IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiffs, v. XAVIER BECCERA, *et al.*, Defendants.	CASE NO.: 8:21-CV-00198-PWG

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

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This case culminates a brazen strategy by a cohort of large, highly profitable pharmaceutical companies, members of Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"), 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 several of PhRMA's members, 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. The 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.

PhRMA's ultimate goal in this suit is manifestly clear in its complaint: It seeks to interfere with HHS's enforcement of the 340B statute against its members. PhRMA seeks to advance that goal by first asking this Court to declare unlawful the twenty-four-plus-year old audit guidelines that manufacturers have followed when auditing a covered entity. In addition to that request, PhRMA

further asks this Court permanently to block implementation of a new rulemaking that establishes the straightforward, statutorily mandated administrative dispute-resolution mechanism Congress devised to resolve certain disputes over 340B Program violations. In other words, PhRMA seeks to shield the manufacturers' recent, industry disrupting changes from consideration during the administrative dispute-resolution process by asking this Court to enjoin the agency's newly available adjudication system—a system required by statute and modeled on numerous other administrative bodies—as well as the audit guidelines for manufacturers before they access that system.

There is no cause for this Court to grant either request because PhRMA's claims uniformly lack merit. The Secretary's audit guidelines are consistent with the text of the statute, the statute's purpose, and, in any event, are a reasonable exercise of the Secretary's statutorily conferred discretion. PhRMA's attacks on the administrative dispute-resolution rule are equally flawed. The Secretary fully explained the reasonable choices made in designing the new dispute resolution system, satisfying substantive APA requirements. And 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.

The Court should dismiss each of PhRMA'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 large annual revenue stream through drug coverage in certain federal health-insurance programs. *Id.*

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' patients. *Id.*

In 1996 HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. *Id.* 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. To effectuate that statutory purpose, the 1996 guidance confirmed: "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. Thus, twenty-five years ago HHS interpreted the statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies. HHS explained the 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.

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"). 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, including that both the covered entity and contract pharmacy must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 10,278. A covered entity bears full responsibility for 340B Program requirements and can lose eligibility if violations occur. *Id.* But 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.* 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.

The 340B statute also requires covered entities to allow HHS and manufacturers to audit "the records of the entity that directly pertain to the entity's compliance" with statutory prohibitions on diversion and duplicate discounting. 42 U.S.C. § 256b(a)(5)(C). Manufacturers are only allowed to conduct these audits, however, "in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." *Id.* In 1996, after providing notice and opportunity for comment, HHS issued the Manufacturer Audit Guidelines in accordance with the statute's direction. Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406 (Dec. 12, 1996) ("Audit Guidelines"). Among other things, the Audit Guidelines limited the number of audits to those instances when a manufacturer has "reasonable cause" to believe that a covered entity violated a statutory prohibition, required the submission of an audit workplan to HHS for review of scope, and generally limited the duration of audits to one year. *Id.* at 65,409-10.

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 regarding the imposition of 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 pursuant to subsection (a)(5)(c). *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 id.*

The ADR Rule creates a mechanism to resolve before the agency disputes arising under the 340B Program. *See id.* 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." *Id.*

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.*

Panel decisions are not self-executing; rather, 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, 42 C.F.R. § 10.24(e). Thus while

the Secretary has delegated to ADR Panels authority to issue binding decisions, authority is retained 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 PhRMA member Eli Lilly[1] 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, et al. v. Cochran, et al.*, No. 1:21-cv-81 (S.D. Ind.), First Am. 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. Shortly thereafter, multiple other PhRMA member companies followed suit with their own unilateral, non-statutory restrictions on covered entities' access to 340B-discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, Sanofi-Aventis began requiring covered entities to provide detailed claims data on patients' prescriptions to a third party in order to permit distribution through a contract-pharmacy mechanism, and Novartis and Novo Nordisk imposed their own, separate restrictions. *See AstraZeneca Pharm. v. Azar*, No. 21-cv-27-LPS, ECF No. 13, Am. Compl. Exs. A, C (D. Del.); *Sanofi-Aventis v. HHS*, No. 21-cv-634, ECF No. 17, Am. Compl., Exh. 1 (D. N.J.); 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.).

[1] *See* About, Members, https://www.phrma.org/en/About/Members.

Unsurprisingly, the pharmaceutical manufacturers' abruptly announced, unilateral restrictions on 340B access caused upheaval to covered entities, 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 while confirming that its analysis of the manufacturers' actions was ongoing. In February one court agreed with HHS 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,* 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—"covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (hereafter "AO") at 8, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf. 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 *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." *Id.* at 4. The General Counsel confirmed that this interpretation is compelled by the statute itself and that 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. *Id.* at 2-4.

