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, *et al.*, *Defendants.*

Civil Action No. 3:21-cv-634

Motion Date: March 19, 2021

Oral argument requested

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The government is eager to smear Sanofi in this case—accusing Sanofi of halting the shipment of covered drugs to contract pharmacies in a "brazen" attempt to upend the 340B Program. But Sanofi has done no such thing. Sanofi still ships 340B-priced drugs to contract pharmacies, so long as covered entities provide minimal, anonymized claims data (that already goes to insurers). Contrary to what the government says, this is not remotely "onerous"—and even the government does not dispute that Sanofi's program can stop the difficult-to-detect problem of duplicate discounting, which Section 340B expressly prohibits (yet HHS has done little about).

If anyone has disrupted the 340B Program here, it is the government. For a decade, HHS flouted Congress's mandate to promulgate ADR procedures. During that time, HHS did nothing to address the abuse of the 340B Program that has resulted from the proliferation of contract pharmacies, which are sometimes thousands of miles away from the covered entity they purport to serve. HHS then rushed to finalize the ADR Rule at the end of the Trump Administration in the face of political and litigation pressure. And now, before this Court, the government's invective confirms Sanofi's well-grounded fear that the ADR Rule prescribes a faux judicial process designed to punish drug manufacturers.

All that is before this Court now is the constitutionality of the ADR Rule—and the government's opposition confirms that the ADR Rule violates Article II and

Article III. By insisting otherwise, the government paints the ADR panelists as a toothless band of junior officials subject to the Secretary's careful oversight. But that is not the rule that HHS wrote. ADR panelists impermissibly exercise the authority of principal officers under Article II, because they issue final agency decisions without supervision or review and are not removable at will. And ADR panelists exercise powers reserved to federal courts under Article III because they issue final judgments, including for money damages and injunctive relief, in disputes over private, common-law rights. Because these constitutional violations cause Sanofi irreparable harm, the ADR Rule should be enjoined.

ARGUMENT

The Court should grant Sanofi's motion because: (1) Sanofi's constitutional claims are likely to succeed on the merits; (2) Sanofi will suffer irreparable harm from an unconstitutional ADR proceeding; and (3) the equities favor an injunction.

I. Sanofi Is Likely to Succeed on the Merits.

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

Sanofi is likely to succeed on its claim that the ADR Rule violates Article II. Under the ADR Rule, panelists make significant final decisions for the Executive Branch, but they are subject *neither* to a superior officer's substantive direction and correction *nor* to the threat of removal at will. These two facts distinguish this case from each of the government's cases and compel the conclusion that ADR panelists

are principal officers under the Appointments Clause who must therefore be presidentially appointed and Senate-confirmed.

1. The ADR Panelists Make Significant Final Decisions.

As an initial matter, the ADR Rule plainly empowers panelists to make significant final decisions for the Executive Branch. Under Section 340B and the ADR Rule, ADR panelists are authorized to "render a final decision on behalf of the United States"—the hallmark of principal-officer status. *Edmond v. United States*, 520 U.S. 651, 665 (1997). The government does not and could not contest that ADR panelists' decisions speak for the Executive Branch as "final agency decision[s]" that are "binding on the parties" and "precedential" within HHS, including for the Secretary himself. 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d); 85 Fed. Reg. 80,632, 80,641, 80,646 (Dec. 14, 2020). Nor does the government dispute that the Secretary delegated "wide" and "significant" "discretion" and "latitude" to ADR panelists, 85 Fed Reg. at 80,635–36, 80,640, including the power to decide "all issues underlying any claim or defense," 85 Fed Reg. at 80,636. "[T]he nature, scope, and duration" of the ADR panelists' sweeping and continuing authority confirms that they are principal officers—and, in turn, not properly appointed under Article II. *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2199 n.3 (2020) (quoting *Edmond*, 520 U.S. at 661, 663); PI Mem. 20–21.

Notwithstanding its concession that ADR panelists make significant final

decisions, the government responds that the panelists are not principal officers because they are subject to supervision and removable at will. Both points are wrong.

