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

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 3:21-CV-634 Motion Day: June 21, 2021

NOTICE OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Defendants respectfully move to dismiss Plaintiff's Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) or, in the alternative, for summary judgment pursuant to Federal Rule of Civil Procedure 56. The grounds for this Motion are set forth in the accompanying Memorandum of Points and Authorities in Support of Defendants' Motion to Dismiss or, in the Alternative, For Summary Judgment. A proposed order is attached.

Dated: April 19, 2021

Respectfully submitted,

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

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

Sanofi's ultimate goal in this suit is manifestly clear in its complaint: It seeks to have this Court sanction Sanofi's rewrite of its statutory obligations in a way that would drastically restrict many providers' access to discounted drugs (and, in so doing, boost Sanofi's profits). Sanofi seeks to advance that goal by first asking this Court to declare unlawful and set aside a reiteration by HHS's General

Counsel of the agency's consistent, twenty-four-plus-year interpretation of the 340B statute—an interpretation with which Sanofi and its peers had complied, without challenge or question, for decades. In addition to that stunning request, Sanofi further asks this Court permanently to block implementation of a new rulemaking that establishes a straightforward, statutorily mandated administrative dispute-resolution mechanism Congress devised to resolve disputes over 340B Program violations. In other words, Sanofi seeks to head off resolution by HHS of the legality of its recent, industry disrupting changes by asking this Court to enjoin the agency's newly available adjudication system—a system established by statute and modeled on numerous other administrative bodies.

There is no cause for this Court to grant either request because Sanofi's claims uniformly lack merit. This Court cannot opine on the merits of the General Counsel's legal advice because its issuance is not a final agency action and because Sanofi's challenge is time-barred, since the analysis broke no new ground and merely reiterated the agency's consistent position since at least 1996. Moreover, even if Sanofi's challenge to the General Counsel's opinion were justiciable, it still would fail on the merits because the opinion imposes no new requirements on manufacturers and instead only confirms obligations imposed when Congress created the 340B Program. Sanofi's attacks on the administrative-dispute resolution rule are equally flawed. Because decision-makers are supervised by, and can be removed at will by, the HHS Secretary, they constitute inferior officers properly appointed under Article II of the U.S. Constitution. Sanofi's Article III challenge fails because it rests on false premises regarding the Board's powers and the claims it may hear. And Sanofi's claims under the Administrative Procedure Act cannot carry the day; HHS followed statutory notice-and-comment procedures and, as the Supreme Court repeatedly has confirmed, it is reversible error to impose additional requirements on the agency under the guise of facilitating "notice" to the public. Finally, the Secretary fully explained the reasonable choices made in designing the new dispute-resolution system, satisfying substantive APA requirements.

The Court should dismiss each of Sanofi's claims or grant summary judgment to HHS.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of Health and Human Services ("HHS"), through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report), and also may benefit uninsured and underinsured patients, when covered entities opt to pass along the discounts by helping patients afford costly medications. Congress expressly conditioned drug makers' access to an incredibly valuable federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). Pharmaceutical companies thus may opt out of providing discounted drugs to safety-net healthcare providers and their low-income patients, but then lose access to "a significant portion of [their] annual revenues" through drug coverage in federal health-insurance programs. *See* Am. Compl. ("Compl.") at ¶ 24, ECF No. 17.

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

relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to the covered entities' low-income patients. *Id.*

In 1996 HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. 61 Fed. Reg. 43,549. HHS explained that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. Rather than imposing any new requirements on manufacturers not found in the 340B statute, the 1996 guidance confirmed: "*It has been the Department's position* that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," and that, "[i]f the entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance." *Id.* at 43,549 (emphasis added). Thus twenty-five years ago HHS interpreted the statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies, and *nothing* in the guidance suggested that the agency viewed this statutory obligation as voluntary on the part of drug makers. On the contrary, the choice presented under the guidance was for covered entities to determine whether to establish such arrangements because they remain liable and responsible, "under any distribution mechanism, [for] the statutory prohibition on drug diversion." *Id.* HHS explained the policy rationale for this interpretation—restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* at 43,550. Critically, the agency explicitly rejected the argument, suggested in comments to the proposed guidance, that the use of contract pharmacies constitutes an unauthorized expansion of the 340B Program: "The statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. On the contrary, "[i]t is clear

that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.*

Consistent with HHS's interpretation of the 340B statute and its 1996 guidance implementing its terms, covered entities have for decades relied on contracts with outside pharmacies to serve their patients and access the discounts Congress provided. Indeed, these arrangements proved so pivotal to covered entities' and their patients' access to drug discounts that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance"). HHS issued that guidance confirming covered entities' rights to rely on contract pharmacies after a demonstration project (*i.e.* a pilot program) showed that such models could benefit patients and safety-net providers "without sacrificing program integrity." *Id.* at 10,273. After issuing notice and soliciting comments, the agency agreed with commenters that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more-flexible use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* The 2010 Guidance includes "essential elements" to prevent unlawful duplicate discounts or diversion of 340B drugs: a "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ships the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 10,278. The guidance makes plain that a covered entity bears full responsibility to ensure adherence to 340B Program requirements and can lose eligibility if violations occur. *Id.*

Most importantly for the present case, the 2010 Guidance again confirmed HHS's earlier interpretation that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* (emphasis added). As before, that interpretation was framed in mandatory terms—the guidance made no suggestion, and in no way supports, the position that manufacturers can choose whether or not to honor 340B purchases by a covered entity that relies on contract-pharmacy arrangements. HHS also explained that the guidance neither created new obligations on manufacturers nor new rights for covered entities because it merely interpreted the 340B statute itself "to create a working framework for its interpretation," rather than promulgating "a substantive rulemaking under the APA." *Id.* Not only were there *no* legal challenges from pharmaceutical manufacturers or trade associations to the substance of the 2010 Guidance but, for more than a decade, *all* participating pharmaceutical manufacturers have complied with the guidance by honoring orders placed by covered entities regardless of the dispensing mechanism chosen. Thus for years many covered entities have relied on the ability to contract with multiple pharmacies to best serve their patients and maintain flexibility in accessing 340B discounts.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *See Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121-22 (2011). Specifically, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to "Improve[] … program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted authority to issue new regulations imposing civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

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

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

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

The Secretary began work to establish that process several months later by issuing an advanced notice of proposed rulemaking to request comments on the development of an ADR process. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sep. 20, 2010). The agency received only about a dozen comments in response. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,382 (Aug. 12, 2016). A Notice of Proposed Rulemaking ("NPRM") then followed, which included proposed ADR regulations establishing a panel within the agency to adjudicate disputes between drug manufacturers and covered entities. *Id.* at 53,381-82. The agency received 31 public comments on that proposal. *See* 340B Drug

Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10). HHS finalized the 340B ADR Rule late last year. In drafting the final Rule, it considered the comments received on the 2016 NPRM and adjusted its proposal in response to several comments. The final ADR Rule was published in the Federal Register on December 14, 2020, and became effective on January 13, 2021. *See* 85 Fed. Reg. 80,632.

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

Importantly, the Rule places no restrictions whatsoever on the Secretary's authority to remove a Board member at any time, with or without cause. Nor does it purport to grant any defined term to any Board member. The HRSA Administrator, however, has authority to remove a particular employee from a particular panel for cause, where necessary, and to substitute that panel member for another member of the Board. *Id.*

ADR proceedings are governed by the Federal Rules of Civil Procedure, including the procedural mechanisms established therein. *Id.* at 80,644-45, 42 C.F.R. § 10.23(b). ADR Panels are granted considerable discretion during the pendency of a claim to "permit a covered entity limited

discovery," to "[r]eview and evaluate documents and other information" as needed to evaluate a claim, and to "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," including through conducting an evidentiary hearing. *Id.* at 80,644-45, 42 C.F.R. §§ 10.20(c)(1), 10.22(a), 10.23(a).

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

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

During the latter half of 2020 several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Eli Lilly (another large pharmaceutical company) that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for only one of its drugs—Cialis, a drug used to treat erectile dysfunction. *See Eli Lilly v. HHS*, No. 21-cv-81 (S.D. Ind.), Compl. ¶ 78. But that relatively modest restriction opened the floodgates to further disruptions of the 340B Program: Only one month later, Eli Lilly extended its new contract-pharmacy restrictions to *all* its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Exh. G, and other pharmaceutical companies promptly followed suit. For its part, Sanofi announced that it would begin *requiring* covered entities to register through a third-party platform and provide detailed claims data on patients' prescriptions in order to continue purchasing its drugs for shipment to contract pharmacies,

purportedly to allow Sanofi to police instances of duplicate discounts. *See* Compl. Ex. 1. Not only did Sanofi not seek prior involvement, approval, or review of its new restriction by HHS, it wrote to then-HHS Secretary Azar confirming that "covered entities will need to register with [its third-party platform] and submit claims-level-detail on all 340B contract pharmacy utilization *in order to be eligible for* 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy." *Id.* Ex. 2 at 2-3 (emphasis added). Sanofi's letter confirmed its intent of targeting prescriptions written by covered entities but filled at outside dispensers, informing the agency that, "if a covered entity refuses to provide the claims data described above, *we will restrict the entity's use of contract pharmacy arrangements*," although the relatively small number of safety-net providers with the means to operate their own, in-house pharmacy "will remain eligible to purchase at 340B prices for shipment to their own facilities." *Id.* at 3 (emphasis added).

Although HRSA published on its official 340B website Eli Lilly's original notice restricting access to Cialis, HRSA refused to post that drug maker's later notice expanding the 340B restrictions or those of other companies, including Sanofi. HRSA then told an industry reporter that the agency "is considering whether manufacturer policies … violate the 340B statute and whether sanctions may apply," including, "but not limited to, civil monetary penalties." ADVOP_1597. HRSA further warned that "manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies"; the agency thus "continues to strongly encourage all manufacturers to sell 340B priced drugs … directly and through contract pharmacy arrangements."

After Eli Lilly and Sanofi acted, other large, global pharmaceutical companies imposed their own unilateral restrictions on covered entities' access to discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, and Novartis and Novo Nordisk imposed their own, separate restrictions soon thereafter. *See AstraZeneca Pharm. v. Azar*, No. 21-cv-27-LPS, ECF No. 13, Am. Compl. Exs. A, C (D. Del.); Novartis 340B Policy Changes,

https://www.novartis.us/news/statements/new-policy-related-340b-program; *Novo Nordisk v. Azar*, No. 21-cv-806-FLW-LHG, ECF No. 1, Compl. ¶¶ 56-58 (D.N.J.).

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

In response to the growing public outcry, HHS's General Counsel issued legal advice on December 30, 2020, confirming his view—in complete alignment with the agency's longstanding guidance—"that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (ADVOP_1, hereinafter "AO") at 1.[1] The General Counsel opined that the 340B statute requires manufacturers, in exchange for access to Medicaid and Medicare Part B, to *offer* discounted drugs for

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

purchase by covered entities, with no qualifications or restrictions on the distribution or dispensing arrangements selected by the covered entity. *Id.* at 2. And contract-pharmacy arrangements unequivocally involve purchase by a covered entity, the Advisory Opinion explained, regardless whether the purchased drugs are delivered to, and dispensed by, a pharmacist employed in-house by the covered entity or an outside, neighborhood pharmacy. *Id.* at 3. Moreover, the opinion continues, covered entities have relied on contract pharmacies for decades—and that system is wholly compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," *i.e.*, "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. A restriction limiting 340B discounts in the manners newly imposed by drug makers would produce "a bizarre result," "inconsistent with the purpose of the Program and common sense." *Id.* The General Counsel confirmed that this interpretation is compelled by the statute itself; as in 1996 and 2010, no rulemaking is required, and no expansion of the 340B Program has been effectuated, because Congress did not permit drug makers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. AO at 2-4.