III. PHARMACEUTICAL COMPANIES AND THEIR REPRESENTATIVE 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 manufacturers filed suit on the same day challenging the General Counsel's Advisory Opinion. *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1; *Eli Lilly*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No. 1; *Sanofi-Aventis v. HHS*, No. 3:21-cv-634 (D.N.J. Jan. 12, 2021), ECF No. 1. The latter two complaints later were amended to also challenge the ADR Rule challenged in this litigation. Another manufacturer filed a similar suit shortly thereafter, *see Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021), and another just two weeks ago, *see Novartis Pharmaceuticals Corporation v. Espinosa, et al.*, 1:21-cv-01479-CRC (D.D.C. May 31, 2021).

As for this action, PhRMA claims to be suing "as the pharmaceutical industry's principal policy advocate" to protect its members' interest "in ensuring that regulations governing the resolution of disputes … are fair, reasonable, and designed to further the proper functioning of [the 340B] program consistent with applicable law." Compl. ¶ 15. Notwithstanding the fact that each of its members that has, at this time, been named in an ADR proceeding has brought its own action against HHS, PhRMA *also* brought suit and asks that this Court set aside the ADR Rule as arbitrary and capricious under the APA and violative of the Appointments Clause, U.S. Const. Art. II, § 2, Cl. 2. *See* Compl. ¶¶ 73-83, 89-95. PhRMA also urges this Court to set aside the Manufacturer Audit Guidelines HHS issued in 1996 and declined to alter during the ADR rulemaking process. *Id.* ¶¶ 84-88.

STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *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, "[t]he standard set forth in Rule 56 of the Federal Rules of Civil Procedure governing summary judgment . . . does not apply. . . ." *Deese v. Esper*, 483 F. Supp. 3d 290, 304 (D. Md. 2020) (quotation omitted). "Because claims brought under the APA are adjudicated without a trial or discovery, on the basis of an existing administrative record, such claims are properly decided on summary judgment." *Audobon Society of the Central Atlantic States, Inc. v. U.S. Dep't of Transp.*, 524 F. Supp. 2d 642 (D. Md. 2007). "[S]ummary judgment is the mechanism by which the court decides as a matter of law whether the administrative record permitted the agency to make the decision it did." *Mayor and City Council of Baltimore v. Azar*, 439 F. Supp. 3d 591, 603 (D. Md. 2020) (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

I. PhRMA FAILS TO STATE A CLAIM THAT THE AUDIT GUIDELINES ARE UNLAWFUL.

After 25 years without legal challenge, PhRMA now alleges that the Secretary exceeded statutory authority in promulgating the audit guidelines and, thus, they are "contrary to law." Compl. ¶ 85. In particular, PhRMA alleges that: (1) "the audit guidelines impermissibly require manufacturers

to establish 'reasonable cause"' of a statutory violation "before they can even commence an audit;" and (2) the "requirement that manufacturers employ third parties to conduct audits . . . conflicts with the plain language" of the statute." *Id.* ¶¶ 86,88. PhRMA's challenge fails as a matter of law. The audit guidelines established by the Secretary are consistent with the plain text of the statute, the broader statutory scheme, and, in any event, are a reasonable exercise of the Secretary's authority.

This issue is one of straightforward statutory analysis, proceeding under the framework set forth in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under a *Chevron* analysis, the Court first "examine[s] the language of the statute to see 'if Congress has directly spoken to the precise question at issue."' *Piney Run Preservation Ass'n v. Cty. Com'rs of Carroll Cty., Md.*, 268 F.3d 255, 267 (4th Cir. 2001) (quoting *Chevron*, 467 U.S. at 843). If so, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* But if the statute is either silent or ambiguous, the court "afford[s] deference 'to the reasonable judgments of agencies with regard to the meaning of ambiguous terms or silence in statutes that they are charged with administering."' *People for the Ethical Treatment of Animals ("PETA") v. USDA*, 861 F.3d 502 (4th Cir. 2017) (quoting *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 739 (1996)).

Here, Congress unambiguously vested the Secretary of HHS with authority to issue audit guidelines cabining the number, duration, and scope of manufacturer's audits of covered entities. And the Secretary did just that. But even if the Court were to determine that the statute is ambiguous, the Secretary's reasoned interpretation as expressed in the audit guidelines warrants deference.

