IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

vs.

XAVIER BECERRA, et al.

Defendants.

Civil Action No. 8:21-cv-198-PWG

Reply Memorandum In Support of Plaintiff Pharmaceutical Research and Manufacturers of America's Cross-Motion for Summary Judgment

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

Defendants' recent filing (ECF No. 31, or "Defs. Opp.") fails to refute PhRMA's showing that the ADR Rule is unconstitutional, procedurally defective, and relies on audit guidelines that are inconsistent with the 340B statute. Defendants argue that the 340B *statute* is constitutional, but it is the ADR *Rule* that violates the Appointments Clause. They defend the audit guidelines based on impermissible post-hoc rationales and by ascribing to Congress their own jaundiced views of pharmaceutical manufacturers—views with no basis in the text or history of the statute. And defendants repeatedly ignore—and even contradict—the facts in the record before HRSA, suggesting, for example, that manufacturer audits are rare because there are no problems with diversion and duplicate discounts, when the evidence shows that such violations are rampant.

None of their arguments can hide the fundamental defects in the ADR Rule.

ARGUMENT

I. The ADR Rule Violates the Appointments Clause.

Defendants contend that the Supreme Court's recent decision in "*Arthrex* confirms that the ADR Rule challenged here is consistent with the Appointments Clause." Defs. Opp. 16. The opposite is true: *Arthrex* confirms that the Rule is unconstitutional because it gives the ADR Board "power to render a final decision on behalf of the United States without any . . . review by their nominal superior or any other principal officer in the Executive Branch." *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1981 (2021) (quoting *Edmond v. United States*, 520 U.S. 651, 665 (1997)).

Defendants assert that a principal officer, the Secretary of Health and Human

Services, "freely may exercise discretionary review of panel decisions" even though "no formal mechanism for appeal to the Secretary is set forth in the regulation." Defs. Opp. 16. The Rule itself, however, refutes this contention. It states that "[t]he agency decision will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim." 42 C.F.R. § 10.24(c); *see id.* § 10.24(b) ("The 340B ADR Panel will prepare an agency decision . . . ."). And it further provides that "[t]he agency decision constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id.* § 10.24(d).

The regulation thus clearly provides that the decision of "the 340B ADR Panel"—whose members are not appointed to that role by the President or confirmed by the Senate, *see id.* § 10.20—is the "final agency decision" for the Executive Branch, reviewable only by "a court," *id.* § 10.24(d). Defendants claim that the Rule "confirms only that the ADR process will result in final agency action." Defs. Opp. 17-18. But sections 10.24(c) and (d), read together, "unambiguously specif[y]," *Arthrex*, 141 S. Ct. at 1981, that the 340B ADR Panel decision *is* the final agency action, with no allowance for further review by a superior Executive Branch official. Just like the statutory provision struck down in *Arthrex*, these provisions are an "express restriction on the Secretary's ability to reverse an ADR decision," Defs. Opp. 18, because they expressly provide that an ADR Panel decision is the final decision of the agency and can be reversed only by a court.

The Rule's preamble confirms this reading. After noting that commenters had criticized the proposed rule because it "does not incorporate an [administrative] appeals process," the preamble states that "HHS does not believe that an appeals process is

necessary given that an aggrieved party has a right to seek judicial review." AR21. Accordingly, the preamble states that HHS will finalize the proposal "that the 340B ADR Panel's final agency decision letter would be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.*

Despite the Rule's clear foreclosure of any administrative appeal, defendants contend that in "the absence of any *statutory* constraint on discretionary review by the Secretary," Defs. Opp. 16 (emphasis added), such authority can be inferred from "congressional silence," *id.* at 17. But the fact that "*Congress* has placed no restrictions on the Secretary's authority to review and revise ADR panel decisions," *id.* (emphasis added), demonstrates only that the Rule, rather than the statute, is unconstitutional. Indeed, that is precisely why PhRMA challenged only the Rule and not the statute: Congress granted the Secretary the authority to create an ADR process that would comport with the Appointments Clause, but the Secretary declined to do so, and is now bound by the Rule that he issued. *Jamil v. Sec'y, Dep't of Def.*, 910 F.2d 1203, 1208 (4th Cir. 1990) ("An agency . . . may change its regulations, but, until it does so, . . . [it must] follow the procedures which it itself has promulgated"); *see United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 267 (1954) ("[A]s long as the regulations remain operative, the Attorney General denies himself the right to sidestep the Board or dictate its decision in any manner.").

