpose of assisting the needy, Section 340B specifies that only 15 types of "covered entities" are entitled to 340B discounts. *See id.* § 256b(a)(4)(A)–(O). Only Congress can expand this list of covered entities; HHS lacks the authority to do so.

II. The Explosion of Contract Pharmacy Arrangements and Accompanying Abuses

Congress did not include contract pharmacies—for-profit third-party pharmacies (like CVS and Walgreens) that fill prescriptions written by other healthcare providers—in the list of covered entities entitled to 340B discounts. Nor did Congress define any role for contract pharmacies in Section 340B or otherwise mention them in the statute. But HHS and its agency HRSA have nonetheless

endorsed the participation of contract pharmacies in the 340B Program through subregulatory (nonbinding) guidance, first in 1996 and then in 2010. *See* 61 Fed. Reg. 43,549, 43,549, 43,555 (Aug. 23, 1996); 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010).

Covered entities' use of contract pharmacies exploded after the 2010 guidance. For-profit contract pharmacies participating in the 340B Program increased in number from 1,300 in 2010 to 28,000 last year—almost half of the U.S. pharmacy industry—with more than 100,000 arrangements between contract pharmacies and covered entities.[1] This extraordinary expansion of contract pharmacy arrangements has been accompanied by significant abuses.

For one thing, contract pharmacies often capture significant amounts of the discounts that Congress intended for non-profit covered entities and their patients.[2] Generally, contract pharmacies will bill patients or insurance for the drugs and pocket

[1] *See* U.S. Government Accountability Office ("GAO"), Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 39, 40 (June 2018), https://www.gao.gov/assets/700/692697.pdf ("GAO Report"); Adam J. Fein, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, Drug Channels (July 14, 2020), https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html; PhRMA, 340B Contract Pharmacy 101 (Sept. 2020), https://phrma.org/-/media/Project/PhRMA/ PhRMA-Org/PhRMA-Org/PDF/0-9/340B-Contract-Pharmacy-101-Deck_Sept-2020.pdf.

[2] *See* GAO Report, *supra*, at 30; HHS Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

much of the margin above the 340B price, by paying a smaller, pre-negotiated amount to the covered entity for each discounted drug dispensed.[3]

Furthermore, the expansion of contract pharmacy arrangements has led to widespread duplicate discounting, in direct violation of Section 340B. 42 U.S.C. § 256b(a)(5)(A). The government itself has recognized that such arrangements "create complications in preventing … duplicate discounts,"[4] and government audits have uncovered numerous violations linked to contract pharmacies.[5] Sanofi, too, has discovered significant duplicate-discounting violations when analyzing Medicaid rebates for its own drugs.

III. Sanofi's Integrity Initiative

Sanofi shares the government's concerns about duplicate discounts when prescriptions are filled at contract pharmacies. Accordingly, on July 28, 2020, Sanofi announced an integrity initiative to prevent duplicate discounts. Under the integrity initiative, which took effect on October 1, 2010, Sanofi continues to offer discounted

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[3] *See* PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients (Oct. 8, 2020), https://phrma.org/Press-Release/New-Analysis-Shows-Contract-Pharmacies-Financially-Gain-From-340B-Program-With-No-Clear-Benefit-to-Patients; PhRMA, For-Profit Pharmacies Make Billions Off 340B Program Without Clear Benefit to Patients (Oct. 7, 2020), https://phrma.org/Graphic/For-Profit-Pharmacies-Make-Billions-Off-340B-Program-Without-Clear-Benefit-to-Patients.

[4] HHS Report, *supra*, at 1–2.

[5] HRSA, Program Integrity: FY19 Audit Results (Dec. 3, 2020), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results (finding widespread duplicate discounting at contract pharmacies).

pricing to all covered entities. The only change is that Sanofi now requests that covered entities submit minimal claims data for 340B-priced drugs dispensed by contract pharmacies, subject to limited exceptions. *See* Ex. 1, Letter from G. Gleeson, Vice President & Head, Sanofi US Market Access Shared Services (July 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (August 13, 2020). The requested claims data enables Sanofi to identify and halt impermissible duplicate discounts that would otherwise go undetected. On February 1, 2021, Sanofi further announced that, as of March 1, 2021, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy at which its patients can receive 340B-priced drugs—regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. *See* Ex. 3, Program Announcement.

Thus, under Sanofi's integrity initiative, a covered entity may acquire 340B-priced drugs three ways: (i) through its own in-house pharmacy; (ii) through a single, designated contract pharmacy (as of March 1, 2021), if the covered entity has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the minimal data requested by Sanofi.