A. The Audit Guidelines Are Consistent with the Unambiguously Expressed Intent of Congress.

As with any question of statutory interpretation, the inquiry begins "with the text of the statute." *Babb v. Wilkie*, 140 S. Ct. 1168, 1172 (2020). Here, the statute provides that covered entities must permit:

> "the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity *(acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits)* to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's

> compliance with the [statutory prohibitions on duplicate discounts and diversion] with respect to the drugs of the manufacturer."

42 U.S.C. § 256b(a)(5)(C) (emphasis added). The Secretary exercised this grant of authority to establish a procedure "relating to" the "number" of audits that a manufacturer may conduct by limiting the number of audits to instances where the manufacturer "has documentation which indicates that there is reasonable cause" to "believe that a covered entity may have violated" the statute. 61 Fed. Reg. at 65409. In other words, the "number" of audits that a manufacturer can perform is coextensive with the number of instances in which it has reasonable cause to believe a statutory violation has occurred.

The "reasonable cause" requirement is also a valid exercise of the Secretary's authority to establish procedures "relating to" to the "scope" of audits. The audit guidelines provide for the submission of an audit workplan to be reviewed by the agency "for reasonable purpose and scope," necessarily entailing a review of whether there is "reasonable cause" to conduct the audit in the first instance. *Id.*

Requiring "reasonable cause" is also consistent with the context and purpose of the statute. *See Home Depot, U.S.A., Inc. v. Jackson*, 139 S. Ct. 1743, 1748 (2019) ("It is a fundamental canon of statutory construction that the words of a statue must be read in their context and with a view to their place in the overall statutory scheme.") (quotation omitted). As PhRMA puts it, "the statutory context makes clear that HRSA's authority is limited to preventing misuse of the manufacturers' audit right—*i.e.,* to ensure that a manufacturer does not engage in too many audits, or audits that are overbroad and unduly long." Compl. ¶ 87. That is exactly what the Secretary has done here. The Secretary is preventing PhRMA's members from "misus[ing]" their audit rights by "ensur[ing]" that they do not "engage in too many audits"—audits are only permitted when there is reasonable cause to believe a statutory violation occurred. *Id.*

PhRMA alleges that the statute's "reference to the 'number' of audits is not a grant of authority to limit the circumstances in which a manufacturer can commence any audit at all." Compl. ¶ 88. But PhRMA's allegation fails to acknowledge that the text of the subsection containing the Secretary's grant of authority also contains an express limit on the circumstances where an audit is appropriate.

Congress was clear that any audit of a covered entity must "directly pertain to the entity's compliance" with the statutory prohibitions on duplicate discounts and diversion. 42 U.S.C. § 256b(a)(5)(C). Congress never intended to provide for free-ranging inquires by well-resourced and highly profitable manufacturers into the business of covered entities, who provide invaluable services to vulnerable populations and are often operating on tight margins. The Secretary's decision to tie the number of permissible audits to the statutory requirement that audits be relevant to statutory violations is thus consistent with Congressional intent.

PhRMA also suggests that the "reasonable cause" requirement is in excess of statutory authority because "HRSA's authority to prescribe audit guideline 'procedures' appears in a part of the statute that imposes requirements on covered entities, not on manufacturers." Compl. ¶ 86. But PhRMA's focus on the section heading labeled, "Requirements for covered entities," 42 U.S.C. § 256b(a)(5), is misplaced. "[A] subchapter heading cannot substitute for the operative text of the statute," *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (citation omitted). The "operative text" here directs the Secretary to issue procedures limiting *manufacturers'* ability to conduct audits, not any requirement for the behavior of covered entities. *See id.*

In addition to limiting the number of audits to circumstances where a manufacturer has reasonable cause to believe a statutory violation is occurring, the Secretary's audit guidelines provide that the manufacturer employs "an independent public accountant" to "perform the audit." 61 Fed. Reg. at 65409. PhRMA alleges that this provision was issued in excess of authority because the statute only permits "the Secretary and *the manufacturer*," to conduct audits. Compl. ¶ 88 (emphasis in original). This allegation defies common sense. "The manufacturer" is not one person who can readily conduct an audit, or has the accounting expertise necessary to conduct an audit. Thus, a manufacturer must necessarily employ someone in order to audit a covered entity. The Secretary has simply required that the person employed by the manufacturer is an independent accountant with the necessary skills to conduct the task at hand. That PhRMA even seriously contests the need for independent accountants to conduct an audit underscores PhRMA's real concern—that independent auditors without a

financial stake in the results of the audit may not uncover nonexistent wrongdoing on the part of covered entities.