2. The ADR Panelists Are Not Subject to Supervision.

ADR panelists make final decisions for the Executive Branch without any review by superior officers. HHS explicitly rejected any internal appeals process when enacting the ADR Rule. *See* 85 Fed. Reg. at 80,641. And the ADR Rule states that panel decisions can only be "invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d).

This critical feature of the ADR Rule distinguishes this case from *Edmond*, which the government repeatedly trumpets. In *Edmond*, the Supreme Court held that Coast Guard judges were inferior officers precisely because their decisions were subject to review by superior officers. *See* 520 U.S. at 665. And *Edmond* makes plain—in a point the government buries in a footnote, *see* Opp. 15 n.5—that supervision of an inferior officer is "not complete" without review by a superior Executive Branch officer. 520 U.S. at 664. Indeed, the *Edmond* Court emphasized how "significant" it was "that the judges [at issue] have no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Id.* at 665. Not so here. The ADR panelists' decisions are "final agency action" from the moment of issuance, with no Executive Branch review whatsoever.

The government's attempts to avoid this straightforward conclusion under

Edmond fall flat. Many courts, including the Supreme Court, have confirmed after *Edmond*—including in cases the government invokes—that Executive Branch review is critical to inferior officer status. In *Free Enterprise Fund v. PCAOB*, the Supreme Court held that board members were inferior officers because the Executive Branch's "oversight authority" included the power to "approv[e] and alter[]" their decisions. 561 U.S. 477, 486, 510 (2010). In *Association of American Railroads v. Department of Transportation*, the D.C. Circuit held that Surface Transportation Board arbitrators were principal officers because the relevant statute did not "provide any procedure by which the arbitrator's decision [was] reviewable by the STB." 821 F.3d 19, 39 (D.C. Cir. 2016); *see* Opp. 20 n.6. And in *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board*, the D.C. Circuit held that regulations made copyright royalty judges "principal officers" because, "unlike the judges in *Edmond*," their determinations were "final for the executive branch." 684 F.3d 1332, 1340 (D.C. Cir. 2012). Most recently, in *Fleming v. Department of Agriculture*, *see* Opp. 17, the D.C. Circuit treated ALJs as inferior officers because the Secretary of Agriculture could "step in and act as [a] final appeals officer in any case." No. 17-1246, 2021 WL 560743, at *8 (D.C. Cir. Feb. 16, 2021).

None of these limitations apply to the ADR panelists. No Executive official can step in and take over their role in a particular case (unlike in *Fleming*). No Executive official can "alter" their decisions (unlike in *Free Enterprise Fund*). Their

decisions are not "reviewable" within the agency (as in *Association of American Railroads*). Instead, as in *Intercollegiate Broadcasting*, the ADR panelists' decisions are "final for the executive branch," and the panelists thus are "principal officers." 684 F.3d at 1340. Indeed, in *Intercollegiate Broadcasting*, the D.C. Circuit so concluded even though the Register of Copyrights could "review[] and correct[] any legal errors" in the judges' determinations—review unavailable under the ADR Rule. *Id.* at 1338–39.

Nor does any officer supervise or direct the ADR panelists' adjudication of ADR claims. ADR panels instead "determine, in [their] own discretion, the most efficient and practical form of the ADR proceeding." 42 C.F.R. § 10.23(a)–(b). And the ADR Rule does not direct the substance of the panels' decisions. *See Intercollegiate Broad.*, 684 F.3d at 1388 (finding Article II violation when a supervising officer had no "room to play an influential role in the CRJs' substantive decisions"). Indeed, under Section 340B, the Secretary lacks authority to promulgate substantive rules governing the ADR process. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014). The ADR panelists are thus singularly responsible for the substance of their decisions.

This lack of supervision sets this case apart from *Pennsylvania v. HHS*, 80 F.3d 796 (3d Cir. 1996), which the government invokes. *See* Opp. 16. There, the officers' substantive authority (to review funding disallowances under the Child Support Enforcement Act) was "strictly limited by the statute and implementing regulations."