IV. Covered Entities Refuse to Participate in Sanofi's Integrity Initiative—and Instead Press HHS to Take Action

Many covered entities have registered to provide claims data to Sanofi's integrity initiative. But, as unobtrusive as the integrity initiative is, many more covered entities have refused to participate—and have instead clamored for HHS to shut

down Sanofi's integrity initiative as a violation of Section 340B. This began with informal requests by the covered entities (or their associations) for HHS to take enforcement action against Sanofi and other manufacturers who have employed different approaches to combat waste and abuse at contract pharmacies. *See, e.g.*, Ex. 4, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020); Ex. 5, Letter from Attorney General Becerra, et al. to Secretary Azar (Dec. 14, 2020). In late 2020, covered entities started taking the matter to federal court, seeking to compel enforcement action by HHS. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806 (N.D. Cal.).

Tellingly, none of these covered entities has ever contended that Sanofi's integrity initiative is unduly burdensome, improperly discriminatory against covered entities as compared to commercial customers, or otherwise unreasonable. Nor has any of these covered entities ever denied the importance of the fight against duplicate discounting or the value of Sanofi's integrity initiative in that battle—if only they would cooperate and provide the requested data.

Covered entities have tried to force action from HHS on these matters because they cannot sue Sanofi directly under Section 340B. *See Astra*, 563 U.S. at 113–14. Section 340B instead permits covered entities to bring claims against manufacturers only through an administrative dispute resolution ("ADR") process that had yet to exist when, in late 2020, covered entities filed the *Ryan White Clinics* and *American*

Hospital Association cases. *See* 42 U.S.C. § 256b(d)(3)(A). But Section 340B explicitly required HHS to establish the ADR process by September 20, 2010—a deadline that HHS missed by *over a decade*. *See id.* As a result, in addition to attempting to compel enforcement action by HHS, covered entities also sought court orders forcing the agency to promulgate the long-overdue ADR regulations. *See Ryan White Clinics for 340B Access*, No. 1:20-cv-2906 (D.D.C.); *NACHC v. Azar*, No. 1:20-cv-03032 (D.D.C.). Moreover, certain plaintiffs filed motions for preliminary injunction seeking relief on an expedited basis. *See* Dkt. 24, *Ryan White Clinics for 340B Access*, No. 1:20-cv-2906 (D.D.C.) (filed Nov. 23, 2020); Dkt. 7, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal.) (filed Dec. 11, 2020).

V. HHS's Response to the Covered Entities' Litigation

With these lawsuits pending against HHS in multiple courts, and in the waning months of the Trump Administration, HHS quickly gave the covered entities what they were looking for in a one-two punch for drug manufacturers. Over the span of just a few weeks, HHS first rushed out a process for adjudicating covered entities' claims against drug manufacturers and then preordained the outcome of those claims against Sanofi and other manufacturers.

A. The ADR Rule

On December 14, 2020, HHS promulgated the ADR Rule, which took effect on January 13, 2021. *See* 340B Drug Pricing Program; Administrative Dispute

Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10) (the "Rule" or the "ADR Rule"). The ADR Rule purports to be authorized by Section 340B's requirement that HHS create an ADR process for the resolution of certain claims. *See* 42 U.S.C. § 256b(d)(3)(A). The ADR rule interprets the statute to authorize administrative resolution of (i) claims by covered entities that manufacturers have overcharged for drugs purchased under the 340B Program or limited covered entities' ability to purchase these drugs, and (ii) claims by manufacturers, after conducting an audit, that a covered entity has violated the prohibitions on duplicate discounts and diversion. As per Section 340B, these regulations also must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving [such] claims." *Id.* § 256b(d)(3)(B)(i).

The ADR Rule provides that the Secretary must establish an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HHS's agency the Health Resources and Services Administration ("HRSA"), the Centers for Medicare and Medicaid Services ("CMS"), and the HHS Office of the General Counsel. 85 Fed. Reg. at 80,644; 42 C.F.R. § 10.20. From this Board, the HRSA Administrator selects three-member panels with "relevant expertise and experience" to adjudicate claims. 85 Fed. Reg. at 80,644–645; 42 C.F.R. §§ 10.20, 10.21(c). Members can be removed from a panel only "for cause," and the only

grounds for removal identified by the ADR Rule are specified "conflicts of interests." 85 Fed. Reg. at 80,644; 42 C.F.R. § 10.20(a)(1)(ii), (2).