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

The pharmaceutical companies' concerted actions to upend the 340B status quo continued in litigation. Three drug makers, including Sanofi, filed suit on the same day challenging the General Counsel's Advisory Opinion. *Sanofi*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), ECF No. 1; *Eli Lilly*, No. 1:21-cv-81-SEB-MJD (Jan. 12, 2021), ECF No. 1; *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1. Two additional, similar suits were filed shortly thereafter. *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

As for this action, notwithstanding the advisory nature of the General Counsel's legal opinion and the fact that it reiterated guidance the agency long ago had issued (and with which Sanofi had complied, without challenge, for twenty-five years), Sanofi now asks this Court to declare the advice

unlawful and to bless Sanofi's intention not "*to provide discounted covered outpatient drugs to contract pharmacies*." Compl., Prayer for Relief No. 4, ECF No. 1 (emphasis added). In other words, Sanofi asks this Court to sanction a substantially more-sweeping change to the 340B Program than the disruptive restrictions Sanofi and its peers already have imposed.

Three weeks after filing this suit, Sanofi amended its complaint to add new claims related to the ADR Rule issued last December. *See* Compl., ECF No. 17. Sanofi contends that the ADR Rule violates the Constitution's Appointments Clause, that it unlawfully impinges on the province of Article III courts, and that it violates the APA's procedural and substantive provisions. Compl. ¶¶ 83-115.

STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden to establish a court's jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted).

Under both Rules 12(b)(1) and 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face" to defeat a motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557)). And while the Court accepts well-pleaded factual allegations as true, "mere conclusory statements" and "legal conclusion[s] couched as … factual allegation[s]" are not entitled to a "presumption of truth." *Id.* at 678, 681 (citation omitted).

In a case involving review of final agency action under the APA, "the usual summary judgment standard" applicable under Federal Rule of Civil Procedure 56 "does not apply in the sense that the district court does not need to determine whether there are disputed facts to resolve at trial since the administrative agency is the finder of fact." *Neto v. Thompson*, No. 20-00618, 2020 WL 7310636, at * 3 (D.N.J. Dec. 10, 2020) (internal quotation marks and citation omitted). Rather, "the district judge sits

as an appellate tribunal, and the entire case on review is a question of law." *Soccer Ctrs., LLC v. Zuchowski*, No. 17-1024, 2017 WL 4570290, at *5 (D.N.J. Oct. 13, 2017) (internal quotation marks and citation omitted). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the" applicable APA standards. *Id.* (citation omitted). The party challenging an agency's action bears the burden of demonstrating a violation of the APA. *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000).

ARGUMENT

Sanofi and its peers are engaged in a no-holds-barred strategy to effect a unilateral sea change in the settled operation of the 340B Program. Congress devised the program to provide affordable medications and much-needed revenue to vulnerable patients and safety-net healthcare providers, and expressly conditioned a valuable federal benefit, coverage of drug manufacturers' products in the nation's largest health-insurance programs, on the companies' agreement to provide deep discounts on *purchases by* covered entities. Now a cohort of large, highly profitable pharmaceutical companies seek to litigate out of the obligation to comply with their end of the bargain, by creating from whole cloth novel restrictions on covered entities' access to 340B discounts, including limitations on the dispensing mechanism chosen by the covered entity, and onerous reporting requirements with no basis in statute or regulation. Sanofi and other manufacturers' abruptly imposed restrictions have caused upheaval by severely curtailing access to the discounts to which covered entities are entitled. Any doubt as to Sanofi's intent is dispelled by the fact that its complaint is larded with grievances about covered entities' use of contract-pharmacy arrangements—complaints which ignore covered entities' twenty-five-year reliance on such agreements.

Sanofi's campaign to end reliance on contract-pharmacy dispensing models also mischaracterizes the transactions at issue by pretending it is the pharmacies, not covered entities, that purchase Sanofi's discounted drugs. As the General Counsel explained, "covered entities enter into written agreements with pharmacies ('contract pharmacies') *to distribute* their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B

drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contract pharmacy has physical possession of the drug, *it has been purchased by the covered entity*." AO at 1 (emphasis added). In other words, pharmacies *cannot*—under the Advisory Opinion or at any time in the history of the 340B Program—purchase 340B-discounted drugs. Contract pharmacies perform an invaluable service by undertaking the necessary investment to maintain the lawful ability to store and dispense controlled substances (such as employing registered pharmacists and maintaining active registration with the Drug Enforcement Administration), accepting delivery of controlled substances purchased by safety-net providers, and dispensing medications to patients on behalf of covered entities that often could not afford to undertake these tasks in-house. But that does not allow a pharmacy to purchase 340B drugs or participate as a covered entity. As HHS explained in 1996: "The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity." 61 Fed. Reg. 43,552.

Sanofi relies on artful drafting to obfuscate and confuse these undeniable facts. For example, Sanofi repeatedly claims that HHS newly is requiring it to "provide 340B discounts to contract pharmacies," Compl. ¶ 12, that it "now must provide its drugs to contract pharmacies at discounted prices," *id.* ¶ 73, and even that contract pharmacies "participat[e] … in the 340B Program, *id.* ¶ 34. *See also id.* Prayer for Relief No. 4 (asking this Court to declare "that Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies"). These portrayals are inaccurate; contract pharmacies *cannot purchase* 340B-discounted drugs, but rather can only fill prescriptions written by covered entities for their own patients using 340B-discounted drugs *purchased by* the covered entities, and then pass along the profit generated back to the covered entities (less a fee for the service provided). That is as Congress designed the program. *See* Background § I. Sanofi's misportrayal of these relationships permeates each of its claims. This Court should not condone Sanofi's extra-statutory self-help efforts to rewrite the legislative scheme devised by Congress—and deny covered entities access to the discounts to which they are statutorily entitled—under the guise of purported "program integrity." *See* Compl. Ex. 2 at 1.

I. THE COURT LACKS JURISDICTION TO REVIEW THE GENERAL COUNSEL'S LEGAL ADVICE.

A. THE ADVISORY OPINION DOES NOT CONSTITUTE FINAL AGENCY ACTION

Because the AO is not "final agency action" subject to review under the APA, *see* 5 U.S.C. § 702, the court lacks jurisdiction to review Sanofi's challenge to the AO. *See Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 247 (3d Cir. 2011) (describing "final agency action" as "a jurisdictional issue"). Agency actions are final if two independent conditions are met: (1) the action "marks the consummation of the agency's decisionmaking process" and is not "of a merely tentative or interlocutory nature;" and (2) the action is one "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). Though failure to satisfy either condition is enough to deprive the court of jurisdiction, the AO fails to satisfy both conditions.

The AO is not an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). To the extent the agency has reached the consummation of its decisionmaking process at all, it did so many years ago, as expressed in the 2010 Guidance. The AO merely restates the position expressed in that guidance, and thus "tread[s] no new ground." *Indep. Equip. Dealers Ass'n ("IEDA") v. EPA*, 372 F.3d 420 (D.C. Cir. 2004). "It left the world just as it found it, and thus cannot be fairly described as implementing, interpreting, or prescribing law or policy." *Id.*

The 2010 Guidance made clear that covered entities may enter into "complex arrangements" that include contracts with "multiple pharmacies." 75 Fed. Reg. at 10,277. It also expressly stated that, "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." *Id.* at 10,278 (emphasis added). Thus, the 2010 Guidance, in no uncertain terms, reflected the agency's position that manufacturers had a statutory obligation to honor the ceiling price when covered entities utilized multiple contract

pharmacies. The AO did not deviate from this prior position.[2] It concluded that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." AO at 1.

When, as here, a later restatement of a prior interpretation is challenged, courts routinely hold that the restatement is not final agency action. *See, e.g. Menominee Indian Tribe of Wisconsin v. EPA*, 947 F.3d 1065 (7th Cir. 2020); *Clayton Cty., Ga. v. FAA*, 887 F.3d 1262 (11th Cir. 2018); *Golden and Zimmerman, LLC v. Domenech*, 599 F.3d 426 (4th Cir. 2010); *IEDA*, 372 F.3d 420. For example, in *Menominee Indian Tribe*, the Seventh Circuit considered whether letters from the Environmental Protection Agency and Army Corps of Engineers were final agency action. 947 F.3d at 1068. The letters reiterated the agencies' positions as set forth in a 1984 document, and thus "did little but restate what the Tribe already knew." *Id.* at 1070. The court explained that each letter "imposes no obligations," "denies no relief," and carries no other "legal consequence." *Id.* Because the letters "only reiterated the status quo," there was "nothing for [the court] to review." *Id.*

The Fourth Circuit reached the same conclusion in a similar case, *Golden and Zimmerman, LLC*. 599 F.3d 426. In that case, plaintiffs sought review of a document published by the Alcohol, Tobacco, and Firearms Bureau ("ATF") designed to help firearm licensees comply with the law, arguing that the answer to one of the Frequently Asked Questions ("FAQ") was "inconsistent" with the Gun Control Act. *Id.* at 428. The trouble was that the FAQ merely restated the ATF's interpretation published in a revenue ruling 40 years earlier. *Id.* Even though the FAQ did, in fact, "inform the regulated community of what violates the law," the court found that the FAQ did not "itself *determine* the law or the consequences of not following it." *Id.* at 433 (emphasis in original). "Its role, as stated in the publication, is simply to *inform* licensees of what the law, previously enacted or adopted, is, and

[2] To the extent Sanofi argues that the language in the AO does not exactly track that of the 2010 guidance, such semantic differences are irrelevant for the purposes of the finality analysis. *See Clayton Cty., Ga. v. FAA*, 887 F.3d 1262 (11th Cir. 2018) (rejecting arguments that different text of a restatement was relevant when "the meaning was clear" and there was no ambiguity "when read in context").

its publication did not itself alter the legal landscape." *Id.* As the court explained, "if the ATF had never published [the FAQ]," it "would still have the authority to prosecute licensees for engaging in the conduct" described in the FAQ because "legal consequences" arise only from the statute and its implementing regulations." *Id.*

So too here. The AO informs the public of the General Counsel's interpretation of the statute, but it does not impose any consequence because it merely restates the interpretation set forth in the 2010 Guidance. In other words, the AO "did little but restate what [Sanofi] already knew." *Menominee Indian Tribe*, 947 F.3d at 1070. Sanofi alleges that, as a result of the AO it is "now exposed to enforcement actions and civil monetary penalties if it fails to comply." Compl. ¶ 81. But even if the AO or the 2010 Guidance had not been issued, covered entities would still be able to challenge Sanofi's practices through the alternative dispute resolution process set forth in the statute, 42 U.S.C. 256b(d)(3)(B)(i), and the authority to impose monetary penalties, etc. would still exist. *Id.* § 256b(d)(1)(B)(vi). Indeed, HRSA explicitly communicated to Eli Lilly in August 2020—months before the General Counsel issued his legal advice—that the agency was "considering whether [its] new proposed policy constitutes a violation of section 340B and whether sanctions apply." ADVOP_1098-99. HHS plainly viewed contract-pharmacy restrictions as potentially violative of *the statute* before the AO was issued. Thus the "legal consequences" arise only from the statute, and not from the AO itself. *See Golden and Zimmerman, LLC.*, 599 F.3d at 433.