80 F.3d at 804 (citing 45 C.F.R. §§ 16.14, 205.40–205.43). Those regulations, since repealed, prescribed "the rules and procedures for calculating [relevant] error rates and for disallowing" federal payments, 45 C.F.R. § 205.43(a) (1995); procedures for reviewing cases, *id.* § 205.42(c); and substantive direction, including on the types of payments that would count as errors, *id.* § 205.42(d). The regulations also expressly required the officers to adopt certain decisions made by a separate HHS panel or by the Secretary. *Id.* § 205.43(g)(1).[1] With the officials' hands so tied, the Third Circuit held that they were inferior officers. To instead read *Pennsylvania* as the government does—to permit inferior officers to take final Executive Branch action even absent these supervisory controls or at-will removal, *see* Opp. 18–19—would run contrary to the Supreme Court's subsequent decisions in *Edmond* and *Free Enterprise Fund*, as well as the D.C. Circuit's decisions described above.

3. The ADR Panelists Are Not Removable at Will.

The ADR Rule also provides that "individuals serving on a 340B ADR Panel may be removed for cause." 85 Fed. Reg. at 80,634. This constraint on removal is a further reason that the ADR panelists are principal officers. *See Edmond*, 520 U.S. at

[1] Indeed, in light of these restrictions, the parties stipulated that the "Board members," who were "bound by all applicable laws and regulations" of the Department and subject to the supervision of the Under Secretary, were not in "policy-making positions." *See* Appellees' Br., *Pennsylvania*, 80 F.3d 796 (No. 94-3692), 1994 WL 16166965, at *20 (citing 45 C.F.R. § 16.14); Statement of Organization, Functions, and Delegations of Authority, 53 Fed. Reg. 38,977-03, 38,977–78 (Oct. 4, 1988) (providing for the Appeals Board to be "supervised by the Under Secretary").

664 (at-will removal supports inferior officer status).

The government disagrees, asserting that "the relevant consideration for constitutional purposes" is removal "*from the Board* altogether." Opp. 20. But the government cites no authority for this proposition. And the ADR Rule limits removal in the only context in which ADR panelists exercise any authority—their service on ADR panels. *See* PI Mem. 22–23; 42 C.F.R. § 10.20(a)(1)(ii), (2).

Not to worry, the government says, because the Secretary may "remove an individual from a panel" at will. Opp. 21. But that contradicts both the text of the ADR Rule and basic principles of officer removal. Any removal power that might be "incident to the power of appointment," *id.* at 20, belongs to the individual that appointed the ADR panelists: the HRSA Administrator, not the Secretary. *See* 42 C.F.R. § 10.20(a)(1). And by authorizing one method for removing a panelist—for the HRSA Administrator to do so, but only for cause—the ADR Rule reserves no residual removal authority in the Secretary. *See Travelers Indem. Co. of Ill. v. DiBartolo*, 171 F.3d 168, 171–72 (3d Cir. 1999) (applying *expressio unius* canon to regulation).

4. The Secretary Cannot Cure the Article II Violation.

The Secretary cannot cure the ADR Rule's Article II problem by simply acting to "eliminate the powers of the [ADR panelists] that are at issue here," such as by deciding claims himself. *Pennsylvania*, 80 F.3d at 803; Opp. 16, 21. That is not an option because Section 340B charges ADR panelists with "*finally* resolving claims by

covered entities." 42 U.S.C. § 256b(d)(3)(B)(i) (emphasis added). Similarly, the ADR Rule requires cases to be decided by three panelists from HHS's operating divisions, with no option for the Secretary to step in. *See* 42 C.F.R. § 10.20(a)(1)(i). And, unlike the special-counsel regulations at issue in *In re Grand Jury Investigation*, 916 F.3d 1047, 1052 (D.C. Cir. 2019), *see* Opp. 18, which were personnel regulations exempt from the APA's notice-and-comment procedures, *see* 916 F.3d at 1052; 5 U.S.C. § 553(a)(2), the ADR Rule cannot be easily withdrawn and replaced. Section 340B requires an ADR process, which HHS cannot supply without "comply[ing] with the procedural requirements for new agency action." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1908 (2020).