The ADR Rule vests the panel members with "wide latitude" and "significant discretion" to exercise substantial authority. 85 Fed. Reg. at 80,635–36. ADR panels have jurisdiction to resolve claims seeking "monetary damages" and "equitable relief," based on the determination of whether the parties violated Section 340B through overcharging, diversion, or duplicate discounting. *Id.* at 80,644–45; 42 C.F.R. § 10.21(a)–(c). And under the ADR Rule, "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636.

In exercising this authority, an ADR panel may "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," may issue instructions governing proceedings as "necessary or desirable," and may "determine the proper course" of each proceeding. *Id.* at 80,645; 42 C.F.R § 10.23; *see also* 85 Fed. Reg. at 80,636 (emphasizing that panels have "wide latitude" to define the "scope of the process" and "proper course of conduct"). Further, an ADR panel has "discretion in admitting evidence and testimony," may conduct "evidentiary

hearing[s]," and may "in its sole judgment request additional information from the parties." 85 Fed. Reg. at 80,636, 80,641, 80,645; 42 C.F.R. §§ 10.22(b), 10.23(a). Like federal courts, the panel employs the Federal Rules of Civil Procedure and Evidence. 85 Fed. Reg. at 80,641, 80,645; 42 C.F.R. § 10.23(b)–(c). And if the panel finds that a party did not adequately comply with its requests, the panel may impose formidable sanctions. 85 Fed. Reg. at 80,645; 42 C.F.R § 10.22(c) (authorizing panel to exclude evidence, preclude a party from presenting or contesting a particular issue, or even enter judgment as a sanction).

Notably, the ADR panel's decision is HHS's last word on the parties' claims. When promulgating the ADR Rule, HHS expressly declined to "incorporate an [administrative] appeals process," 85 Fed. Reg. at 80,641, and instead the Rule provides that each panel decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id.* at 80,646; 42 C.F.R. § 10.24(d); *see also* 85 Fed. Reg. at 80,644; 42 C.F.R. § 10.20 (ADR panels "make precedential and binding final agency decisions"); 42 U.S.C. § 256b(d)(3)(C) (stating that the "administrative resolution" of 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").

As a binding legislative rule, the ADR Rule needed to comply with the notice-and-comment requirement of the Administrative Procedure Act ("APA"). 5 U.S.C.

§ 553; *Dia Navigation Co. v. Pomeroy*, 34 F.3d 1255, 1264–65 (3d Cir. 1994). But in its rush to issue regulations in the face of the covered entities' pending litigation, HHS chose not to solicit comments on the ADR Rule before finalizing it. Instead, HHS decided that the ADR Rule was covered by an *earlier* notice-and-comment period on a different ADR rule that was proposed in 2016—but withdrawn in 2017, after the change in administration. *See* 85 Fed. Reg. at 80,633.

B. The Advisory Opinion

HHS's work was not done with the promulgation of the ADR Rule. Again, covered entities were separately insisting in litigation against HHS that Sanofi and other manufacturers were improperly refusing to provide 340B-priced drugs to contract pharmacies.

On December 30, 2020—less than three weeks after the ADR Rule was promulgated—HHS made its next move, when its Office of General Counsel issued Advisory Opinion 20-06. *See* Advisory Opinion at 1. The Advisory Opinion—which, again, did not go through the APA's notice-and-comment process—effectively dooms Sanofi's integrity initiative within the ADR process, without ever giving Sanofi an opportunity to defend its program.

In the Advisory Opinion, HHS concludes (for the first time) that drug manufacturers have a legal obligation to provide 340B-priced drugs to contract pharmacies—notwithstanding the widespread recognition (including by HHS itself) of

waste and abuse at contract pharmacies. In particular, HHS "conclude[d] 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 340B-priced drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." *Id.* at 1, 8. The Advisory Opinion even prohibits manufacturers from imposing conditions on the delivery of discounted drugs to contract pharmacies based on concerns about duplicate discounting or diversion. *Id.* at 5.