Sanofi's allegations focus on the practical consequences of what it thinks will happen as a result of the AO. Compl. ¶ 81. But such "practical consequences," including "the threat of having to defend itself in an administrative hearing" are "insufficient" to render agency action final or reviewable. *IEDA*, 372 F.3d at 428; *see also Ocean Cty. Landfill Corp. v. USA EPA Region II*, 631 F.3d 652, 656 (3d Cir. 2011) (no final agency action when the decision did not "contemplate immediate compliance"). Where, as here, Sanofi "continue[s] to operate" its so-called "integrity initiative" until

some further action is taken, it cannot claim that the finality test is satisfied. *See Ocean Cty. Landfill Corp.*, 631 F.3d at 656. [3]

Sanofi's challenge to the AO should be dismissed for lack of final agency action.

B. SANOFI'S ATTEMPT TO UPEND THE SETTLED OPERATION OF THE 340B PROGRAM IS TIME-BARRED

Even if Sanofi were correct that the agency has imposed new obligations on manufacturers outside those imposed directly by the 340B statute—and it assuredly has not, *see infra* § II.C—Sanofi's challenge to the General Counsel's legal advice still fails as a matter of law because it is jurisdictionally barred by the six-year statute of limitations. After Sanofi and several other pharmaceutical companies engaged in a self-serving attempt to upend the long-settled 340B status quo, the General Counsel issued the AO to reiterate the agency's established statutory interpretation, first published in the Federal Register in 1996 and reaffirmed in 2010, both after public comment—an interpretation with which Sanofi and its peers had complied, without challenge, ever since. Sanofi's failure to challenge the agency's statutory interpretation when it was published twenty-five years ago, and republished more than a decade ago, is fatal to its claim here. The General Counsel *repeated* the agency's longstanding position but did not *reopen* the previous interpretations and thus did not restart the six-year limitations clock.

"[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues," 28 U.S.C. § 2401(a), and this express limitation on the ability to sue the federal government applies with equal force to challenges to agency action brought under the APA. *Nat'l Ass'n of Mfrs. v. Dep. of Defense*, 138 S. Ct. 617, 626-27 (2018); *see also Paucar v. Att'y Gen. of the U.S.*, 545 Fed. App'x 121, 124 (3d Cir. 2013) ("It is well established that the six-year statute of limitations applies to claims brought pursuant to the APA," and "the right of action first accrues on the date of the final agency action.") (internal quotations omitted). "Once the challenged agency action becomes final and invades a party's legally protected interest, the party's right

[3] Sanofi also fails to establish that the AO marks the "consummation of the agency's decisionmaking process" *Bennett*, 520 U.S. at 177-78, because the agency's position on the statutory question has not changed since the 1996 Guidance was issued. *See* Part I.B., *infra*.

to redress that injury under the APA accrues, and § 2401(a)'s six-year clock starts ticking." *Herr v. U.S. Forest Svc.*, 803 F.3d 809, 818-19 (6th Cir. 2015). This restriction is not subject to waiver or tolling because the government enjoys sovereign immunity "save as it consents to be sued … and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit." *Diliberti v. United States*, 817 F.2d 1259, 1261 (7th Cir. 1987) (citing *Lehman v. Nakshian*, 453 U.S. 156, 160 (1981)). "Courts have consistently held that where the government's consent as sovereign to be sued is conditioned upon the filing of suit within a specified period of time, strict compliance with that condition is a jurisdictional prerequisite." *Id.*; *see also Kannikal v. Att'y Gen. of the U.S.*, 776 F.3d 146, 150 (3d Cir. 2015) (recognizing that § 2401(a) constitutes waiver of sovereign immunity that cannot be expanded by federal courts).

An agency's reiteration or application of an earlier decision does not constitute a new decision subject to challenge or start the limitations clock anew. In *IEDA*, 372 F.3d at 421-24, as in this case, the plaintiff challenged an agency's statement of its definitive legal interpretation, as set forth in an official letter from an EPA Director to regulated entities. The D.C. Circuit nonetheless explained that, because the most recent interpretation "reflects no change in the position announced" in earlier guidance, it was not a new agency action. *Id.* at 426; *id.* at 427 (the "Letter merely restated in an abstract setting—for the umteenth [sic] time—EPA's longstanding interpretation of the" legal requirements and "neither announced a new interpretation of the regulations nor effected a change … The Letter was purely informational in nature"). The court explained that, under the "reopening doctrine," an agency's existing legal interpretations and regulations "are not newly reviewable" unless they have been reopened by agency action—*i.e.*, unless the administrative record evinces an intent by the agency to reevaluate and reconsider its earlier position, as opposed to merely explaining the earlier decision and applying it in a new context. *Id.* at 428. "Just as it would be folly to allow parties to challenge a regulation anew each year upon the annual republication of the Code of Federal Regulations, so too it is silly to permit parties to challenge an established regulatory interpretation each time it is repeated," because a contrary rule "would quickly muzzle any informal communications between agencies and their regulated entities." *Id.*

This holding repeatedly has been applied. In *General Motors Corp. v. EPA*, the court of appeals dismissed as untimely a challenge to an agency's legal interpretation, as embodied in official letters reiterating the agency's earlier position. 363 F.3d 442, 451 (D.C. Cir. 2004). Because the letters did not announce any intention to reevaluate the earlier pronouncement and instead "stated that outstanding violations would have to be addressed on the basis of EPA's long-held interpretation," the agency had not reopened its earlier decision. *Id.* at 449-50. Even though the earlier "interpretation was not published in the Federal Register," the court explained, the agency "can inform those affected simply by posting its new guidance or memoranda or policy statement on its website." *Id.* at 451. And because the plaintiff had failed to challenge the agency's interpretation within the applicable period for judicial review, its later attempt to attack that same position when embodied in an official letter was time-barred. Indeed, a contrary rule "to permit review whenever [an agency] reiterates" an interpretation but "has not changed its position," "would allow [plaintiff] to avoid the consequences of its failure to adhere to the congressionally prescribed jurisdictional window" of the relevant statute. *Edison Elec. Inst. v. OSHA*, 411 F.3d 272, 277-78 (D.C. Cir. 2005); *see also Biggerstaff v. FCC*, 511 F.3d 178, 155-56 (D.C. Cir. 2007) (confirming that proper way to challenge a longstanding agency interpretation as violative of a statute is through petition for rulemaking and, in absence of such petition, plaintiff must demonstrate clear intent in administrative record to reopen earlier rulemaking); *Pub. Citizen v. Nuclear Reg. Comm'n*, 901 F.2d 147, 150 (D.C. Cir. 1990) (confirming applicability of reopening doctrine to determination "whether an agency's restatement of an existing rule or policy" in a new format renders the issue "challengeable anew"); *Peri & Sons Farms, Inc. v. Acosta*, 374 F. Supp. 3d 63, 71-73 (D.D.C. 2019) (rejecting as untimely challenge to 2019 agency notice that "implement[ed] the decisions it made long ago [in 2010 Rule] and reflect[ed] the Department's continued adherence to them"). Stated simply, the reopening doctrine confirms that a policy established in an earlier action is not subject to fresh challenge when reiterated or applied subsequently unless a plaintiff can show that the agency has reopened its previous position for renewed consideration—as distinguished from explication.

Sanofi's challenge to the AO is an untimely collateral attack on the agency's consistent, twenty-five-year statutory interpretation. As explained *supra*, Background § I, in 1996 HHS concluded that the

340B statute does not allow manufacturers to refuse discounted-drug purchases by covered entities that rely on contract pharmacies. *See* 61 Fed. Reg. 43,549 (interpreting 340B statute to affirmatively require drug makers to honor purchases by covered entities, confirming if the "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). There is nothing voluntary in that interpretation; on the contrary, the only voluntary aspect of the 1996 guidance was the choice of covered entities whether to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen for covered drugs. *See id.* at 43,549-50.

Again in 2010 HHS promulgated contract-pharmacy guidelines after issuing notice and providing a 60-day comment period for interested parties, such as Sanofi, to participate. *See* 75 Fed. Reg. at 10,272. Once again HHS definitively set forth its statutory interpretation: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug* at a price not to exceed the statutory discount price." *Id.* at 10,278 (emphasis added). That mandatory language reiterated the agency's considered decision on what the 340B *statute* requires—not, as Sanofi portrays, a suggestion from the agency that manufacturers may elect to follow or ignore. Compl. at 3. Indeed, HHS specifically explained that the 2010 Guidance does not "represent a substantive rulemaking under the APA" because it "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law" and instead constitutes "interpretive guidance" of the statute itself. *Id.* at 10,273. And as in 1996, there was no ambiguity in the agency's view that manufacturers are obliged to honor purchases by covered entities regardless whether contract pharmacies are used; the guidance made no suggestion that pharmaceutical companies can reject purchases by covered entities that rely on contract pharmacies. True, the agency's interpretation of the obligation imposed on manufacturers was coupled with other voluntary guidance, advising covered entities on best practices to structure pharmacy agreements so as to prevent diversion or duplicate discounting. *See, e.g.*, *id.* at 10,279 (outlining "suggested contract provisions … for illustrative purposes … not intended to be comprehensive, exhaustive or required"). But the coupling of HHS's interpretation of the statutory

obligations on manufacturers with other, voluntary provisions advising covered entities in no way indicated that manufacturers had a choice unilaterally to opt out of providing 340B discounts whenever a covered entity serves its patients through outside pharmacies.

Had Sanofi disagreed with the agency's decision that the 340B statute requires manufacturers to honor purchases from covered entities regardless whether a contract-pharmacy model is used, Sanofi should have brought suit challenging the 2010 Guidance (or the earlier, equally mandatory interpretation in 1996). Likewise, had Sanofi contended that this obligation exceeded the 340B statute and thus must be imposed through legislative rulemaking, not an interpretive rule, Sanofi could have mounted a procedural challenge to the 2010 or 1996 Guidance. But neither Sanofi nor any other pharmaceutical manufacturer ever sued to challenge either of HHS's previous contract-pharmacy interpretations (or even petitioned the agency to revisit its interpretation). Instead, Sanofi and other drug companies complied fully with HHS's interpretation for the past two and half decades—a timeframe in which covered entities have relied heavily on contract pharmacies to access 340B-discounted drugs.

Nor did the General Counsel's legal advice reopen those earlier interpretations. Far from making *any* change to the preexisting status quo, as Sanofi portrays (Compl. ¶ 73), the General Counsel simply reaffirmed the agency's "longstanding interpretation of the statute," AO at 4, in response to havoc wrought by manufacturer's unilateral contract-pharmacy restrictions. The AO does not rely on changed circumstances or even assert that anything *has* changed in the operation of the 340B Program (aside from recent, disruptive restrictions by drug makers). Abjectly false is Sanofi's claim that "[t]he Advisory Opinion concludes (*for the first time*) that drug manufacturers are legally obligated to provide 340B-priced drugs to contract pharmacies." Compl. ¶ 63 (emphasis added). Putting aside the fact that it is covered entities, not contract pharmacies, which enjoy the legal right to obtain discounted medications, Sanofi cannot ignore the 1996 and 2010 Guidances out of existence. Contrary to its portrayal, the agency could hardly have been clearer in its mandatory phrasing regarding what the statute requires of manufacturers, 75 Fed. Reg. at 10,278, and Sanofi points to *nothing* in the guidance to support its assertion that the interpretation was viewed as voluntary. Rather than break any new

ground, the General Counsel's recent legal advice simply confirmed the agency's "consistent position over the past 24-plus years." AO at 4. That reiteration does not permit Sanofi to launch an untimely collateral attack on HHS's 1996 and 2010 decisions interpreting the 340B statute; any claim Sanofi might have had to challenge the substance or promulgation of the agency's contract-pharmacy interpretation became time barred on March 5, 2016, six years from publication of the 2010 Guidance in the Federal Register. *Id.* at 10,271 (publication date of March 5, 2010).