Nor would eliminating the ADR Rule's removal constraints cure the Article II violation, given the ADR panelists' sweeping authority. This approach sufficed in *Intercollegiate Broadcasting*, but there another Executive official could "review[] and correct[]" the copyright royalty judges' decisions. 684 F.3d at 1338–39. Notably, the Supreme Court has never said that at-will removal alone is sufficient to classify an officer as inferior. Quite the opposite. In *Edmond*, the Judge Advocate General's authority to remove Coast Guard judges "without cause" *did not* suffice to make them inferior officers, because oversight was "not complete" without the "power to reverse decisions." 520 U.S. at 664. So too with the ADR panelists.

By insisting that the Secretary can "revise the regulation" to cure the ADR

Rule's Article II problem, Opp. 21, the government also violates basic principles of administrative law. The agency itself, not its lawyers later defending its action, must provide the justification on which a rule will stand or fall. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *W.R. Grace & Co. v. EPA*, 261 F.3d 330, 338 (3d Cir. 2001).

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In sum, the government offers no case excusing Presidential appointment and Senate approval for an officer who is subject *neither* to Executive supervision or review *nor* to removal at will by a principal officer. This Court should not be the first.

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

Sanofi is also likely to succeed on its claim that the ADR Rule violates Article III. The government does not dispute that Article III bars agencies from exercising judicial power over disputes concerning private rights. Opp. 25–27. ADR panels do just that, resolving "action[s]" for "monetary damages or equitable relief" concerning the core private, common-law rights of property and contract. 42 C.F.R. § 10.21(a). Article III courts must adjudicate such claims. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 55–56 (1989); *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1855); *see also Billing v. Ravin, Greenberg & Zackin, P.A.*, 22 F.3d 1242, 1246 (3d Cir. 1994) ("the right … to recover contract damages … is private"). To try to save the ADR Rule under Article III, the government responds that the ADR Panels (i) do not exercise judicial power, because they cannot award damages and

equitable relief, Opp. 23–25, and (ii) do not adjudicate private rights, *id.* at 25–30. Neither point is correct.

1. The ADR Panels Exercise Judicial Power.

The ADR Rule plainly authorizes ADR panels to exercise powers reserved to the judiciary—including the power to award damages and equitable relief. Under the ADR Rule, covered entities may initiate "an action for monetary damages or equitable relief against a manufacturer" by filing a petition for "damages" or "equitable relief." 42 C.F.R. § 10.21(a)–(c). And ADR panels shall "make precedential and binding final agency decisions regarding claims filed by covered entities." *Id.* § 10.20; *see also id.* § 10.21(b). These "claims" within the ADR panels' authority are unquestionably claims for damages and equitable relief—as another court has recognized. *See Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *3, *6 (N.D. Cal. Feb. 17, 2021). Indeed, an ADR panel has already been asked to "employ its equitable authority" to enter a "preliminary injunction" against Sanofi. PI Mem. Ex. 7.

The government, however, insists that the ADR panels are powerless to order such relief, and that panel decisions are not "self-effectuating," because the ADR Rule directs panels to "'submit'" their decisions "'to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.'" Opp. 23–24 (quoting 42 C.F.R. § 10.24(e)). The government reads this language to mean that an ADR panel can find liability but cannot impose any remedies.

But the ADR Rule empowers panels to adjudicate not simply questions of liability but rather "*action[s]* for monetary damages or equitable relief." 42 C.F.R. § 10.21(a) (emphasis added); *see id.* § 10.21(f); 85 Fed. Reg. at 80,635. Indeed, "[t]he ADR Rule repeatedly discusses the availability of equitable relief," *Am. Hosp. Ass'n*, 2021 WL 616323, at *6, and provides that ADR panels will resolve "proceeding[s] for damages," in which the petitioner must "introduce evidence sufficient to support its claim for damages," 42 C.F.R. § 10.21(f). These provisions would make no sense if ADR Panels were in fact powerless to award damages or equitable relief.