Covered entities promptly seized on the Advisory Opinion to challenge Sanofi's integrity initiative. Literally the day the ADR Rule took effect, an association of 328 covered entities filed an ADR complaint against Sanofi and other manufacturers that invoked the Advisory Opinion. *See* Ex. 6, Dep't of Health and Human Servs. Administrative Dispute Resolution Panel Petition No. 210112-2. The complaint even seeks a preliminary injunction enjoining Sanofi from operating its integrity initiative. *See id.* at 14–15; Ex. 7, Motion for Preliminary Injunction. Sanofi also received a notification from HRSA that it must "file a written response to the petition as set forth in Rule 12 or 56 of the Federal Rules of Civil Procedure." Ex. 8, E-mail from HRSA to C. Lee. But the members of the ADR Panel have not yet been named, nor has there otherwise been any substantive activity in this ADR proceeding against Sanofi. Sanofi has also received other threats of further litigation, but no

other ADR proceedings have been filed against it. *See* Ex. 9, Letter from T. Nova to J. Jehnke (Oct. 6, 2020); Ex. 10, Letter from W. Schultz to C. Lee (Jan. 7, 2021); Ex. 11, Letter from Jamestown S'Klallam Tribe (Jan. 19, 2021).

VI. Procedural History

On January 12, 2021—the day before the ADR Rule took effect—Sanofi filed this action against HHS, HRSA, and the HHS General Counsel (Dkt. 1). On February 2, 2021, Sanofi filed the operative amended complaint (Dkt. 17).

The amended complaint asserts nine claims challenging the ADR Rule and the Advisory Opinion under the U.S. Constitution and the APA. The only claims relevant here are the allegations that the ADR Rule violates Articles II and III of the Constitution. Based on these claims, Sanofi now moves to preliminarily enjoin HHS from implementing or enforcing the ADR Rule.

ARGUMENT

A "court ruling on a motion for a preliminary injunction must consider: (1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting the preliminary relief will be in the public interest." *Am. Express Travel Related Servs. Co. v. Sidamon-Eristoff*, 755 F. Supp. 2d 556, 573 (D.N.J. 2010) (Wolfson, J.).

All four factors here weigh in favor of a preliminary injunction. Sanofi is likely to prevail on the merits of its claims that the ADR Rule violates Article II and Article III of the Constitution. Requiring Sanofi to defend claims before an unconstitutional panel imposes irreparable injury, and imminently, as Sanofi has already been served with a complaint seeking preliminary injunctive relief under the ADR Rule, with more ADR complaints to come. And the remaining factors counsel in favor of an injunction as well, because the government and the public have no interest in the enforcement of an unconstitutional regulation like the ADR Rule.

I. Sanofi Is Likely to Succeed on the Merits in Challenging the ADR Rule.

Sanofi is likely to succeed on the merits of its claims challenging the ADR Rule under Article II and Article III of the Constitution. By virtue of their sweeping authority, broad discretion, and removal protection, the ADR panelists are principal officers of the United States who—per the Appointments Clause of Article II—must be appointed by the President with the advice and consent of the Senate. The ADR Rule also impermissibly allows agency bureaucrats to adjudicate private disputes over manufacturers' common-law rights—and to award money damages and equitable relief, to boot. The Constitution reserves those powers exclusively to Article III courts.

A. The ADR Rule Violates Article II of the Constitution.

Article II of the Constitution requires principal officers of the United States to be appointed by the President with the advice and consent of the Senate. *See* U.S. Const. art. II, § 2, cl. 2 ("[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint … Officers of the United States."). Only inferior officers may be appointed by the President alone or by the head of an Executive Department. *See id.* ("[B]ut the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments."); *Edmond v. United States*, 520 U.S. 651, 659–60 (1997).

Because ADR panelists exercise sweeping authority with broad discretion, they are officers of the United States under the Appointments Clause. And because their decisions are not subject to review by any superior within the Executive Branch, ADR panelists are also *principal* officers. Yet under the ADR Rule, panelists are neither appointed by the President nor confirmed by the Senate. Instead, ADR panelists are appointed by the HHS Secretary and assigned to panels by the HRSA Administrator. *See* 42 C.F.R. § 10.20. Sanofi is thus likely to succeed on the merits of its claim that this scheme violates the Appointments Clause.

1. ADR Panelists Are "Officers of the United States" Under Article II.

ADR panelists are without question "Officers of the United States" subject to the Appointments Clause. *See* U.S. Const. art. II, § 2, cl. 2. Two characteristics define a constitutional officer. *First*, officers "occupy a 'continuing' position established by law," not an "occasional or temporary" appointment. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (quoting *United States v. Germaine*, 99 U.S. 508, 511 (1878)). *Second*, officers exercise "significant authority pursuant to the laws of the United States." *Id.* (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam)).