II. EVEN IF THE GENERAL COUNSEL'S LEGAL ADVICE WAS REVIEWABLE, SANOFI'S CLAIMS FAIL

A. NOTICE-AND-COMMENT RULEMAKING IS NOT REQUIRED BECAUSE THE ADVISORY OPINION IS AN INTERPRETIVE RULE

Even if the AO were final agency action, and Sanofi's claims were not time-barred, its notice-and-comment claim would still fail for the additional reason that the AO is not a legislative rule. The AO is, at most, an interpretive rule that advises the public of HHS's interpretation of a statute, and is exempted from the APA's notice and comment requirements. *See* 5 U.S.C. § 553(b)(3)(A).

"[T]he critical feature of interpretive rules is that they are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015) (quotation omitted). These rules do not "have the force and effect of law," *id.*, or "alter legal rights." *Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994); *see also Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003) (Interpretive rules "do not themselves shift the rights or interests of the parties, although they may change the way in which the parties present themselves to the agency."). Instead, they "state the agency's view of what existing law requires," "merely clarify[ing] or explain[ing] existing law or regulations." *Sekula*, 39 F.3d at 457.

The AO is a quintessential interpretive rule. It does not "alter legal rights," *id.*, but rather explains the agency's interpretation of the statutory phrase "purchased by." The 340B statute requires the Secretary to enter into agreements with drug manufacturers "under which the amount required to be paid" for certain drugs "purchased by a covered entity" does not exceed the ceiling price on those drugs. 42 U.S.C. § 256b(a)(1). The AO interprets this unambiguous text to conclude that the phrase

"purchased by a covered entity" includes scenarios where "contract pharmacies are acting as agents of a covered entity." AO 1-2. Noting that the textual analysis is dispositive "given the lack of ambiguity in the plain text of the statute," the AO explains that "neither the agency nor a private actor" is authorized to "add requirements" to the statute. *Id.* at 2. It goes on to explain how the purpose and history of the 340B Program also support this conclusion, and how the contrary rationale of certain pharmaceutical manufacturers is unpersuasive. *Id.* at 3-8. Although Sanofi attempts to paint a different picture, 42 U.S.C. § 256b(a)(1) "was fully operative" without the AO, *see Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 113 (3d Cir. 1996), and the AO exists only to "advise the public of the agency's construction of [the statute]." *Mortgage Bankers Ass'n*, 575 U.S. at 97.

Courts routinely identify agency guidance as interpretive rules in analogous circumstances. For example, in *Shalala v. Guernsey Mem. Hosp.*, 514 U.S. 87 (1995), the Supreme Court considered whether the HHS Secretary's adoption of a Medicare Provider Reimbursement Manual was invalid for failure to comply with the APA's notice and comment requirements. *Id.* 91. The dispute arose when the Secretary relied on the manual to determine that a reimbursable loss by the challenging hospital should be amortized, rather than reimbursed at once. *Id.* at 97. In promulgating the relevant provision of the manual, the Secretary determined "that amortization is appropriate" to ensure compliance with a statutory prohibition on cross-subsidizing health services at one time that were rendered over a number of years. *Id.* 97-99. Though the court noted the apparent benefits of recognizing the loss at once, it explained that the Secretary's Manual requiring amortization was a "prototypical example of an interpretive rule" because it was simply an "application of the statutory ban on cross-subsidization and the regulatory requirement that only the actual cost of services rendered to beneficiaries during a given year be reimbursed." *Id.* at 99. The court also emphasized that the manual did not adopt "a new position inconsistent with any . . . existing regulations." *Id.* at 100. So too here. The AO simply applies the statutory requirement that drugs "purchased by" covered entities be reimbursed at a certain price; it does not adopt any "new position" inconsistent with the statute or existing regulations.

Pennsylvania Department of Human Services v. United States, a recent Third Circuit decision, is also instructive. 897 F.3d 497 (3d Cir. 2018). There, the court considered whether a 1994 State Medicaid

Director Letter explaining that training program costs were not reimbursable under the Medicaid statute was an interpretive rule. *Id.* at 500. The court noted that, as with the AO, the agency issued the letter at issue after an influx of questions and activities to "reiterate its longstanding policy." *Id.* at 501 (citation omitted). Emphasizing that the letter "explains . . . the statutory requirement," and "reiterates" the agency's interpretation of the statute, the court held that the letter "thus qualifies as an interpretive rule on several levels." *Id.* at 504. Because the letter "represent[ed]" what the Secretary "thinks" the statute means, and also "clarifie[d] and explain[ed] the statute," the letter was an interpretive rule. *Id.* at 505. There can be no meaningful distinction drawn between the AO and the letter at issued in *Pennsylvania Department of Human Services*. Both represent the interpretation of a statutory requirement, and are representations of what an agency "thinks" the statutory requirement means.

Sanofi's arguments to the contrary cannot be reconciled with this binding precedent or the language of the AO. In its amended complaint, Sanofi alleges that the AO is a "legislative rule" because its "requires drug manufacturers to provide discounted drugs to contract pharmacies" and "restricts the ability of manufacturers to impose conditions on the delivery of drugs to contract pharmacies." Am. Compl. ¶¶ 12, 119. But the *AO* imposes no such requirements—the *statute* does. The AO concludes that *42 U.S.C. § 256b(a)(1)* requires participating drug manufacturers to "deliver its covered outpatient drugs" and that no one, including the agency, is *authorized by the statute* "to add requirements to the statute." AO 1-2. Sanofi surely disagrees with that conclusion. But, the fact that Sanofi disagrees with the AO's statutory interpretation does not render the AO a legislative rule any more than the disagreement of the plaintiffs with the interpretations set forth in the interpretive rules in *Shalala* or *Pennsylvania Department of Human Services*.

Under these circumstances, even if the Court were to determine that the AO was reviewable, Sanofi's notice-and-comment claim should be dismissed.

B. SANOFI FAILS TO STATE A CLAIM THAT THE AO VIOLATES HHS' GOOD GUIDANCE RULE.

Sanofi claims that the AO violates the APA because it is "contrary" to HHS's Rule, Good Guidance Practices, 85 Fed. Reg. 78,770-02 (Dec. 7, 2020) (to be codified at 45 C.F.R. pt. 1) (hereafter, "Good Guidance Rule"). Am. Compl. ¶¶ 122-15. The Court need not look past the first page of the Good Guidance Rule to see the frivolity of Sanofi's claim. There, the Good Guidance Rule clearly states that it is not effective until January 6, 2021. 85 Fed. Reg. at 78770. Because the AO was issued on December 30, 2020, before the effective date of the Good Guidance Rule, it could not possibly be subject to the rule's provisions. Accordingly, Sanofi's fails to state a claim.

C. SANOFI FAILS TO STATE A CLAIM ON THE MERITS BECAUSE ITS OBLIGATION TO OFFER DISCOUNTED DRUGS TO COVERED ENTITIES IS IMPOSED BY THE 340B STATUTE ITSELF

Even if the AO contained any new decisionmaking—rather than simply a reiteration of longstanding agency position—Sanofi still would fail to state a claim that the AO exceeded statutory authority. Compl. ¶¶ 136-42 (alleging that AO should be set aside under 5 U.S.C. §§ 706(2)(A), (C)). Sanofi's claim relies on the false premise that the AO "require[s] drug manufacturers to provide 340B discounts to for-profit contract pharmacies." *Id.* ¶ 10. This claim finds no support in the AO. Sanofi also urges this Court to reach the stunning conclusion that when Congress required manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1), it implicitly allowed *manufacturers*—parties with a vested interest in minimizing the volume of deeply discounted sales—unilaterally to "impose[] a … condition" on safety-net providers and *refuse purchases* placed by providers who do not accede to the manufacturer's demands. Compl. ¶ 140. This claim finds no support in the statute (and defies common sense). Far from exceeding lawful authority, the AO merely confirms what would be true in the absence of its advice, and what has been true since the inception of the 340B Program: Manufacturers, including Sanofi, *must offer* 340B discounted drugs to covered entities in order to remain eligible to participate in Medicaid and Medicare Part B, and any attempt unilaterally to condition those sales to covered entities on claims-data demands or particular dispensing models runs afoul of manufacturers' statutory

obligation. Because the AO simply confirms a straightforward application of the statute, it was not issued in excess of authority.

The General Counsel's advice hewed closely to the statutory text, which expressly conditions access to Medicaid and Medicare Part B on a manufacturer's 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) (analyzed at AO 2). The AO further noted that each participating manufacturer, including Sanofi, has signed a contract with HHS embodying its agreement "to charge covered entities a price for each unit of the drug that does not exceed [the ceiling price]," and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," only "that the discounted drug be 'purchased by' a covered entity." *Id.* And just as HHS cannot add new requirements or obligations to the statute, the General Counsel explained, nor can manufacturers. "It is difficult to envision a less ambiguous phrase" than "purchased by," and "no amount of linguistic gymnastics" can rework the statutory language into authorization *for Sanofi* to condition fulfillment of its obligation to make discounted sales on a covered entity's agreement to undertake the expense of turning over detailed prescription-claims data, operate an in-house pharmacy, or select any particular drug-dispensing model. In short, the statute is unambiguous in mandating that Sanofi make sales *to covered entities*, and Sanofi cannot skirt that obligation by erecting hurdles that limit a safety-net provider's choice among lawful dispensing models to serve its own patients. *Id.*; *see also id.* at 3 ("the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and … pays the manufacturer … [t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" because the covered entity maintains ownership of the discounted drug until it is dispensed to a qualified patient).

Although that "analysis is dispositive" in light of the total absence of ambiguity in the statute's command to honor *purchases by* covered entities, *id.*, the General Counsel went on to explain how it also fulfills Congress's purpose and comports with the decades-long operation of the 340B Program. When Congress created the program in 1992, only 500 out of 11,500 covered entities in existence

operated an in-house pharmacy; the other 95+% relied on outside pharmacies to dispense medications to their patients. AO at 4 (citing 61 Fed. Reg. at 43,550). And because Congress created the 340B Program for the express purpose of providing much-needed *revenue* to covered entities, it could not possibly have intended to require the overwhelming majority of safety-net healthcare providers to undertake the enormous expense of establishing and maintaining *a pharmacy* in order to access the discounted drugs to which they are statutorily entitled. *Id.* at 3-4 (citing H.R. Rept. No. 102-384(II), at 12 (1992)). Congress legislates against the backdrop of real-world facts and, the General Counsel noted, it directed 340B "at benefiting providers that are small, resource-limited, receiving federal assistance, or serving disadvantaged populations." *Id.* at 4. "To champion a policy" such as Sanofi now urges, "ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with [the] purpose of the Program and common sense." *Id.* The General Counsel persuasively explained that, had Congress intended to require the overwhelming majority of covered entities to fundamentally overhaul the method by which they provide drugs to patients (abandoning use of outside pharmacies to obtain all the necessary licensure, controls, employees, etc. to dispense in-house), rather than for covered entities to benefit from discounted drugs *through existing dispensing models*, "it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel." *Id.*

Importantly, the General Counsel also noted that HHS has interpreted the 340B statute to require drug makers "to offer ceiling prices even where contract pharmacies are used" "consistent[ly] [] over the past 24-plus years." AO at 4. Although in this suit Sanofi inaccurately insists that this interpretation was issued "for the first time" in the AO, Compl. ¶ 63, the AO correctly notes that both the 1996 and 2010 contract-pharmacy guidances are plain that the use of such arrangements are voluntary *for covered entities*, who must structure their contracts to prevent duplicate discounting and diversion—but the obligation for drug companies to fill orders by covered entities is, and always has been, mandatory. *Id.* (citing 1996 guidance); *id.* (noting that "contract-pharmacy arrangements have been utilized, and honored by manufacturers, *since 1996 and earlier*") (emphasis added). The General

Counsel also noted that judicial review of this longstanding position would take into account agency expertise interpreting the statute it administers, the common practice of regulated entities operating under 340B for decades, and Congressional acquiescence in the agency's settled interpretation.