Attempting to give these provisions meaning, the government makes the puzzling assertion that the ADR Rule authorizes "equitable relief" solely so that a panel can "declare specified conduct to be unlawful—the equivalent of a cease-and-desist order." Opp. 24. But the ADR Rule authorizes not "declaratory relief" (as the government essentially argues) but "*equitable* relief" without limitation. 42 C.F.R. § 10.20, 10.21(a)–(b) (emphasis added). By definition, "equitable relief" includes "injunction[s]." Black's Law Dictionary (11th ed. 2019); *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993). The ADR Rule also adopts the Federal Rules of Civil Procedure, 42 C.F.R. § 10.23(b), which expressly authorize preliminary injunctions and restraining orders, Fed. R. Civ. P. 65. Unsurprisingly, the only court to have ruled on this question determined that the "equitable relief" "repeatedly discusse[d]" by the ADR Rule includes "forward-looking relief" (such as an injunction) and not simply

"retrospective remedies" (such as a determination that a manufacturer has violated the statute). *Am. Hosp. Ass'n*, 2021 WL 616323, at *6 (internal quotation marks omitted).[2]

Moreover, the ADR Rule does not say that panel decisions are "binding once approved by HRSA." Instead, they are "final agency decision[s]," 42 C.F.R. §§ 10.20, 10.24(d)—which means they are "the 'consummation' of the agency's decisionmaking process" and determine the parties' "rights or obligations." *Ocean Cnty. Landfill Corp. v. EPA*, 631 F.3d 652, 655 (3d Cir. 2011) (quotation omitted). ADR Panel decisions would not be "final" if a separate remedial phase needed to follow. *Cf. Marshak v. Treadwell*, 240 F.3d 184, 190 (3d Cir. 2001) ("A finding of liability that does not also specify damages is not a final decision.") (citation omitted).

Instead, under the ADR Rule, HRSA's role is limited to ordering *additional* remedies: "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," such as for civil monetary penalties. 42 C.F.R. § 10.24(e); *see* 85 Fed. Reg. at 80,642. The ADR Rule does not authorize HRSA to modify or nullify the binding and precedential final agency decisions already made by ADR panels, including decisions to award equitable relief and damages.

[2] Their remedial powers aside, the ADR panels also exercise other powers traditionally assigned to courts—they take evidence, hear testimony, apply the Federal Rules, and issue precedential decisions that bind private parties. These powers hardly make "no difference," Opp. 7, 25, but rather illustrate that ADR panels exercise Article III authority. *See CFTC v. Schor*, 478 U.S. 833, 851 (1986).

The text of the ADR Rule, then, simply does not line up with what the government now argues. Basic administrative law prohibits an agency from salvaging a regulation through "post hoc rationalizations" like this. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983); *see also Regents*, 140 S. Ct. at 1909 (discounting government's "convenient litigating position"); *Caruso v. Blockbuster-Sony Music Ent. Ctr.*, 193 F.3d 730, 737 (3d Cir. 1999).[3]

With all that said, even if the ADR Rule did give HRSA the powers that the government's brief describes, that still would not solve the Article III problem—because HRSA is not an Article III court. Splitting judicial power across different components of an agency does not make the constitutional defect go away.

2. The ADR Panels Adjudicate Disputes Over Private Rights.

The government also contends that the ADR panels' powers are appropriate under Article III because only public rights are at stake. Not so. Contrary to the government's claims, ADR panels adjudicate core common-law rights that are unquestionably private—namely, Sanofi's rights to hold and alienate the drugs it manufactures on terms of its choice. Indeed, the ADR Rule acknowledges that ADR panels will adjudicate rights arising out of "complex commercial arrangements between private actors." 85 Fed. Reg. at 80,635. HHS expressly rejected the

[3] If the ADR Rule truly means what the government now contends, HHS's failure to reasonably and clearly explain the ADR Panel's powers is arbitrary and capricious. *See Christ the King Manor, Inc. v. HHS*, 730 F.3d 291, 305 (3d Cir. 2013).

established method of resolving disputed public rights—Administrative Law Judges who "resolve disputes between the Department and private entities involving federal funds"—precisely because of the nature of the rights at issue. *Id.* at 80,634–35. But Article III does not permit these rights to be adjudicated by agency bureaucrats.