The ADR panelists satisfy both requirements for "officer" status. *First*, they occupy a continuing office established by both statute and regulation. Congress directed the Secretary to promulgate regulations designating "a decision-making official or decision-making body" to adjudicate claims between manufacturers and covered entities. *See* 42 U.S.C. § 256b(d)(3)(B)(i). And the Secretary did just that in the ADR Rule. *See* 85 Fed. Reg. at 80,644; 42 U.S.C. § 10.20. Neither provision for the panelists' appointment includes any tenure limitation. Indeed, the ADR Rule itself compares ADR panelists to federal court of appeals judges. *See* 85 Fed. Reg. at 80,634.

Second, the ADR panelists exercise precisely the complement of powers that the Supreme Court has held amount to "significant authority" under Article II, because the panelists have "all the authority needed to ensure fair and orderly adversarial

hearings—indeed, nearly all the tools of federal trial judges." *Lucia*, 138 S. Ct. at 2051; *see also Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868 (1991). Under the ADR Rule, panelists exercise "significant discretion in determining relevant material to consider and the manner to conduct its evaluation," with "wide latitude" and "discretion in admitting evidence and testimony." 85 Fed. Reg. at 80,635, 80,636, 80,640–42. They conduct "evidentiary hearing[s] when there are material facts in dispute" and may sanction parties by "[e]xcluding evidence" or dismissing a proceeding. *Id.* at 80,645; 42 C.F.R. § 10.22(c), 10.23(a). And their decisions are precedential and binding on the parties. 85 Fed. Reg. at 80,634. Lest there be any doubt that ADR panelists are functionally equivalent to "federal trial judges," *Lucia*, 138 S. Ct. at 2051, the ADR proceedings are presumptively governed by the Federal Rules of Civil Procedure and the Federal Rules of Evidence. 85 Fed. Reg. at 80,633, 80,641, 80,645; 42 C.F.R. § 10.23(b)–(c). Because they unquestionably exercise "significant authority" as defined by the Supreme Court, the ADR panelists are officers of the United States.

2. ADR Panelists Are Principal Officers of the United States.

So too ADR panelists are *principal* officers of the United States. "'[I]nferior officers' are officers 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." *Edmond*, 520 U.S. at 663, 664–65 (holding Coast Guard Court of Criminal Appeals judges to be inferior officers because "another Executive Branch entity, the

Court of Appeals for the Armed Forces," exercises "control" over them); *Free Enter. Fund v. Public Co. Acct. Oversight Bd.*, 561 U.S. 477, 486, 510 (2010) (concluding members of the PCAOB are inferior officers because the SEC exercises "oversight authority" over their decisions). Principal officers, by contrast, answer to no superior Executive Branch officer but the President. *See Ass'n of Am. R.R. v. Dep't of Transp.*, 821 F.3d 19, 39 (D.C. Cir. 2016) (holding that Surface Transportation Board arbitrators are principal officers solely because their decisions were not reviewable by the Board).

The ADR panelists are principal officers because their decisions are not subject to oversight or review by any superior Executive Branch officer. Under the ADR Rule, a panel decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 85 Fed. Reg. at 80,641, 80,646; 42 C.F.R. § 10.24(d). That decision is not subject to review by the Secretary or any other agency actor. Indeed, HHS explicitly declined to "incorporate an [administrative] appeals process" in the ADR Rule. 85 Fed. Reg. at 80,641. Given this lack of oversight, the "inescapable" conclusion is that the ADR panelists are principal officers. *Ass'n of Am. R.R.*, 821 F.3d at 39; *cf. Pa. Dep't of Pub. Welfare v. HHS*, 80 F.3d 796, 803–04 (3d Cir. 1996) (holding that officials appointed under the Child Support Enforcement Act whose

powers were "strictly limited by the statute and implementing regulations," and who were subject to oversight of a Senate-confirmed official, were inferior officers).

Nor are the ADR panelists removable at will—another hallmark of their status as principal officers. The "'power to remove officers" is a "powerful tool for control" that characterizes principal officers' authority over inferior officers. *Edmond*, 520 U.S. at 664; *Free Enter. Fund*, 561 U.S. at 510; *Pa. Dep't of Pub. Welfare*, 80 F.3d at 803 (holding Appeals Board members were inferior officers in part because they were removable by a superior Executive officer, including for "unacceptable performance"). Indeed, even when officials are subject to supervisory oversight from Senate-confirmed officials, limits on the officials' removal can render them principal officers who must themselves be Senate-confirmed under Article II. *See, e.g.*, *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1335 (Fed. Cir. 2019), *cert. granted*, 141 S. Ct. 551 (2020).