B. At a Minimum, the Secretary's Reasonable Interpretation of the Statute Is Entitled to Deference.

Though the text of the statute supports the Secretary's exercise of his authority, the Court should defer to his reasonable interpretation of the statute to the extent that the Court finds any ambiguity. The rationale underlying *Chevron* deference is that "ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion"—decisions that "involve[] difficult policy choices that agencies are better equipped to make than courts." *Nat'l Cable and Telecom. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005). *Chevron* thus applies where "Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001).[2] In such circumstances, "courts are bound to uphold an agency interpretation as long as it is reasonable—regardless whether there may be other reasonable, or even more reasonable, views." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1321 (D.C. Cir. 1998); *see also PETA*, 861 F.3d at 510 ("[T]he reasonableness inquiry requires us to determine whether the [agency's] understanding of the [statute] is a sufficiently rational one to preclude a court from substituting its judgment for that of the agency.") (internal quotation omitted).

The Secretary's adoption of the reasonable cause standard and the requirement for independent auditors easily satisfy this standard. As the Secretary explained in the audit guidelines, establishing reasonable cause is important "to ensure that the audits pertain to compliance" with the statutory prohibitions on duplicate discounts and diversion. 61 Fed. Reg. at 65406. Moreover, the submission of an audit work plan explaining the reasonable cause allows HHS to "ensure that the

[2] There can be no serious dispute that the prerequisites to applying *Chevron* deference are easily met here. The statute authorizes the Secretary to establish "procedures . . . relating to the number, duration, and scope of audits," and only permits manufacturers to audit covered entities in accordance with these procedures. 42 U.S.C. § 256b(a)(5)(C). The guidelines challenged here, promulgated with notice and an opportunity for comment, and carrying the force of law, are clearly an exercise of that authority.

audits are performed where there are valid business concerns and are conducted with the least possible disruption to the covered entity." *Id.* Though PhRMA would seem to prefer an approach whereby the Secretary allowed manufacturers to conduct a finite number of audits for any reason they chose, the Secretary's approach to limit the number based on a substantive reason was decidedly less arbitrary. By tying the number of audits allowed to the substantive basis to conduct audits contained in the statute, rather than choosing some small number of audits, the Secretary reasonably avoided *cabining* manufacturers' abilities to conduct audits when there may have been cause to believe that a covered entity was violating the statute.

PhRMA argues that the Secretary's decision was unreasonable because HRSA recognizes that "covered entities may conduct spot audits of their contract pharmacies" and HRSA itself "conducts both targeted and risk-based audits of covered entities." Compl. ¶ 87. But PhRMA provides no explanation or justification for why pharmaceutical manufacturers, whose interests are diametrically opposed to those of covered entities, should be treated the same as covered entities conducting essentially internal audits of their own contract pharmacies, or the agency charged with neutrally administering and enforcing the statute. Indeed, the Secretary was expressly concerned that manufacturers may attempt audits where there are no "valid business concerns," and reasonably tried to limit the circumstances where that would be the case. 61 Fed. Reg. at 65406. And while PhRMA complains that its members "may not use a risk-based audit to uncover potential violations," no statute expressly permits risk-based audits in the first place. Compl. ¶ 87. Moreover, the standard for reasonable cause is not unduly burdensome—the Secretary explained that "significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity" all may be a basis for establishing reasonable cause. 61 Fed. Reg. at 65406.

With respect to the Secretary's requirement for independent auditors, the Secretary identified a number of reasons why this requirement is important. First, the Secretary explained that the requirement "will provide assurances that audits will be performed in accordance with generally accepted auditing standards relating to professional qualifications of the auditors, independence, due

professional care, field work, and reporting of the audit findings." 61 Fed. Reg. at 65407. Second, the Secretary emphasized the need to "ensure audit uniformity and consistency and adequacy of documentation to permit independent review in cases where disputes arise." *Id.* PhRMA offers nothing to rebut the Secretary's reasonable explanation other than a conclusory allegation that the requirement is contrary to law. Compl. ¶ 88.

In light of the statute's text, context, and the Secretary's reasonable explanation of the need for the audit guidelines, PhRMA cannot establish that the guidelines are contrary to law, and the claim fails as a matter of law.