The Court cannot read into the Rule an administrative appeal process that the agency clearly rejected. Doing so would impermissibly "intrude upon the domain which Congress has exclusively entrusted to an administrative agency." *Sec. & Exch. Comm'n v.*

Chenery Corp., 318 U.S. 80, 88 (1943); *see also Smithfield Packing Co. v. NLRB*, 510 F.3d 507, 519 (4th Cir. 2007) ("[*Chenery*] rests on the 'basic proposition that a reviewing court may not decide matters that Congress has assigned to an agency.'") (quoting *W. Va. Highlands Conservancy, Inc. v. Norton*, 343 F.3d 239, 248 (4th Cir. 2003)).

For instance, creating an administrative appeal process would require agency judgments determining who would hear the appeals,[1] the standard of review, and the procedures for appeals, including deadlines for appealing and whether and under what circumstances new evidence may be submitted following the ADR Panel decision. *See, e.g.*, 21 C.F.R. § 10.33 (setting forth procedures for FDA Commissioner to review FDA determinations). These "line[s] would not be self-defining," and the ADR Rule must be vacated and remanded for the agency to make these policy determinations in the first instance. *Harmon v. Thornburgh*, 878 F.2d 484, 494-95 (D.C. Cir. 1989) (when agency action is unlawful, court should "not attempt, even with the assistance of agency counsel, to fashion a valid regulation from the remnants of the old rule"); *Indep. Ins. Agents of Am. v. Bd. of Governors of Fed. Reserve Sys.*, 838 F.2d 627, 635 (2d Cir. 1988) ("declin[ing] [agency's] invitation to amend [its] order in order to preserve its validity" because courts "have no authority to predict" how an agency will exercise discretion).

Finally, defendants' argument that the Rule is constitutional because the Secretary "may freely remove ADR Board members at will" is erroneous. Defs. Opp. 18. *Arthrex*

[1] HHS has 22 different presidentially appointed and Senate-confirmed officers who would be constitutionally eligible to hear such appeals. *See* Cong. Rsch. Serv., RL30959, *Presidential Appointee Positions Requiring Senate Confirmation and Committees Handling Nominations* 22, 29, 36 (updated May 3, 2017), https://bit.ly/3hW31A9.

rejected an indistinguishable argument that Administrative Patent Judges ("APJs") were constitutionally-appointed inferior officers because the Director of the Patent and Trademark Office "may . . . remov[e] an APJ 'from his judicial assignment without cause' and refus[e] to designate that APJ on *future* PTAB panels." 141 S. Ct. at 1982. The Supreme Court held that this removal authority was not a sufficient means of control because "reassigning an APJ to a different task going forward gives the Director no means of countermanding the final decision already on the books." *Id. See also id.* at 1990 (Gorsuch, J., concurring in part and dissenting in part) (providing fifth vote, stating that "[i]t's the combination of these provisions—the exercise of executive power and *unreviewability*—that violates the Constitution[]") (emphasis added). Thus, an unfettered power simply to remove members from the ADR Board is constitutionally irrelevant.

To the extent removal power is relevant, defendants concede that "it is removal from one's office—not reassignment from the task at hand—that has constitutional significance." Defs. Opp. 19. But, given the Court's focus on reviewability, even the ability to remove Board members from federal service without cause would not suffice. And even if it would, most of the members are not "'meaningfully controlled'" by such a threat, because they appear to enjoy civil service protections. *Id.* at 1982.[2] The ADR Rule is unconstitutional.

[2] While PhRMA must rely on public information to assess the competitive-service status of the members of the Board, *see* 86 Fed. Reg. 33317, 33317 (June 24, 2021) (appointing Board), defendants are in a position to know whether the Board members have the same protection from removal without cause that APJs enjoy. Yet, despite the fact that PhRMA raised the issue, PhRMA Br. at 27-28, defendants have declined to take a definitive position on the Board members' civil service protections. *See* Defs. Opp. at 19 n. 9.

II. The Manufacturer Audit Guidelines Are Contrary to Law.

A. The Reasonable Cause and Third-Party Auditor Requirements Are Inconsistent with the Statute's Text, Structure, and Purpose.

1. Reasonable Cause: Defendants assert that the Secretary properly "[e]xercis[ed] the discretion granted him" and adopted a "sensible" limit on manufacturer audits. Defs. Opp. 2-3. But the inquiry at *Chevron* step 1 is whether the reasonable cause standard is consistent with the statute's plain meaning, as determined using ordinary tools of statutory construction. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 & n.9 (1984). Defendants have failed to show that it is.