But the ADR panelists are subject to no such control. Their responsibility for "*finally* resolving claims by covered entities" is prescribed by statute, meaning the Secretary cannot abridge their authority. 42 U.S.C. § 256b(d)(3)(B)(i) (emphasis added); *cf. Pa. Dep't of Pub. Welfare*, 80 F.3d at 803 (explaining that Appeals Board members were inferior officers because "the Secretary could altogether eliminate the powers of the Board that are at issue here"). And the ADR Rule provides that a panelist may be removed only "for cause," which the rule defines as a panelist having

a conflict of interest. *See* 85 Fed. Reg. at 80,644; 42 C.F.R. § 10.20(a); *see also* 85 Fed. Reg. at 80,634 ("HHS proposed that individuals serving on a 340B ADR Panel may be removed for cause. … In this final rule, if there is a conflict of interest, as described in paragraph (b), with respect to a claim, the 340B ADR Panel member will be removed from the 340B ADR Panel and replaced by another individual from the Board.").

In short, because the ADR panelists' decisions are subject to review only by Article III courts and, further, are not subject to review by a Senate-confirmed principal officer, and because the ADR panelists are not even removable except for cause, the ADR panelists must themselves be appointed by the President and confirmed by the Senate. By not requiring this, the ADR Rule violates Article II.

B. The ADR Rule Violates Article III of the Constitution.

The ADR Rule also violates Article III of the Constitution by authorizing the ADR Panel to adjudicate private rights, including by entering injunctive relief commanding the conveyance of property and awarding money damages. Article III vests the judicial power of the United States in "one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." U.S. Const. art. III, § 1. A statute or regulation is unconstitutional if it "confer[s] the Government's 'judicial Power' on entities outside Article III," such as Executive Branch officers like the ADR panelists. *Stern v. Marshall*, 564 U.S. 462, 484 (2011). As

the Supreme Court has explained, "[w]hen a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789, and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts." *Id.* (internal citations and quotation marks omitted).

Congress does, to be sure, have "significant latitude to assign adjudication of public rights, " *i.e.*, those held by the entire community or involving disputes between the government and a private party, "to entities other than Article III courts." *Oil States Energy Servs., LLC v. Geene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018); *see also Stern*, 564 U.S. at 491 (describing "public rights" as "'rights' against the Government"). But Congress has no such authority with respect to private rights, which are rights "between private parties." *Stern*, 564 U.S. at 491. Private rights, such as freedom of contract and the right to hold and transfer private property, "lie at the core of the historically recognized judicial power." *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 70 (1982) (plurality op.); *see also Ortiz v. United States*, 138 S. Ct. 2165, 2185 (2018) (Thomas, J., concurring) (describing "life, liberty, and property" as "[t]he three classic private rights"); *Newland v. Marsh*, 19 Ill. 376, 383 (1857) ("The legislative power … cannot directly reach the property or vested rights of the citizen, by providing for their forfeiture or transfer to another, without trial and judgment in the courts.").

The ADR Rule authorizes agency adjudication of private contract and property rights reserved under the Constitution to Article III courts. For example, as this case shows, the ADR Rule empowers an administrative panel to resolve a dispute between private parties—Sanofi and covered entities—over whether Sanofi must provide its property to a third party (a contract pharmacy) at a discounted price over Sanofi's objection as well as all issues underlying any claim or defense. These are "matter[s] which, from [their] nature, [are] the subject of a suit at the common law." *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1855). And that is true even though a covered entity's entitlement to a discount is established by a federal statute. *See Stern*, 564 U.S. at 488 (holding that a bankruptcy court cannot adjudicate state-law counterclaims, even when they arise out of proceedings under the federal bankruptcy code).

Moreover, the private rights the ADR panel will determine do not "derive[] from a federal regulatory scheme." *Id.* at 490. Sanofi has an underlying right to compensation in the absence of Section 340B (and, indeed, in the absence of federal law altogether). *See id.* at 491 (explaining that administrative panel at issue in *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985), "did not violate Article III" because "'[a]ny right to compensation … results from [the statute] and does not depend on or replace a right to such compensation under state law'"). Nor does it matter that Sanofi's distribution of drugs is subject to federal regulation. Indeed, the

ADR Rule forthrightly acknowledges that "the 340B ADR Panels are more 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. In short, the ADR Rule authorizes an administrative panel to determine whether and how Section 340B abridges Sanofi's common-law rights to sell its property and to contract freely with third parties, which is something that only an Article III court can do.