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

A. The ADR Rule is Substantively Compliant with the APA.

PhRMA claims that the ADR Rule is arbitrary and capricious under the APA, 5 U.S.C. § 706(2)(A). It asserts two arguments in this respect, both of which lack merit. *See* Compl. ¶¶ 74–83.

Judicial review under the APA's arbitrary-and-capricious standard is "highly deferential, with a presumption in favor of finding the agency action valid." *Appalachian Voices v. State Water Control Bd.*, 912 F.3d 746, 753 (4th Cir. 2019) (citation omitted). This standard requires only "that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.* (*Prometheus*), 141 S. Ct. 1150, 1158 (2021). "[A] court may not substitute its own policy judgment for that of the agency," *id.*, and "should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus*, 141 S. Ct. at 1158 (citations omitted).

First, HHS was not required to respond to comments recommending that it revise HRSA's manufacturer audit guidelines before moving forward with the ADR Rule. *See* Compl. ¶ 76. However, as PhRMA acknowledges, *see id.* ¶ 78, 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. PhRMA nevertheless

faults HHS for failing to elaborate on this conclusion or to address the substance of these comments. Compl. ¶¶ 78–80.

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, *North Carolina v. FAA*, 957 F.2d 1125, 1135 (4th Cir. 1992); *accord South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983) ("There is no requirement for [an agency] to discuss every fact or opinion contained in the public comments."), 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 comments raising "relevant, significant issues," *N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 769 (4th Cir. 2012)—*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).

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 audit guidelines. *See, e.g.*, *Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 231 (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)); *see also Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) ("[An agency] no doubt has significant latitude as to the manner, timing, content, and coordination of its regulations . . . ."). Comments regarding HRSA's audit 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 audit 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 N.C. Growers' Ass'n*, 702 F.3d at 769.

Arguing to the contrary, PhRMA suggests that it was unreasonable for HHS not to substantively respond to comments seeking revisions to HRSA's audit guidelines because HHS "specifically requested" these comments in its advanced notice of proposed rulemaking ("ANPRM"). Compl. ¶¶ 77, 80. Indeed, the ANPRM did invite comments on a wide array of topics, including "whether it is appropriate or necessary to modify" the existing audit guidelines "prior to implementing the [ADR] regulation or whether the current final guidelines are sufficient," AR 3. But the ANPRM requested these comments only to assist HHS in "*draft[ing]* a proposed rule" to establish an ADR process for the 340B Program pursuant to 42 U.S.C. § 256b(d)(3)(A). AR 1–2. Thus, like other advanced notices of proposed rulemaking, the ANPRM did not announce "a concrete plan" with respect to the anticipated rulemaking. *See Roman Catholic Archdiocese of N.Y. v. Sebelius*, 907 F. Supp. 2d 310, 333 (E.D.N.Y. 2012); *see id.* ("[With an ANPRM], there is no way to tell where [an agency] will go."). Instead, the ANPRM was "only directed at possibilities," *id.* at 334, a "preliminary step" at a time when HHS's position on the scope of anticipated rulemaking "remain[ed] indeterminate," *see Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 39–40 (D.D.C. 2012); *accord Roman Catholic Diocese of Dallas v. Sebelius*, 927 F. Supp. 2d 406, 419 (N.D. Tex. 2013) ("The ANPRM merely states that the government expects to address concerns similar to those raised by Plaintiff and solicits comment on the same. The ANPRM is not a proposed amendment and does not proffer contents or substance of a proposed amendment. (citation omitted)); *Archdiocese of N.Y.*, 907 F. Supp. 2d at 327 ("[The ANPRM] merely seeks input to allow the Departments to consider possible revisions to the [existing rule].

[However], [t]he Departments need not make any changes . . . at all."). And after considering the comments on the ANPRM, *see* AR 5, HHS chose not to draft the subsequent NPRM to include proposed revisions to HRSA's audit guidelines. That conscious decision further shows that revising the audit guidelines was outside the scope of the proposed ADR rulemaking at issue in this case.