Finally, the General Counsel demonstrated the folly in certain manufacturers' newfound objection to the 24-plus-year status quo, as reflected in certain communications from manufacturers to the agency. First, Sanofi and its cohort's "primary rationale offered for cutting off contract pharmacies," to prevent diversion and duplicate discounting, is an extra-statutory self-help mechanism that directly contravenes the express command of Congress. To the extent manufacturers' concerns are sincere (rather than a thinly veiled tactic to shrink the program), the 340B statute spells out precisely how suspected or actual diversion or duplicate discounting must be addressed: The manufacturer "must (1) conduct an audit, and (2) submit the claim to the [ADR] process." AO at 5 (citing 42 U.S.C. § 256b(a)(5)(A), (B) and (d)(3)(A)). No language in the statute, however, permits a manufacturer to deny a covered entity's discounted-drug order on the basis of the dispensing mechanism chosen, and the "manufacturers' … unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute." *Id.* Second, HHS already has confirmed in a previous, duly promulgated regulation that "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *Id.* (citing 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)). Third, the suggestion that covered entities' decades-old reliance on contract pharmacies constitutes "diversion" is specious. AO at 6. The statute provides that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the covered entity." *Id.* (citing 42 U.S.C. § 256b(a)(5)(B)). This language quite plainly means that covered entities may not resell discounted drugs to non-patients, nor transfer the drugs to other, non-covered healthcare providers for prescribing to their own patients. But it is "absurd" to suggest that this straightforward prohibition requires a safety-net provider to ensure that 340B drugs are physically dispensed—*i.e.*, individually *handed*—to its patients by a pharmacist employed by that covered entity. AO at 7. Nothing in the statute restricts commonplace, real-world supply-chain logistics or outlaws preexisting dispensing

models employed by covered entities at the program's inception, such as the use of outside pharmacies. Indeed, taken to its logical conclusion, manufacturers' argument that use of contract pharmacies constitutes "diversion" would mean that, "if a covered entity uses a courier service" or mail-delivery service "to send discounted drugs to its patient, this, too, would [] be an illegal 'transfer' to the shipper." AO at 7. It also would mean that, for decades, covered entities have relied upon and manufacturers have acquiesced in a scheme that does violence to the statutory text. Such a radical reworking of the 340B Program's settled operation—driven by a small cohort of supposed competitors—finds no support in the statute. As the General Counsel concluded, "[l]arge portions of the current 340B Program" cannot be made to turn on "solely manufacturers' voluntary choice to offer the ceiling price," rather than "a statutory mandate"; thus, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." AO at 7-8.

The AO plainly did not "expand[] the list of entities entitled to acquire 340B-priced drugs," Compl. ¶ 10, because it merely confirmed what always has been true—that only covered entities may purchase 340B drugs, but they need not dispense them in-house. Similarly, the AO did not "expose[] Sanofi to enforcement actions, severe monetary penalties, and revocation of its ability to participate in the Medicare and Medicaid programs for operating its integrity initiative," *id.*; rather, *the 340B statute subjects Sanofi to these sanctions for refusing purchases made by covered entities. See* 42 U.S.C. § 256b(a)(1). Because the General Counsel's analysis faithfully interprets the 340B statute, is grounded in Congressional intent, as expressed in its terms, and in no way expands the statute to require of manufacturers anything not already mandated by law, Sanofi fails to state a claim that the General Counsel's legal advice exceeded statutory authority. Even were this claim justiciable, it fails as a matter of law and must be dismissed.[4]

[4] Sanofi alleges that the AO is arbitrary and capricious for the same reasons it alleges the AO exceeded statutory authority—because the AO purportedly concluded that "drug manufacturers must provide discounted covered outpatient drugs to contract pharmacies," Compl. ¶ 145, and "cannot impose conditions on the use of contract pharmacies," *id.* at ¶ 146. These claims fail for the same reasons that the claims fail when framed as statutory merits claims. Thus, Sanofi has not satisfied the standard

III. THE ADMINISTRATIVE-DISPUTE RESOLUTION MECHANISM MANDATED BY CONGRESS WAS LAWFULLY ESTABLISHED

A. ADR BOARD MEMBERS ARE LAWFULLY APPOINTED INFERIOR OFFICERS

Sanofi's claim that the ADR Rule creates principal officers in contravention of the Appointments Clause, U.S. Const. art. II, § 2, cl. 2, *see* Compl. ¶¶ 83-89, contorts the Rule's plain language and ignores precedent holding that similar schemes create inferior, not principal, officers. Sanofi insists that the ADR Rule permits members to "make final precedential determinations on behalf of HHS that are not subject to any further executive branch review," and "install[s] in this role agency employees who are … protected by for-cause removal restrictions and thus not even politically accountable," Compl. ¶¶ 87, 8, but neither premise finds support in the plain text of the Rule. Although the Rule does not create an internal agency appeals process, there are no restrictions on the Secretary's oversight and supervision of the Board. The Secretary appoints ADR Board members and delegates to them responsibility for issuing final decisions, and the Secretary retains the ability to revoke that delegation at any time, to issue binding regulations that constrain the Board members, and may remove a Board member at will, at any time. Under established precedent, Board members thus serve as inferior officers who may be appointed by the Secretary.

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

Although the Supreme Court has "not set forth an exclusive criterion for distinguishing between principal and inferior officers," it has explained that, "[g]enerally speaking, the term 'inferior officer' connotes a relationship with some higher ranking officer or officers below the President: Whether one is an 'inferior' officer depends on *whether he has a superior*." *Edmond v. United States*, 520

for pleading an arbitrary and capricious claim. *See FCC v. Prometheus Radio Proj.*, 141 S. Ct. 1150, 1158 (2021) (A court need "simply ensure[] that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision").

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

The Supreme Court again addressed the line between principal and inferior officers in *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 561 U.S. 477 (2010). There, after striking down a statutory removal restriction, thus rendering Board members subject to at-will removal by the Securities and Exchange Commission, the Court had "no hesitation in concluding that under *Edmond* the Board members are inferior officers." *Id.* at 510. "Given that the Commission is properly viewed, under the Constitution, as possessing the power to remove Board members at will," and given the Commission's general oversight abilities, no constitutional concerns were presented by the absence of Presidential appointment. *Id. Free Enterprise Fund* emphasizes the importance of removal as a relevant and "powerful" form of control for Appointment Clause purposes—regardless of the fact that

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

oversight of the Board was not "plenary." *Id.* at 504, 510. "[T]he Board is empowered to take significant enforcement actions, and does so largely independently of the Commission," which lacks statutory authority "to start, stop, or alter individual Board investigations." *Id.* at 504.

Applying these principles, the Third Circuit held that members of HHS's Appeals Board, which were empowered to review "*a ruling by the Secretary of HHS*," constituted inferior officers properly appointed by the Secretary. *Commonwealth of Pennsylvania v. HHS*, 80 F.3d 796, 798 (3rd Cir. 1996) (emphasis added). The Appeals Board at issue in *Pennsylvania* had been created by the Secretary through regulation (and later granted additional authority by Congress through statute) to resolve disputes between the Secretary and states arising under a complicated regulatory scheme related to child support. *Id.* at 800. Board members were appointed by the Secretary, and Board rulings constituted final agency action reviewable only in district court. *Id.* at 800-01. Pennsylvania argued board members must be principal officers in light of: (1) the broad "scope of the Board members' authority"; (2) the Board's statutory jurisdiction, which placed "much of the Board's jurisdiction … beyond the reach of the Secretary"; and (3) that "Board members will serve indefinitely unless removed for misconduct." *Id.* at 802. The Third Circuit agreed with the government that Board members were inferior, not principal, officers because the Board was bound by the Secretary's regulations, "*i.e.*, it applies, rather than makes, agency policy"; because its review was restricted to certain categories of disputes "limited by regulation"; because the Secretary could remove board members; and because the Secretary "retains discretion to terminate or reassign all but a few of the Appeals Board's functions." *Id.* at 803. "[P]erhaps most significantly," the court continued, "the Secretary could altogether eliminate the powers of the Board that are at issue here." *Id.*; *see also id.* at 804 (confirming "it is difficult to imagine how Appeals Board members could be principal officers" under controlling Supreme Court authorities). Importantly, this conclusion was in no way displaced by the fact that Appeals Board rulings were reviewable only in district court under the APA.

Pennsylvania is far from unique; on-point, persuasive appellate authorities have reached similar conclusions, and demonstrate the different ways in which an inferior officer's work may be "directed and supervised at some level," *Edmond*, 520 U.S. at 662-63, by superior officers. For example, the D.C.

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

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

Likewise, that same court recently concluded that Special Counsel Mueller was an inferior officer, even though DOJ regulations "impose various limitations on the Attorney General's ability to exercise effective oversight of the Special Counsel." *In re Grand Jury Invest.*, 916 F.3d 1047, 1052 (D.C. Cir. 2019). That conclusion turned on the Attorney General's "authority to rescind" those regulations "at any time," thereby allowing him to exercise supervisory authority. *Id.* In other words, regulations restricting a principal officer's supervisory authority make no difference from a constitutional

perspective, because the agency head retains plenary authority to revise or rescind the regulations. Applying that reasoning, the court of appeals confirmed that the Special Counsel is a validly appointed inferior officer because he "effectively serves at the pleasure of" the Attorney General. *Id.* at 1052-53.

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

Sanofi's Article II claim is *irreconcilable* with binding circuit precedent. The Appeals Board members at issue in *Pennsylvania* operated with significantly greater independence than ADR Board members here—indeed, they reviewed *decisions of the Secretary*—and, as here, issued binding decisions reviewable only in district court, yet the Third Circuit found it "difficult to imagine" they could be anything other than inferior officers. 80 F.3d at 798, 804. In its complaint Sanofi wholly ignores this controlling authority. The inferior-officer conclusion turned on the facts that the Board's powers were "limited" in that it could review only certain types of cases and was required to "appl[y], rather than make[], agency policy," 80 F.3d at 803, in addition to the "oversight" related to the Secretary's removal power and ability to withdraw some of the Board's delegated authority. Those factors are equally

present here, *except* that the Secretary may remove ADR Board members at will, rather than only for-cause.