The government responds that ADR panels simply answer "questions of program compliance," but without "command[ing] the conveyance of private property." Opp. 23–24, 27. But this again ignores the actual ADR Rule, which confers precisely those powers by authorizing panels "to resolve *all* issues underlying *any* claim or defense." 85 Fed. Reg. at 80,636 (emphasis added); *see also* 42 C.F.R. § 10.21(b), (c). Under the ADR Rule, panels can therefore decide that an entity is covered by the statute (thus requiring manufacturers to offer the entity discounted pricing); decide that a manufacturer's placement of conditions on such sales violates "statutory requirements," Opp. 27 & n.8; and issue "precedential and binding final agency decisions" imposing financial and injunctive penalties, 42 C.F.R. § 10.20.

In other words, ADR panels may order private manufacturers to convey their property (in the form of outpatient drugs or money damages) to private covered entities at certain prices and subject to certain conditions, notwithstanding the property and contract rights that would otherwise govern the parties' relationships. Resolving "the liability of one individual to another under the law as defined" is the very definition of private-rights adjudication. *Crowell v. Benson*, 285 U.S. 22, 51 (1932);

accord Oil States Energy Servs. v. Greene's Energy Grp., 138 S. Ct. 1365, 1378 (2018).

The government contends—principally on the basis of *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985)—that there is nonetheless no Article III problem because this case involves "new rights" that Congress "create[d]" by statute. Opp. 26. But no private rights were at stake in *Union Carbide*. That case instead involved a right to compensation that existed exclusively under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), for the use of data submitted to the EPA by pesticide registrants. Critically, the statute created this right only after the registrant had, "[a]s a matter of state law," "extinguished" its preexisting "property rights" and "property interest[s]" by submitting the data. 473 U.S. at 584. Because the FIFRA right was created by Congress and did not "replace" any rights "under state law," it was a public right that could be adjudicated outside of an Article III court. *Id.* at 584, 588–89, 594; *see Stern v. Marshall*, 564 U.S. 462, 491 (2011).

In invoking the same principle here, the government disregards the Third Circuit's warning that *Union Carbide*'s holding has "rather limited scope" and "should not be read too expansively." *Beard v. Braunstein*, 914 F.2d 434, 440 (3d Cir. 1990). Unlike with the FIFRA dispute in *Union Carbide*—and contrary to the government's argument, Opp. 28—covered entities' entitlement to discounted drugs and manufacturers' participation in federal programs are not the only rights at issue under the ADR Rule. Manufacturers' rights to hold and alienate property are creatures of

state common law, not Section 340B. Indeed, Sanofi was selling medications long before Congress enacted Section 340B, which merely limited Sanofi's preexisting rights by imposing "ceilings on prices drug manufacturers may charge for medications sold to specific health care facilities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). And, unlike the compensation right under FIFRA, those preexisting rights have not been "extinguished" as "a matter of state law." *Union Carbide*, 473 U.S. at 584. Subjecting them to administrative adjudication would violate Article III.

Indeed, contrary to the government's argument, the Supreme Court has required Article III courts to adjudicate claims involving private rights even when those rights are integral to a regulatory scheme. Opp. 26–27. In *Granfinanciera*, the Supreme Court held that a fraudulent-conveyance claim arising under *a federal statute* required an Article III forum because its resolution would dictate how much one private party owed another. 492 U.S. at 34–35. And in *Oil States*, the Supreme Court made clear that patent infringement actions require an Article III forum, even though they arise from a federal statutory scheme. 138 S. Ct. at 1379. So too here, while ADR claims arise from a "comprehensive regulatory scheme," Opp. 26, they implicate common-law rights—and an Article III court must therefore resolve them.[4]

[4] Nor did *Astra* bless the administrative adjudication of these rights. *See* Opp. 25. The *Astra* Court said nothing about Article III, instead merely observing that Section 340B required an ADR process (and thus created no private right of action).