Second, for those reasons just explained and others, the Secretary was also not obligated to address the issues raised in PhRMA's petition for proposed rulemaking. *See* Compl. ¶¶ 81–83. PhRMA's petition—submitted to HHS three weeks prior to issuance of the final ADR Rule—asked HHS to initiate a *new* rulemaking (or, in the alternative, to reopen the comment period) to revise both HRSA's audit guidelines and guidelines regarding the 340B statute's definition of a covered entity's "patient."[3] *See* Compl., Ex. A at 4-5, 12-18. PhRMA suggested that expanding the scope of the ADR rulemaking to implement these two additional regulatory measures would solve certain program-compliance issues (*e.g.*, drug diversion and duplicate discounting). *See id.* at 4-10-, 12-18. These suggestions, however, were submitted well after the close of the comment period on the NPRM, and HHS was thus "free to ignore" them. *See Reytblatt v. U.S. Nuclear Regul. Comm'n*, 105 F.3d 715, 723 (D.C. Cir. 1997) (citation omitted). And 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*, 498 U.S. at 230-31; *see also Md. Dep't of Health & Mental Hygiene v. Ctrs. for Medicare & Medicaid Servs.*, 542 F.3d 424, 427–28 (4th Cir. 2008) (explaining that reversal under the arbitrary-and-capricious standard is proper only where the agency clearly erred or failed to consider an important or relevant aspect of the problem it sought to address with the proposed action).

B. ADR Board Members Are Lawfully Appointed Inferior Officers.

PhRMA'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. ¶¶ 89-95, contorts the Rule's plain

[3] *See generally* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996).

language and ignores precedent holding that similar schemes create inferior, not principal, officers. PhRMA insists that the ADR Rule permits members to "make final precedential determinations for HHS that are not subject to any further executive branch review," and protects members from removal except "for cause," Compl. ¶¶ 93-94, but neither premise finds support in the plain text of the Rule. Although the Rule does not create an internal agency appeals process, there are no restrictions on the Secretary's oversight and supervision of the Board. The Secretary appoints ADR Board members and delegates to them responsibility for issuing final decisions, and the Secretary retains the ability to revoke that delegation at any time, to issue binding regulations that constrain the Board members, and may remove a Board member at will, at any time. Under established precedent, Board members thus serve as inferior officers who may be appointed by the Secretary.

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

Although the Supreme Court has "not set forth an exclusive criterion for distinguishing between principal and inferior officers," it has explained that, "[g]enerally speaking, the term 'inferior officer' connotes a relationship with some higher ranking officer or officers below the President: Whether one is an 'inferior' officer depends on *whether he has a superior*." *Edmond v. United States*, 520 U.S. 651, 661-62 (1997) (emphasis added). The focus is not merely on whether the officer has some "superior" who "formally maintain[s] a higher rank," but on whether the officer is one "whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.* at 662-63. *Edmond* involved a challenge to military judges of the Coast Guard Court of Criminal Appeals—officers that exercised significant discretion and responsibility, including the authority to resolve constitutional challenges, review death sentences, and independently weigh evidence to determine guilt and sentence. *Id.* at 662. In deeming the judges inferior officers, the Court emphasized that "the line between principal and inferior officer" 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.*[4]

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 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 courts of appeals have held that schemes analogous to the ADR Rule create inferior officers. For example, 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. *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

[4] 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.

(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 that 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. But 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 even though the judges "issue[d] 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 Investigation*, 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 regulations issued by the Secretary, 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 Investigation*, 916 F.3d at 1052-53).

PhRMA's Article II claim is irreconcilable with these precedents. 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 PhRMA ignores this on-point 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," *id.* 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 contrary precedent, PhRMA misconstrues the Rule and misapplies both the supervision and removal prongs of the Appointments Clause analysis. As to the first prong, PhRMA ignores all the relevant, powerful tools for control that the Secretary may exercise, instead insisting that ADR members are principal officers operating wholly without supervision because "[t]hey independently determine how to conduct proceedings, and make final precedential

determinations for HHS that are not subject to any further executive branch review." Compl. ¶ 93. 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 court of appeals 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 other persuasive, directly on-point appellate authorities agree; 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.

PhRMA's argument as to the removal prong rests on a flatly false premise—ignoring the fact that the Rule does not place *any* restrictions on Board members' removal by the Secretary, PhRMA nonetheless argues that for-cause removal protection renders them principal officers. Compl. ¶ 94. 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*). PhRMA's insistence that for-cause removal applies 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.").

PhRMA 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. Compl. ¶¶ 65, 94; 42 C.F.R. § 10.20(a)(1)(ii), (a)(2). In other words, PhRMA 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.[5] Put simply, PhRMA is flatly incorrect in portraying ADR members as protected by for-cause removal restrictions, Compl. ¶ 94, 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.

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

[5] PhRMA's assertion that the HRSA Administrator may only remove a panel member for conflicts of interest, Compl. ¶ 65, 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). PhRMA'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.

CONCLUSION

Because each of PhRMA's claims are meritless, the Court should dismiss each count or, in the alternative, grants summary judgment for Defendants.

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