Defendants' own definition of "number"—"the result of enumeration, . . . quantity . . . 'the precise sum or aggregate," Defs. Opp. 2—confirms that Congress authorized procedures that relate to a "numerical *quantity*" of audits. Defendants do not even mention, much less dispute, PhRMA's showing, PhRMA Br. 29-30, that reasonable cause has no necessary connection to a numerical limit on audits, as both can co-exist. Nor can defendants show that the phrase "relating to" has any meaningful limit under HRSA's interpretation. They assert that, "by defining the circumstances in which audits are permitted, the 'reasonable cause' requirement certainly has a 'connection with or reference' to the 'number' of audits." Defs. Opp. 3. But any specification of circumstances where audits are permitted has the effect of limiting the number of audits, and thus has the same unduly attenuated "connection" to a "number" as a rule that permits audits only in leap years. By arguing that the *effects* of the standard, rather than its *substance*, provide the necessary "relationship" to the number of audits, defendants effectively

confirm that HRSA's interpretation renders the phrase "relating to" impermissibly indeterminate.

Tacitly recognizing this, defendants spend most of their brief attacking PhRMA's reading and offering improper *post-hoc* justifications. They argue that, if "reasonable cause" is not a procedure, then a number is not a procedure either, and HRSA would not be able to prescribe a number of audits at all. *Id.* at 4. PhRMA's point, however, was that reasonable cause is an evidentiary standard, not an aspect of a procedure that relates (in any meaningful way) to the number of audits. Moreover, the audit guidelines show that HRSA can prescribe procedures consistent with the statutory text: the guidelines permit "[o]nly one audit of a covered entity . . . at any one time." AR393. That rule "relates to" the number of audits, without stretching the meaning of that phrase beyond reasonable bounds. And it refutes defendants' claim, Defs. Opp. 2-3, that establishing a limit on the number of audits is inherently arbitrary.

Because reasonable cause has no meaningful relationship to the number of audits, defendants are forced to claim that the test really relates to the "scope" of audits. *Id.* at 4. In an effort to support this claim, defendants note that the guidelines require a review of a manufacturer's audit workplan "for reasonable purpose and scope," including whether it targets documents that directly pertain to statutory violations. *Id.* In fact, the guidelines confirm that HRSA did *not* justify reasonable cause as a procedure relating to the scope of audits. The guidelines discuss "reasonable cause" under the heading "(a). *Number* of Audits," but discuss the separate restrictions on the purpose and scope of audits (and the documents they may target) under the heading "(b). *Scope* of Audits." *See* AR393-94

(emphases added). The guidelines make clear, moreover, that HRSA first determines "if reasonable cause exists," AR394 at § II(c), then reviews the purpose and scope of the audit workplan under various factors, none of which refers to "reasonable cause," *id.* at § II(e).

In addition to being impermissibly after-the-fact, *see Chenery*, 318 U.S. at 88, defendants' new justification fails on its own terms. The term "scope" concerns the "extent" or "range" of an activity. *See* PhRMA Br. 31 (citing dictionary definitions). Reasonable cause governs whether an audit can occur at all, not its scope.

Nor does the statute's limitation on the records that can be audited support defendants' post-hoc theory. After claiming that this provision expressly limited "the *circumstances* where an audit is appropriate," Defs. Opening Br., ECF No. 26-1 at 13-14 (emphasis added), defendants now concede that the provision is "distinct from" reasonable cause, Defs. Opp. 5. Nevertheless, they claim that this limitation reflects a congressional concern that the reasonable cause test addresses—*i.e.*, that manufacturers would "unfairly burden providers without any reason to believe that violations of the statute are occurring." *Id.* This argument, however, mischaracterizes Congress' concerns.

The House Report that defendants cite discussed the problems of diversion and duplicate discounts at length, then described "three requirements" the law would impose "*on 'covered entities'* to assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384(II), at 16-17 (1992) (emphasis added). One of these was permitting audits of covered entities by manufacturers *and* by HHS. *Id* at 17. The Report then expressed an expectation that "the Secretary will make every effort to minimize the administrative and financial burdens that *these* audits impose on 'covered entities,' and to limit the allowable

scope of *these* audits to records directly pertinent to a determination of compliance with the specific prohibitions." *Id.* (emphases added).