Rather than confront this precedent, Sanofi misconstrues the Rule and misapplies both the supervision and removal prongs of the Appointments Clause analysis. As to the first prong, Sanofi ignores all the relevant, powerful tools for control that the Secretary may exercise, instead insisting that ADR members operate wholly without supervision because "[t]hey independently determine how to conduct proceedings, and they make final precedential determinations on behalf of HHS that are not subject to any further executive branch review." Compl. ¶ 87. That assertion lacks merit for numerous reasons: the Supreme Court has never held that an inferior adjudicative officer's decisions *must* be reviewed, individually, by a principal officer; the Court's reasoning in *Edmond* and *Free Enterprise Fund* emphasizes other means of "supervision" than direct review of an officer's decisions; and the Third Circuit in *Pennsylvania* confirmed that a similar adjudicatory board within HHS was comprised of inferior officers even though its decisions also were not subject to direct review by a superior officer. And outside this circuit, persuasive, directly on-point appellate authorities squarely have rejected Sanofi's contention. For example, the lack of direct, intra-agency review was true of the judges in *Intercollegiate Broadcasting* too, yet the court of appeals was "confident" in deeming them inferior officers. 684 F.3d at 1341. At bottom, the absence of an internal review mechanism does not prevent the Secretary from supervising Board members—nor does it render them principal officers.

Sanofi's argument as to the removal prong rests on a flatly false premise. Sanofi wholly ignores the fact that the Rule does not purport to place *any* restrictions on Board members' removal, yet nonetheless argues that for-cause removal protection renders them principal officers. Compl. ¶ 8. But no protection from removal applies; the statute contains no restriction on the Secretary's removal of Board members, 42 U.S.C. § 256b(d)(3)(A)-(B), and the regulation likewise does not suggest any restriction on the Secretary's ability to remove members at will (and a regulatory for-cause provision would *have no impact* on the Secretary's power regardless, *In re Grand Jury*, *supra*). Sanofi's insistence that Board members lack "accountab[ility]" because they are protected from removal, Compl. ¶ 8, contravenes "[t]he general and long-standing rule [] that, in the face of statutory silence, the power of

removal presumptively is incident to the power of appointment." *Kalaris v. Donovan*, 697 F.2d 376, 389 (D.C. Cir. 1983); *see also Free Enter. Fund*, 561 U.S. at 509 ("Under the traditional default rule, removal is incident to the power of appointment.").

Sanofi attempts to elide this lack of constraint by pointing to a provision delegating *to the HRSA Administrator* the power to remove a panel member "for cause," including for a conflict of interest. *E.g.*, Compl. ¶ 55; 42 C.F.R. § 10.20(a)(1)(ii), (2). In other words, Sanofi engages in subterfuge by discussing only the circumstances in which a panelist is removed *from a particular assignment* for cause, including conflicts, and falsely equating that standard with removal *from the Board* altogether—*i.e.*, the relevant consideration for constitutional purposes. This attempt fails; that delegation of partial authority to take ADR Board members from a particular panel merely allows the HRSA Administrator to share in the supervision of the ADR process; it in no way constrains the Secretary's ability to remove an individual from a panel, or from the Board, at will—with or without a conflict of interest.[6] Put simply, Sanofi is flatly incorrect in portraying ADR members as "protected by for-cause removal restrictions," Compl. ¶ 8, because the Secretary may rescind his delegation of authority at any time by removing a Board member for any reason. This "powerful tool for control," *Edmond*, 520 U.S. at 664, demonstrates that members serve as inferior officers.

Sanofi's challenge fails because Board members are inferior officers whose work is "directed and supervised at some level" by the Secretary, a principal officer appointed by the President with Senate confirmation. *Edmond*, 520 U.S. at 663. Like the Appeals Board members in *Pennsylvania*, 80 F.3d at 801-04, ADR Board members issue final agency decisions subject to APA review in district court, yet remain subject to the Secretary's general supervision. Like the officers in *Intercollegiate Broadcasting*, 684 F.3d at 1341, and *Free Enterprise Fund*, 561 U.S. at 510, Board members are freely removable at will. Like the Special Counsel in *In re Grand Jury Investigation*, 916 F.3d at 1052-53, the

[6] Sanofi's assertion that the HRSA Administrator may only remove a panel member for conflicts of interest, Compl. ¶ 55, also is incorrect; the regulation delegates authority to remove members "for cause," without limiting that term. 42 C.F.R. § 10.20(a)(1)(ii). Sanofi's inaccuracy is irrelevant, however, since it is the Secretary's power—not that of the HRSA Administrator, acting through delegation—that matters for constitutional purposes.

Secretary could revoke or modify the ADR Rule—and thus the members' authorizing regulations—at any time. And like the inferior officers in *Edmond*, 520 U.S. at 664, Board members must follow their superior's rules of procedure and substantive policy, and members may be removed from any particular assignment. The Secretary retains plenary authority to revise the Rule and, in so doing, modify the workings of the Board. Board members thus have received a proper appointment as inferior officers from the Secretary of HHS as the Head of a Department. Sanofi's Article II challenge to the ADR Rule fails as a matter of law and should be dismissed.

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

As with its Article II challenge, Sanofi's Article III claim, Compl. ¶¶ 90-94, rests on a fundamentally inaccurate portrayal of the Board's remedial powers and of the claims it is empowered to hear. Far from "granting 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," as Sanofi charges, *id.* ¶ 8, the ADR Rule creates a straightforward mechanism for the agency to determine compliance with a statutory scheme Congress entrusted to HHS—precisely the type of administrative adjudication that courts have blessed for much of the past century. The Rule creates no Article III concerns.

As an initial matter, Sanofi falsely claims that the Board is empowered "to resolve disputes between private parties over … the price of a drug." Compl. ¶ 8. This assertion is nonsensical because, under the 340B statute, a sale of Sanofi's medications to a covered entity at the statutory ceiling price *is full payment* (*i.e.*, the price is firmly set by statute), and Sanofi must comply with its obligation to fulfill orders *placed by covered entities* at no more than the ceiling price if it wishes to retain access to Medicaid and Medicare Part B. The Board determines compliance by both covered entities and manufacturers with statutory requirements—it does not set prices or command the conveyance of private property.

Moreover, the ADR Rule facially disproves Sanofi's claim as to the Board's powers. Although ADR Panels are empowered to issue a final agency decision, those decisions are *not* self-effectuating. *Contra* Compl. ¶¶ 86, 108. Panel decisions must be "submit[ted] … to HRSA for appropriate action

regarding refunds, penalties, removal, or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e). Indeed, in response to comments, some of which expressed "concern[]" that the proposed rule *lacked* a specific enforcement mechanism, the agency rejected calls for more-specific provisions by explaining that ADR panels "may make recommendations to HRSA for sanctions" that may be the basis for imposition of civil monetary penalties and that the absence of specific enforcement mechanisms in the Rule is designed "to permit HHS maximum flexibility in determining what is appropriate" when a panel determines a violation has occurred. *See* 85 Fed. Reg. at 80,642. Sanofi's clamoring about the Rule "enabling those panels to enforce such decisions [over price] through binding money judgments," and to unilaterally issue "binding and precedential" "award[s] [of] money damages and equitable relief" with immediate impact, *e.g.*, Compl. ¶¶ 93, 7, ignores the Rule's plain text requiring panels to submit decisions *to HRSA* "for appropriate action." § 10.24(e).

Sanofi's complaints about potential "equitable relief" further misconstrue the Rule; contrary to its portrayal, *e.g.*, Compl. ¶ 9, the Rule does not purport to authorize panels to issue sweeping injunctions. Rather, the "equitable relief" referred to in the Rule establishes a jurisdictional floor on the claims heard by a panel, to exclude *de minimis* claims. 42 C.F.R. § 10.21 (a), (b) (granting jurisdiction "to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000" within twelve months); 85 Fed. Reg. at 80,633 (explaining that provision is designed to exclude *de minimis* claims). Read in context, the "equitable relief" contemplated in the Rule means an order determining whether a manufacturer or covered entity has violated the statute—not a self-executing, judicial-style remedy. The 340B statute clearly contemplates that the new ADR process will resolve questions of program compliance, and that is all the Rule purports to authorize, since panel decisions must be referred to HRSA for enforcement. Nowhere does the Rule allow panels to grant a sweeping "injunction," under penalty of contempt, as can be issued by an Article III court. *Contra* Compl. ¶ 9. Rather, the "equitable relief" issued by a panel would declare specified conduct to be unlawful—the equivalent of a cease-and-desist order, which can be obeyed or appealed—not a self-executing injunction.

Far from unusual, the orders contemplated in the ADR Rule find analogues throughout the federal bureaucracy. "Some agencies have the power in an adjudication, similar to the power that courts possess, to order the payment of money, either to the Government or to a third party, subject to judicial review. More typically, agencies will issue orders that resemble court-issued injunctions, though they may be called something else, such as 'cease and desist orders' (Federal Trade Commission (FTC)), 'exclusion orders' ([Securities and Exchange Commission]), or 'deportation orders' directing an alien to leave the country (U.S. Citizenship and Immigration Service)." Alan B. Morrison, *Administrative Agencies Are Just Like Legislatures and Courts-Except When They're Not*, 59 Admin. L. Rev. 79, 99-100 (2007); *see also id.* n.66 (noting that National Labor Relations Board can order an employee's reinstatement, with back pay, and Commodity Futures Trading Commission can order fines "of the higher of $100,000 or the gain of the wrongdoer" plus restitution).

Sanofi's complaints about the ADR Board's authority to conduct proceedings are easily dispatched. Sanofi urges this Court to find an Article III problem because, it claims, "the ADR Rule empowers ADR panels to function like federal courts." Compl. ¶¶ 58-60 (discussing procedures). But the adoption of court-like procedures makes no difference, because the Supreme "Court has never adopted a 'looks-like' test to determine if an adjudication has improperly occurred outside of an Article III court," since "[t]he fact that an agency uses court-like procedures does not necessarily mean it is exercising the judicial power." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1378 (2018) (rejecting argument that non-judicial patent adjudication "violates Article III because it shares 'every salient characteristic associated with the exercise of the judicial power," including "motion practice …; discovery, depositions, and cross-examination of witnesses; introduction of evidence and objections based on the Federal Rules of Evidence; and an adversarial hearing before the Board") (citation omitted). In short, the procedures adopted by the ADR Rule mirror those found, and upheld, in other agency adjudications. *See also* ADR_1105; ADR_1205; ADR_1321.

That leaves only Sanofi's argument that the Board usurps the power of federal courts by adjudicating private rights. Article III prevents Congress from "withdraw[ing] from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty."

Stern v. Marshall, 564 U.S. 462, 484 (2011) (quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1855)). In other words, non-judicial fora may not be assigned adjudication of "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789." *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*,, 458 U.S. 50, 90 (1982) (Rehnquist, J., concurring). But when Congress creates a new right by statute—*i.e.* a "public right[]"—"it depends upon the will of [C]ongress whether a remedy in the courts shall be allowed at all," so "Congress may set the terms of adjudicating" that right. *Stern*, 564 U.S. at 489 (citation omitted). The separation of powers is not offended by adjudication of public rights outside the judiciary because, when Congress creates new rights (such as through a novel, comprehensive regulatory scheme), it has broad latitude to grant jurisdiction to federal courts or assign adjudication in another branch.

Public rights capable of resolution before an administrative agency are not limited to rights collectively held by the public at large or involving disputes between the government and a private party. On the contrary, the Supreme Court long ago "rejected the limitation of the public rights exception to actions involving the Government as a party," instead explaining that it encompasses "cases in which the claim at issue derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority." *Stern*, 564 U.S. at 490-91 ("[W]hat makes a right 'public' rather than private is that the right is integrally related to particular Federal Government action."). Thus it matters not that the dispute may arise between private parties; it is the character of the *right* at issue—one specially created by Congress—that renders it amenable to non-judicial resolution.