The ADR Rule also violates Article III because ADR panels "exercise[] the range of jurisdiction and powers normally vested only in Article III courts." *CFTC v. Schor*, 478 U.S. 833, 851 (1986). As explained, ADR panels have the 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. *See supra* pp. 12–13. These powers exceed the scope of administrative review schemes the Supreme Court has approved. *See, e.g*, *Schor*, 478 U.S. at 853 ("CFTC orders … are enforceable only by order of the district court."). Indeed, plaintiffs have already asked the ADR panel to issue a preliminary injunction against Sanofi, illustrating that the panel's authority mimics the federal courts'. And in light of their independent powers, the ADR panels can hardly be described as an "adjunct" of an Article III court. *Stern*, 564 U.S. at 500.

Sanofi has not consented to this scheme. *Cf. Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1939 (2015) ("Article III is not violated when the parties knowingly and voluntarily consent to adjudication by a bankruptcy judge," a non-Article III judge). Submitting to ADR panels and compliance with their orders as a condition of Medicare participation is hardly a voluntary choice. *See, e.g.*, *Stern*, 564 U.S. at 493 (holding consent was absent where party "had nowhere else to go if he wished to recover from [the] estate."). Moreover, Sanofi entered into the 340B Program before the ADR Rule was promulgated. Nor has Sanofi consented to the conclusion the ADR panels will ultimately reach—that it is required to provide 340B-discounted drugs to contract pharmacies without imposing any conditions, even reasonable ones—where it has challenged that conclusion in this very lawsuit.

By empowering ADR panels to require manufacturers like Sanofi to transfer their property to contract pharmacies at an extraordinary loss and giving those panels the power to enforce their decisions through orders conveying money damages and prescribing injunctive relief, the ADR Rule confers the judicial power on Executive Branch officers in violation of Article III. Sanofi is likely to succeed on the merits of this claim.

II. Sanofi Will Suffer Irreparable Injury From the ADR Rule Absent an Injunction.

Absent an injunction, Sanofi will suffer irreparable injury as a result of the ADR Rule's unconstitutional features. "Harm is presumed" for a violation of the

Constitution's structural protections (such as Article III and the Appointments Clause), because those provisions "safeguard[]" "individual liberty." *Cirko ex rel. Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 154 (3d Cir. 2020) (presuming plaintiff suffered harm as a result of alleged Appointments Clause violation); *see also Bond v. United States*, 564 U.S. 211, 222 (2011) ("Separation-of-powers principles … protect the individual."). And because the Constitution's structural protections safeguard individual rights, a violation of those protections—such as "subjection to an unconstitutionally constituted decision-maker"—is "in itself a constitutional injury sufficient to warrant injunctive relief." *United Church of the Med. Ctr. v. Med. Ctr. Comm'n*, 689 F.2d 693, 701 (7th Cir. 1982); *see also Valley v. Rapides Parish Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (holding reputational injury, "not to mention the egregious and constitutionally infirm hearing [plaintiff] was subject to, sufficient to satisfy irreparable injury"); *Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cnty.*, 893 F. Supp. 301, 309 (D.N.J. 1995) (holding "a violation of rights under the dormant Commerce Clause constitutes the 'irreparable harm' necessary for a plaintiff to avoid denial of a preliminary injunction").

When a party is haled before an unconstitutional tribunal, "[t]he injury is submission itself; the [tribunal's] decision may also result in injury, but it is a separate, distinct one." *Hammond v. Baldwin*, 866 F.2d 172, 177 (6th Cir. 1989). Indeed, Sanofi may in the future suffer significant financial and other injury as a result of ADR panel

decisions, and it could separately challenge the merits of those decisions. But in the meantime, being forced to submit to unconstitutional proceedings itself imposes irreparable injury by depriving Sanofi of the liberty interests that the Constitution's structural provisions protect. *See United Church of the Med. Ctr.*, 689 F.2d at 701; *Ironridge Glob. IV, Ltd. v. SEC*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015) (holding in Appointments Clause case that "Plaintiffs will be irreparably harmed if this injunction does not issue because if the SEC is not enjoined, Plaintiffs will be subject to an unconstitutional administrative proceeding").