This legislative history reflects no concern unique to manufacturer audits. Instead, Congress' concern with the burdens of audits on covered entities applied equally to audits by manufacturers and by the agency. Having concluded that its own without-cause audits are consistent with this congressional concern, HRSA has no basis to claim that the legislative history justifies a more stringent standard for manufacturer audits.[3]

Finally, defendants have no answer to PhRMA's showing, PhRMA Br. 32, that, because 42 U.S.C. § 256b(d)(3)(A) conditions manufacturer's ability to bring ADR claims on completion of an audit, the authority to prescribe audit procedures is not properly understood to include the power to create another condition on manufacturers' rights to initiate ADR. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972) (per curiam)). Defendants assert that "Congress also knows how to confer discretion on agencies, and did so here." Defs. Opp. 5. But that *ipse dixit* simply begs the question. By prescribing only one condition on manufacturer ADR claims and conferring power to prescribe procedures relating to the *number* of audits, Congress made

[3] Thus, PhRMA is not "quibbl[ing] with Congress," Defs. Opp. 5, but instead objects to defendants' efforts to ascribe their jaundiced view of manufacturers to a Congress concerned with diversion and duplicate discounts by covered entities.

plain that it was not authorizing HRSA to create a second condition on manufacturers' rights to bring ADR claims – much less one that has an unduly attenuated "relationship" to the "number . . . of audits." The reasonable cause standard thus fails *Chevron* step one.

2. Third-Party Auditors: Defendants' attempt to defend the third-party auditor requirement is equally defective. The statute entitles a "*manufacturer*," acting at its own "expense" and "in accordance with procedures established by the Secretary," to audit a covered entity. 42 U.S.C. § 256b(a)(5)(C) (emphasis added). A procedure that denies manufacturers the right to conduct audits themselves is inconsistent with the plain text of the statute. Defendants contend that this requirement "ensure[s] that the audits are conducted fairly and without bias." Defs. Opp. 6. But as discussed above, nothing in the statute's text or legislative history shows that Congress had any unique concern with manufacturers conducting audits, much less that it expected the agency to override the language of the statute and preclude manufacturers from conducting audits themselves.

The third-party auditor requirement thus also fails *Chevron* step one.

B. The Reasonable Cause and Third-Party Auditor Requirements Are Based on an Unreasonable Interpretation of the Statute.

Even if the Court concludes that the statute is ambiguous, HRSA's resolution of any ambiguities would still be unreasonable.

1. Reasonable Cause: As PhRMA explained, the reasonable cause test creates a Catch-22 that unreasonably prevents manufacturers from using the ADR process. PhRMA Br. 35. Defendants claim there is no real impediment, because manufacturers "may" be able to show reasonable cause based on (1) "complaints from patients/other

manufacturers" or (2) significant increases in a covered entity's purchases of specific drugs. Defs. Opp. 8 (quoting AR390). As to the first point, diversion and duplicate discounts affect manufacturers, not patients. Defendants do not explain how patients would even know what duplicate discounts and diversion are, how they would learn of such activities, or why they would complain about them to manufacturers. Defendants likewise do not explain why any individual manufacturer would know about such misconduct, since all face the same access-to-information problem.

As to the second point, diversion and duplicate discounts can occur without any significant changes in covered outpatient drug purchases by covered entities. And covered entities' use of contract pharmacies makes it difficult for manufacturers to detect significant changes in purchasing patterns or in requests for 340B pricing, especially when the contract pharmacy uses (as most do) a virtual inventory and replenishment model in which "[t]he covered entities never physically possess the drugs" and where the contract pharmacy makes determinations about a transaction's 340B eligibility after the fact. *See AstraZeneca Pharms. v. Becerra*, 2021 WL 2458063, at *11 n.19 (D. Del. June 16, 2021); *see also* AR307 (manufacturers have "no readily available automated tools for monitoring duplicate discounts or diversion," the practices of covered entities "are diverse and opaque," and contract pharmacy arrangements "exacerbate[] this opacity"); AR233 (manufacturers "lack visibility into pharmacy transactions"); PhRMA Br. 14 n.3, 16-17 (citing studies showing how contract pharmacies "create 'complications' in preventing diversion and duplicate discounts" and increased risks of such misconduct).

The Catch-22 manufacturers face is confirmed by real-world evidence. Fourteen

years after the guidelines were issued, HRSA acknowledged that manufacturers had "rarely" conducted audits. AR3. Commenters confirmed that the burdens the guidelines imposed, including the reasonable cause requirement, made manufacturer audits too difficult. *See* AR232-33, AR293, AR355-56. Remarkably, defendants suggest that audits are rare because "manufacturers lack reasonable cause to suspect widespread noncompliance." Defs. Opp. 9. This self-serving suggestion ignores the nature of the Catch-22—manufacturers lack access to the information needed to show reasonable cause to conduct audits, *see* PhRMA Br. 35—and the numerous findings by HRSA, which can conduct audits without cause, that reveal extensive problems of diversion and duplicate discounts. *See id.* at 16-17, 20-21. The reasonable cause standard plainly creates an undue barrier to manufacturer audits.