In fact, the argument Sanofi presses here—that the "Rule violates Article III by … empower[ing] ADR Panels to determine the liability of one individual to another," Compl. ¶ 93—has been explicitly rejected by the Supreme Court. After canvassing various agency adjudicative schemes, all of which "surely determine liabilities of individuals," the Court explained that, "[i]f the identity of the parties alone determined the requirements of Article III … the constitutionality of many quasi-adjudicative activities carried on by administrative agencies involving claims between individuals would be thrown into doubt." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 587, 589 (1985);

see also id. 571-75, 584 (upholding binding arbitration to resolve disputes between private companies because "[a]ny right to compensation … results from [the statute] and does not depend on or replace a right to such compensation" under state or common law). These principles recently were reaffirmed in *Oil States*, which upheld a procedure whereby an administrative board, through adversarial proceedings between private parties, determines the validity of patent rights. The Court's conclusion was not displaced by the fact that patents might be "property for purposes of the Due Process Clause or the Takings Clause." 138 S. Ct. at 1379. As the Third Circuit succinctly has summarized, "public rights" post-*Union Carbide* are those "involv[ing] rights that [a]re an integral part of a public regulatory scheme, assigned to an administrative agency." *Beard v. Braunstein*, 914 F.2d 434, 441 (3rd Cir. 1990).

Sanofi's assertion that the Rule violates Article III by allowing non-judicial adjudication of private rights, Compl. ¶¶ 92-93, rests on a warped interpretation of the disputes presented to the Board. The ADR process does not decide Sanofi's right to sell its product at its chosen price, nor can a panel "resolve disputes between private parties over … the price of a drug," or extinguish private-property rights, *id.* at ¶¶ 8, 93. The ADR process, like other administrative determinations of public rights, *supra*, determines compliance with the statutory provisions enacted by Congress. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.3. The panels cannot determine disputes over the prices Sanofi may charge for its products; the statutory ceiling price accomplishes that task. The panels do not decide to whom Sanofi must offer discounted drugs; the 340B statute determines this, too. The ADR panels, contrary to Sanofi's portrayal, do not have independent authority to order the disgorgement of private property—only compliance with the statutory regime. And the statutory disputes ADR panels resolve emphatically are not "traditional actions at common law," *Stern*, 564 U.S. at 484, since they are entirely creatures of the 340B Program.[7]

Congress created the 340B Program, thereby granting covered entities the statutory *right* to discounted medications, and pharmaceutical manufacturers, like Sanofi, the statutory *right* to access

[7] Indeed, Sanofi cannot credibly argue that a claim for overcharging, duplicate-discounting, or diversion could have been tried by the common-law courts at Westminster in 1789. *See N. Pipeline Const. Co.*, 458 U.S. at 90.

incredibly valuable revenue streams (Medicaid and Medicare Part B) in exchange for providing its property in the form of discounted drugs. The rights of both covered entities and manufacturers under this scheme are quintessential public rights, created by a comprehensive and well-established regulatory system. Sanofi can opt out of the 340B Program and lose the right to access Medicaid and Medicare Part B, but it cannot enjoy those rights while shirking its obligations under 340B (or unilaterally deciding to place conditions on whether, when, and under what circumstances it will comply with those obligations). The Board, for its part, decides only whether manufacturers and covered entities each are complying with statutory requirements, not Sanofi's preexisting natural property rights. *See Kalaris*, 697 F.2d at 388 ("The law is emphatically clear that when Congress creates a substantive federal right, it possesses substantial discretion to prescribe the manner in which that right may be adjudicated."); *id.* at 400 (upholding administrative resolution of workers' compensation claims, noting "the scores of administrative boards and tribunals in the Executive Branch that currently adjudicate claims to federal statutory rights").

Tellingly, Sanofi ignores the fact that the claims it seeks to thwart—claims by covered entities that it has denied their statutory entitlement to 340B discounts—arise wholly from a public right, given that it exists only as a matter of statute. This point is dispositive; as demonstrated above, the Supreme Court repeatedly has upheld administrative adjudication of statutory, public rights notwithstanding that the disputes arose between private parties and resulted in the exchange of property. The ADR Rule does not concern private rights any more than those sanctioned in, *e.g.*, *Union Carbide*, 473 U.S. at 587-89. Sanofi likely will attempt to confuse the applicable standard (as it did in its emergency motion, ECF No. 19-1 at 24-27), by hanging its Article III argument on inapposite bankruptcy cases such as *Stern* and *Northern Pipeline*. Article III challenges arising in bankruptcy proceedings *necessarily* involve state or common-law counterclaims (since Congress does not assign adjudication of complex regulatory schemes to bankruptcy courts), meaning that bankruptcy challenges often involve the adjudication of private rights. By contrast, cases involving administrative-

agency adjudications arising under complex regulatory schemes, such as *Union Carbide* and *Oil States*, provide the rule of decision for public-rights claims such as this.[8]

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

"Congress has been creating quasi-judicial boards subject to Executive control for years, and the courts have not previously prevented them from doing so. To do so now 'would be to turn the

[8] Sanofi's contention that "adjudication of private rights must be overseen by Article III courts," Compl. ¶ 92, also is wrong. Private rights sometimes may be adjudicated by agencies serving as adjuncts of the Third Branch. *See Schor*, 478 U.S. at 853; *Crowell v. Benson*, 285 U.S. 22, 47 (1932) (upholding administrative scheme that displaced traditional common-law claim and created "expert and inexpensive method for dealing with a class of questions of fact … peculiarly suited to … determination by an administrative agency"); *Kalaris*, 697 F.2d at 386 ("Article III does not require Article III judges to perform every stage of adjudication where 'private rights' are at stake.").

clock back on at least a century of administrative law." *Kalaris*, 697 F.2d at 401 (citation omitted). This Court should grant summary judgment for HHS on Sanofi's meritless Article III claim.[9]

C. THE SECRETARY FULLY COMPLIED WITH NOTICE-AND-COMMENT REQUIREMENTS IN PROMULGATING THE ADR RULE

1. HHS did not terminate the ADR Rulemaking in advance of issuing the final rule.

Sanofi's procedural APA claim also fails as a matter of law. Under the APA, when an agency is required to undertake notice-and-comment rulemaking, the agency must publish a notice of proposed rulemaking that includes "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The agency must then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). Noticeably absent from the APA is any requirement that a final rule follow an NPRM within a specified amount of time, or any provision that causes an NPRM to expire. Indeed, there is often a significant amount of time between the end of a comment period and the issuance of a final rule. *See, e.g.*, Food Labeling; Gluten-Free Labelling of Fermented or Hydrolyzed Foods, 85 Fed. Reg. 49,240, 49,244 (Aug. 13, 2020) (final rule issued nearly five years after notice of proposed rulemaking). HHS fully complied with the APA's notice and comment procedures. HHS first issued an advanced notice of proposed rulemaking requesting comments on the development of an ADR process in 2010. 75 Fed. Reg. 57,233 (Sept. 20,

[9] Count III of Sanofi's complaint, ¶¶ 95-101, relies on the same contentions as its Article II and III claims, but asks the Court to set aside the Rule as exceeding statutory authority under the APA. That claim fails for the same reasons outlined above. Sanofi also posits that the Rule "impermissibly expands the scope of Section 340B" because the statute mandated creation of a process to determine "claims by covered entities that they have been overcharged for drugs," 42 U.S.C. § 256b(d)(3), while the Rule defines an overcharging claim to encompass allegations "that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs," 42 C.F.R. § 10.21(c)(1). This contention is meritless; there is no meaningful daylight between a provider's claim that it was *overcharged* for a drug versus that it was *denied the ability to purchase* the drug at a discounted price. Where a 340B-discounted purchase is denied, the covered entity necessarily is overcharged (unless it foregoes purchase of the drug altogether). Moreover, it is absurd to suggest that Congress required the Secretary to establish a process to adjudicate overcharges but did not intend that process to resolve claims that a covered entity wrongly was denied the ability to make a purchase in the first place. Sanofi's claim that the rule "expands" the scope of the ADR claims Congress intended is nonsensical and should be denied.

2010). It then issued an NPRM on the same topic in 2016. 81 Fed. Reg. 53,381 (Aug. 12, 2016). After reviewing the comments it received on both notices, HHS issued the final ADR Rule in 2020. 85 Fed. Reg. 80,632 (Dec. 14, 2020).

Sanofi's sole argument to the contrary is that HHS "withdrew" the rulemaking from the Unified Agenda of Regulatory and Deregulatory Actions ("Unified Agenda") after the NPRM's comment period and prior to issuance of the ADR Rule, supposedly nullifying the NPRM. Am. Compl. ¶ 107. But removing a rulemaking from the Unified Agenda alone is not sufficient to terminate a rulemaking or render an NPRM invalid. The agency must formally withdraw the NPRM, accompanied by a statement explaining its reasons for the withdrawal, often accomplished by a publication of the withdrawal notice in the Federal Register. *See Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 42 (D.C. Cir. 2004) (acknowledging withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 844 (D.C. Cir. 1983) (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same). Indeed, HHS's usual practice is to publish a notice of withdrawal in the Federal Register. *See, e.g.*, 78 Fed. Reg. 12,702-01 (Feb. 25, 2013); 79 Fed. Reg. 19,848-01 (Apr. 10, 2014); 83 Fed. Reg. 60,804-01 (Nov. 27, 2018); 84 Fed. Reg. 37,821-01 (Aug. 2, 2019). Because HHS made no such statement here, in the Federal Register or otherwise, Sanofi has not persuasively alleged that HHS withdrew the 2016 NPRM.

In a recent decision on a motion for preliminary injunction in another case, a judge in the Southern District of Indiana rejected HHS's arguments, concluding that the "relevant inquiry," in determining whether HHS withdrew the ADR Rule, "is whether, through their actions and statements, [HHS] effectively communicated a withdrawal of the proposed rule to the public." Lilly PI Order 21. That court's approach at the preliminary-injunction stage is foreclosed by well-established Supreme Court precedent and, in any event, is not supported by the APA. In *Lilly*, the court essentially imposed a new (and highly subjective) procedural requirement on agencies not found in the APA—that agencies must publish a new NPRM and re-do the notice and comment process if the totality of the circumstances would lead a reasonable observer to view the original NPRM as withdrawn. But as the Supreme Court has oft repeated, "the [APA] established the maximum procedural requirements which

Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures." *See, e.g.*, *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council*, 435 U.S. 519, 524 (1978). It is reversible error to create additional requirements constraining the agency's ability to engage in rulemaking directed by Congress.

Moreover, this "totality-of-the-circumstances" test, created in the first instance by the *Lilly* court, is incompatible with existing law setting forth the procedures for review of agency action under the APA. The decision to terminate rulemaking proceedings is typically reviewable as final agency action under the APA. *Ctr. for Auto Safety*, 710 F.2d at 846. As such, when an agency terminates a rulemaking, it must provide "an explanation that will enable the court to evaluate its rationale at the time of the decision." *Int'l Union*, 358 F.3d at 42. In additional to being foreclosed by well-established precedent, the Court's totality of the circumstances approach would not allow for this classic review under APA principles based on a statement of decision accompanied by any administrative record. Here, HHS provided no such statement, and did not terminate the ADR Rule.