Finally, contrary to the government's bare assertions, *id.* at 29, Sanofi did not "knowingly and voluntarily" consent to the constitutional violation here. *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1939 (2015). Rather, Sanofi is an "objecting defendant forced to litigate involuntarily before a non-Article III court." *Id.* at 1947. The government cites no case holding that participating in government programs signs away the right to an Article III forum. To the contrary, the Supreme Court has recognized that individuals lacking realistic alternatives do not "truly consent" even when they choose to participate in non-Article III adjudications, much less when they participate in wide-ranging government programs like Medicaid and Medicare. *Stern*, 564 U.S. at 493; *cf. Nat'l Fed. of Indep. Bus v. Sebelius*, 567 U.S. 519, 581–82 (2012) (noting threatened loss of Medicaid funding "leaves States with no real option but to acquiesce in the Medicaid expansion."). Moreover, while Section 340B might have put Sanofi "on notice," Opp. 29, that HHS would eventually establish a "decision-making body," 42 U.S.C. § 256b(d)(3)(B)(i), the statute gave Sanofi no reason to suspect HHS would attempt to give the body powers that Article III reserves to the judiciary.

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ADR panels exercise powers—including the power to award damages and equitable relief—that the Constitution reserves to Article III courts. And ADR panels use these powers to adjudicate disputes that implicate Sanofi's private, common-law

property and contract rights. As a result, the ADR Rule violates Article III.

II. Sanofi Will Suffer Irreparable Harm Absent an Injunction.

Absent an injunction, Sanofi will suffer irreparable harm by being forced to submit to an ADR process that violates the Constitution's structural protections. The government ignores the Supreme Court's instruction that "[t]he structural principles secured by the separation of powers protect the individual," *Bond v. United States*, 564 U.S. 211, 222 (2011). That is why "[t]he entitlement to an Article III adjudicator is 'a personal right.'" *Wellness Int'l Network, Ltd.*, 135 S. Ct. at 1944. The Appointments Clause, too, "ultimately" protects "individual liberty," which is why the Third Circuit presumes that an individual suffers harm from an Appointments Clause violation. *Cirko ex rel Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 155 (3d Cir. 2020). The government offers no reason why a violation of these provisions protecting individual rights is not irreparable when violations of other individual constitutional rights unquestionably inflict irreparable harm. *See* PI Mem. 27–29. Nor does the government dispute that sovereign immunity will prevent Sanofi from recovering damages caused by participating in an unconstitutional ADR proceeding. *See id.* at 31; *Am. Express Travel Related Servs. Co. v. Sidamon-Eristoff*, 755 F. Supp. 2d 556, 614 (D.N.J. 2010) (Wolfson, J.), *aff'd*, *N.J. Retail Merchs. Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012).

III. The Equities Favor an Injunction.

Because the government has no interest defending an unconstitutional regulation, the equities favor injunctive relief. *See id.* at 614–15. Nor would an injunction preclude the resolution of 340B Program disputes. Rather, HHS could still "handle[] overcharge complaints through informal procedures," as it has for twenty-five years. *Astra*, 563 U.S. at 116 (citing Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,412 (Dec. 12, 1996)).

And it is the government, not Sanofi, that has upset the status quo. The ADR Rule was not in effect when Sanofi announced and implemented its integrity initiative. HHS rushed out the ADR Rule only after multiple lawsuits subsequently sought to compel the promulgation of ADR procedures. Given that Congress had required HHS to implement such procedures by September 2010—a deadline HHS missed by over ten years—HHS has only itself to blame for any "disruption of a carefully crafted legislative scheme." Opp. 34. Moreover, during that decade, HHS sparked an unregulated explosion in contract pharmacies, accompanied by significant increases in illegal duplicate discounting—about which it did nothing. *See* PI Mem. 5–7. HHS cannot now seek to benefit from its delay at the cost of irreparable harm to manufacturers like Sanofi.

CONCLUSION

The Court should grant Sanofi's motion for a preliminary injunction.

Dated: March 8, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2021 a copy of the foregoing was filed with the Clerk of the Court using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

March 8, 2021 *s/ Jennifer L. Del Medico*