Moreover, Sanofi's injury is imminent, because its irreparable constitutional injuries "will occur before a trial on the merits can be had" in this action. *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000). Sanofi has already been served with a complaint under the ADR Rule. *See supra* p. 15. That complaint asks the ADR panel to grant a preliminary injunction against Sanofi. Given that HRSA has already indicated that Sanofi will need to respond to the pending petition, that proceeding will commence as soon as HHS and HRSA give the signal, which could literally happen tomorrow. More ADR complaints against Sanofi are sure to follow. Indeed, Sanofi has already received threats of further litigation. *See* Exs. 4–7. Plus, Sanofi additionally faces the threat of HHS enforcement action, including the threat of crippling civil monetary penalties and the potential loss of its ability to participate in Medicare through termination of its PPA, if it refuses to

comply with the ADR panel's decision. *See* 42 U.S.C. § 256b(d)(1)(B)(vi) (authorizing HHS to impose civil monetary penalties in the amount of $5,000 per day); *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614 (noting "threat of prosecution" in finding irreparable harm).

Sanofi's injury is especially severe because the results of the unconstitutional ADR proceedings are effectively preordained. The Advisory Opinion has already held—without Sanofi ever having had a chance to defend itself—that Sanofi may not impose conditions on the provision of 340B-priced drugs to contract pharmacies. *See* Advisory Opinion at 2, 5. And ADR panels will undoubtedly follow the Advisory Opinion. The panels exclusively consist of HHS officials advised by the Office of General Counsel, which issued Advisory Opinion. *See supra* p. 18; Advisory Opinion at 8 n.10 (invoking HHS's Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 54,581-02, 54,583 (Sept. 2, 2020), under which the Office of General Counsel provides "all legal services and advice" to "all offices" within HHS). And the ADR panelists in any given case will be hand-selected by the HRSA Administrator, predisposing them to follow the agency's preferred path. 85 Fed. Reg. at 80,644–45; 42 C.F.R. §§ 10.20, 10.21(c). Thus, the ADR panel not only flouts bedrock constraints on its composition and authority but can be reliably expected to rule against Sanofi no matter what evidence or arguments are presented. *See Hope v. Warden York Cty. Prison*, 972 F.3d 310, 320 (3d Cir. 2020) (explaining that

"fundamental" fairness requires a meaningful "opportunity to be heard" (quoting *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972)); *Neal v. Sec'y of Navy*, 639 F.2d 1029, 1044 (3d Cir. 1981) (recognizing that "'one-sided determination[s]'" inflict "injustice" and deny "'fairness'" (quoting *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 170 (1951) (Frankfurter, J., concurring))).

The government's sovereign immunity only underscores the irreparable nature of Sanofi's injuries. No matter what damages Sanofi incurs in defending itself before the ADR panel or complying with the ADR panel's orders—all under a cloud of constitutional doubt—it cannot recover a dime from the government. "[E]conomic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend to damages claims." *Dist. of Columbia v. Dep't of Agric.*, 444 F. Supp. 3d 1, 34 (D.D.C. 2020); *see* 5 U.S.C. § 702 (waiving sovereign immunity under the Administrative Procedure Act only where the plaintiff is "seeking relief other than money damages"). Such harm is irreparable by definition. *See Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614, *aff'd*, *N.J. Retail Merchs. Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (affirming preliminary injunction where plaintiffs "would not be entitled" to recover funds from the government if a law "is later found to be unconstitutional" due to sovereign immunity).

III. The Equities Favor a Preliminary Injunction.

Finally, the equities favor a preliminary injunction. The government's interests and the public interest "merge when the government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Because the ADR Rule is unlawful, the equities straightforwardly favor Sanofi. As this Court has itself stated, "in the context of a motion for preliminary injunction, the Government does not have an interest in the enforcement of an unconstitutional law, and the public interest is not served by the enforcement of an unconstitutional law." *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614–15; *see also N.J. Retail Merchs. Ass'n*, 669 F.3d at 388–89. That is true even when the unconstitutional law purports to advance the public interest. *See, e.g.*, *Am. Civil Liberties Union v. Ashcroft*, 322 F.3d 240, 247 (3d Cir. 2003) (affirming preliminary injunction against enforcement of the Child Online Protection Act as overbroad and noting district court's conclusion that the "the Government does not have an interest in the enforcement of an unconstitutional law"). Sanofi stands to suffer irreparable harm if the ADR Rule is not enjoined, but enforcing the ADR Rule will serve no public interest. The equities thus support Sanofi's request for preliminary injunctive relief.

CONCLUSION

For the reasons explained, the Court should grant Sanofi's motion for a preliminary injunction.

Dated: February 2, 2021

Respectfully submitted,

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