But even if the Court disagrees with Defendants on the appropriate inquiry, Sanofi has failed to allege any circumstances that would lead a reasonable observer to conclude that the 2016 NPRM was, in fact, withdrawn. The listing or delisting of rulemaking on the Unified Agenda is not presumed to provide notice to regulated individuals of agency action. Though the Unified Agenda exists to provide "uniform reporting of data on regulatory and deregulatory activities under development" in the Executive Branch, *About the Unified Agenda*, REGINFO.GOV,[10] listing a rulemaking on the Unified Agenda does not satisfy statutory requirements to provide notice of rulemaking, 5 U.S.C. § 553(b), or establish presumptive notice of regulation required for enforcement, *cf.* 44 U.S.C. § 1507. Accordingly, de-listing a rulemaking from the regulatory agenda is not sufficient to withdraw that rulemaking for the purposes of the APA. The Unified Agenda is simply an administrative tool to assist the Executive Branch in the organization and exercise of its regulatory authority.

Thus, under either test, Sanofi's notice and comment claim fails as a matter of law.

[10] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp (last visited Feb. 16, 2021).

2. The ADR Rule is a logical outgrowth of the NPRM.

Because the NPRM gave Sanofi adequate notice of the topics covered by the ADR Rule, as required by the APA, Sanofi's "logical outgrowth" claim fails as a matter of law. Am. Compl. ¶ 108. Even when a final rule differs from the NPRM, the standards of the APA may be satisfied. *See Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 249 (3d. Cir. 2010). A NPRM need only "apprise interested parties of all significant subjects and issues involved." *NVE, Inc. v. HHS*, 436 F.3d 182, 191 (3d. Cir. 2006) (quotation omitted). Accordingly, "a final rule is a logical outgrowth of a proposed rule" if "interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Council Tree Commc'ns, Inc.*, 619 F.3d at 249 (quotation omitted).

Sanofi argues that two aspects of the ADR Rule fail under these standards because Sanofi was not "provided" the "opportunity to comment" on them: (1) ADR panels' supposed authority to "issue binding judgments for money damages;" and (2) the "precedential" weight of ADR decisions." Am. Compl. ¶ 108. But that argument cannot succeed, as it is based on a demonstrably false reading of the ADR Rule and, in any event, concerns topics that were clearly addressed in the NPRM.

First, as shown above, Sanofi is incorrect that an ADR Panel has authority to issue binding judgments for money damages. The ADR Rule requires the Panel to make a decision on the merits of the alleged statutory violation, but only empowers it to "make recommendations to HRSA," Rule at 80,646, "for appropriate action regarding refunds, penalties, removal, or referral," 40 C.F.R. § 10.24(e).

Sanofi's misunderstanding of the Rule appears to stem from language in response to comments on an unrelated provision of the Rule. In the NPRM, HHS advised, "covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for de minimis claims given the investment of the time and resources required of the parties involved." NPRM at 53,382. Commenters urged HHS to "clarify" what would constitute such a de minimis claim. Rule at 80,633. HHS set a threshold monetary value for claims raised with the ADR Panel in response, stating, "[w]e believe that an appropriate threshold for a claim or claims for money damages should be $25,000." *Id.* But nowhere does HHS state that the Panel would have authority to award such damages. Sanofi

cannot rely on its misreading of the Rule to support its assertion that HHS failed to give proper notice to interested parties.

As properly read, the provision of the Rule requiring the Panel to submit its decisions to HRSA is also "materially identical" to the NPRM, further dooming Sanofi's claim. *See Post Acute Med. at Hammond, LLC v. Azar*, 311 F. Supp. 3d 176, 185 (D.D.C. 2018). Just as the Rule provides that the Panel "will submit the final agency decision to all parties, and to HRSA for appropriate action regarding refunds, penalties, removal, or referral," 42 C.F.R. § 10.24(e), the NPRM proposed regulatory language requiring the Panel to "submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action." NPRM at 53,388 (proposed 42 C.F.R. § 10.23(b)(2)). Simply spelling out the type of enforcement actions that HRSA may take does not constitute a change in the agency's position, much less a material change.

Second, Sanofi takes issue with HHS's alleged change in position on the precedential nature of ADR Panel decisions. In the NPRM, HHS proposed that the Panel's decisions would be "binding upon the parties involved." NPRM at 53,385. In the Rule, however, HHS determined that the Panel's decision would also be "precedential" in other ADR proceedings, in addition to being "binding on the parties." 85 Fed. Reg. at 80,641. But the fact that HHS expanded the effect of the Panel's decisions does not mean that Sanofi had inadequate notice. *See Am. Med. Ass'n v. United States*, 887 F.2d 760, 768 (7th Cir. 1989) (noting "that courts have upheld final rules" which represented "outright reversal of the agency's initial position"). The relevant question is simply "whether or not potential commentators would have known that an issue in which they were interested was 'on the table' and was to be addressed by a final rule," and "if interested parties favor a particular regulatory proposal, they should intervene in the rulemaking to support the approach an agency has tentatively advanced." *Id.* Here, the effect of the Panel's decision was clearly "on the table." *Id.* And particularly where HHS was "writing on a clean slate" in developing the ADR process, Sanofi cannot claim that it lacked notice of the agency's intent to define the effect of Panel decisions. *Id.* at 769.

"The object, in short, is one of fair notice," *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007), and Sanofi has not sufficiently alleged it lacked fair notice here.

D. THE ADR RULE IS SUBSTANTIVELY COMPLIANT WITH THE APA

Sanofi asserts various arbitrary-and-capricious claims challenging the ADR Rule, all of which lack merit. *See* Compl. ¶¶ 111–14 (citing 5 U.S.C. § 706(2)(A)). As explained previously, the APA's arbitrary-and-capricious standard is extremely deferential and "requires [only] that agency action be reasonable and reasonably explained." *Prometheus*, 141 S. Ct. at 1158.

First, HHS was not required to respond to comments recommending that it revise HRSA's manufacturer auditing guidelines before moving forward with the ADR Rule. *See* Compl. ¶ 114. Nonetheless, HHS *did* address these comments and concluded that they were not pertinent to the development of the ADR process. *See* 85 Fed. Reg. 80,633. But whether HHS "adequately responded to these comments makes no difference" under the APA because the agency "had no obligation to respond to them in the first place." *See City of Portland v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007). Agencies need not address every comment submitted on a proposed rule, *La. Forestry Ass'n Inc. v. Sec'y of Dep't of* Labor, 745 F.3d 653, 679 (3d Cir. 2014), and they are under no obligation to respond to comments raising issues beyond the scope of the rulemaking process, *see Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 549 (D.C. Cir. 1997). The APA requires an agency to address only "'relevant' and 'significant' public comments," *Nazareth Hosp. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 747 F.3d 172, 185 (3d Cir. 2014) (citation omitted)—*i.e.*, those "comments that are 'relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule,'" *Nat'l Mining Ass'n*, 116 F.3d at 549 (citation omitted); *see also NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d 182, 190 (3d Cir. 2006) ("[W]hether an agency acted arbitrarily and capriciously" turns on "whether the agency relied on factors outside those Congress intended for consideration, [or] completely failed to consider an *important* aspect of the problem . . . . Reversal is appropriate only where the administrative action is irrational or not based on *relevant* factors." (emphasis added)).

Here, HHS proposed a rule to develop requirements and procedures for an ADR process, as mandated under 42 U.S.C. § 256b(d)(3). NPRM at 53,381. Congress required the Secretary to develop a dispute-resolution mechanism, and the Secretary was not required to expand the scope of that mandatory rulemaking to encompass a separate matter—potential revisions to HRSA's auditing

guidelines. *See, e.g.*, *Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 230-31 (1991) ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures, and priorities … [and it] need not solve every problem before it in the same proceeding." (citations omitted)). Comments regarding HRSA's auditing guidelines raised an issue that was simply beyond the scope of this rulemaking process. In fact, these comments did not even seek "a change in [the] proposed [ADR] rule," *see Nat'l Min. Ass'n*, 116 F.3d at 549 (citation omitted), but instead asked HHS to abandon the rule altogether and to turn its attention to a different course of action, *see* Rule at 80,633 ("Commenters recommend that, *before* HRSA develops the ADR process, HRSA should … reform its guidelines regarding manufacturer audits of covered entities.") (emphasis added). But comments cannot "unilaterally expand the scope of [a proposed rule]," nor can they compel an agency "to initiate a separate rulemaking to address" a different problem. *See Sec. Indus. & Fin. Mkts. Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 429 (D.D.C. 2014). At bottom, HRSA's auditing guidelines were neither a "significant" nor "relevant" issue that HHS was required to consider in the ADR rulemaking, particularly in light of the fact that Congress expressly mandated development of the ADR process. *See Nazareth Hosp.*, 747 F.3d at 185 (citation omitted).

Second, for those reasons just explained, the Secretary was also not obligated to address the issues raised in Pharmaceutical Research and Manufacturers of America's ("PhRMA") petition for proposed rulemaking. *See* Compl. ¶ 61, 112.[11] PhRMA's petition (submitted to HHS three weeks prior to issuance of the ADR Rule) asked HHS to initiate a *new* rulemaking to revise both HRSA's auditing guidelines and guidelines regarding the 340B statute's definition of a covered entity's "patient," two additional measures that PhRMA felt would solve certain program-compliance issues (*e.g.*, drug diversion and duplicate discounts).[12] *See generally* Notice Regarding Section 602 of the Veterans Health

[11] Sanofi alleges more generally that "HHS failed to account for changed legal and factual circumstances" in the years preceding the ADR Rule's promulgation, but it fails to specify any such circumstances aside from the "new evidence" in PhRMA's petition. *See* Compl. ¶ 112.

[12] PhRMA's petition is not attached as an exhibit to Sanofi's amended complaint. It can be found at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Petition-for-340B-ADR-Rulemaking_November-2020.pdf (also noting increased participation in the 340B Program by covered entities, including those utilizing contract pharmacies).

Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996). But again, the ADR Rule is the culmination of a congressionally mandated rulemaking for the development of a 340B dispute-resolution mechanism. In meeting this mandate, the Secretary was not required to propose an omnibus rule to address separate matters or to solve every potential problem brought to his attention. *See Mobil Oil Expl. & Producing Se.*, 498 U.S. at 230-31; *see also NVE, Inc.*, 436 F.3d at 190 (explaining that reversal under the arbitrary-and-capricious standard is proper only where the agency acted irrationally or failed to consider an important or relevant aspect of the problem it sought to address with proposed action).

Lastly, Sanofi's claim that "HHS failed to reasonably explain its reasons for choosing the design of the ADR process," *see* Compl. ¶ 113, is so vague and conclusory that it prevents HHS from substantively responding. The entire ADR Rule, from beginning to end, concerns "the *design* of the ADR process." *See id.* (emphasis added). Yet, Sanofi fails to specify a single component of this multifaceted process that HHS allegedly explained insufficiently. Accordingly, Sanofi's "bald assertion[]" that HHS acted arbitrarily and capriciously cannot survive HHS's motion to dismiss. *See Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citation omitted); *see also Seward v. N.J. Div. on Civ. Rights*, 2012 WL 10667917, at *2 (D.N.J. March 29, 2012) ("[A] court will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations.").

CONCLUSION

Because each of Sanofi's claims is meritless, the Court should dismiss each count or, in the alternative, grant summary judgment for HHS.

Dated: April 19, 2021

Respectfully submitted,

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

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

PROPOSED ORDER

Upon consideration of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment and Plaintiff's cross-motion, the Court hereby GRANTS Defendants' motion and dismisses each count of Plaintiff's Amended Complaint.

SO ORDERED.

Dated: _____

Signed:_____
The Honorable Freda L. Wolfson
Chief Judge