Defendants' efforts to justify that barrier are unavailing. They claim that reasonable cause ensures that audits are conducted only "where there are valid business concerns." Defs. Opp. 6. But random audits are inherently valid: they serve to deter diversion and duplicate discounts, which is why HRSA employs them and allows covered entities to do so as well. *See* PhRMA Br. 34-35. Defendants claim it is "nonsensical" and "strains credulity" to think that manufacturers should have the same right to conduct spot audits as HRSA and covered entities, arguing that such an idea "ignores the very basis for congressional and regulatory action in the first place." Defs. Opp. 6-8. But defendants cite nothing in the administrative record to justify their assumption that manufacturers will misuse the right to conduct spot audits, nor anything in the text or history of the statute to show that Congress shared that assumption. To the

contrary, the legislative history shows that Congress drew no distinction between manufacturer and agency audits, and viewed both as a remedy to address one of its actual concerns—diversion and duplicate discounts by covered entities. *See supra* at 8-9.

Undaunted, defendants try to conjure a basis for their cynical assertions, implying that manufacturers will misuse their audit rights because of their "vested interest in limiting the amount of deeply discounted sales." Defs. Opp. 7. But audits can only be used to identify *illegitimate* practices; they cannot "limit" the rights or ability of covered entities to obtain discounts on legitimate sales. The fact that HRSA reviews audit workplans in advance, that manufacturers must pay for the audits, and that only one audit of a covered entity is permitted at any one time, further ensures that audits cannot be used in a coercive manner.

2. Third-Party Auditors: To defend the third-party auditor requirement, defendants again ignore evidence in the record and rely on unfounded insinuations. Defendants scoff at the idea that the costs of a third-party auditor would matter to manufacturers. Defs. Opp. 9. But not all manufacturers are large, and the costs of third-party audits can be prohibitive when large numbers of smaller covered entities engage in diversion or duplicate discounts. *See* AR232, AR355. Moreover, defendants assert as a "fact" that manufacturers "continue[] to conduct such audits under the guidelines." Defs. Opp. 9-10. Yet HRSA acknowledged ten years ago that manufacturers had "rarely" done so, AR3, and the record shows that this remains the case, *see* AR355, AR311 (manufacturer audits are "exceedingly rare"). Thus, like the requirement to establish pre-audit reasonable cause, the third-party auditor requirement creates unreasonable burdens.

Defendants have failed to justify that burden. They concede that generally accepted auditing standards do not require third-party auditors, but claim that manufacturers can never be seen as unbiased because their financial interests are "contrary" to those of covered entities. Defs. Opp. 10. The generally accepted auditing standards do not support this contention, and it fails for at least two reasons. First, a manufacturer's interest in rooting out diversion and duplicate discounts is not contrary to any *legitimate* financial interest of covered entities, as they have no right to benefit from such unlawful activities. Second, any ambiguity about statutory language that allows "manufacturers" to conduct audits of covered entities cannot *reasonably* be resolved based on a presumption that manufacturers are *never* qualified to conduct audits. If Congress had shared that view, it would never have written the statute the way it did.

III. Defendants' Adoption of the ADR Rule Was Arbitrary and Capricious.

A. HRSA Entirely Failed to Address Whether the Audit Guidelines That Restrict Manufacturers' Access to the ADR Process Should Be Modified.

The ADR Rule is arbitrary and capricious because HRSA failed to consider an "important aspect of the problem," *Mayor of Baltimore v. Azar*, 973 F.3d 258, 275 (4th Cir. 2020) (en banc)— reform of the audit guidelines that unduly restrict manufacturers' ability to file ADR claims. *See* PhRMA Br. 38-42. Defendants claim HRSA "considered and responded to" comments on this topic. Defs. Opp. 11 n.2. But simply asserting that "updated manufacturer audit guidelines" are not "needed to finalize the ADR process," AR13, is not a meaningful or "'substantive[] respon[se].'" PhRMA Br. 39. It does not show that HRSA "'adequately analyze[d] . . . the consequences' of its actions," *Casa de Md., Inc.*

v. Wolf, 486 F. Supp. 3d 928, 961 (D. Md. 2020), and does not "enable a reviewing court" to understand "why the agency reacted . . . the way it did." *South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 886 (4th Cir. 1983).

Unable to show otherwise, defendants contend that the agency did not need to consider the issue because the audit guidelines "were neither relevant nor important to the proposed rulemaking." Defs. Opp. 10-11. But when it requested comments on "directly relevant" issues, HRSA *singled out* the question "whether it is appropriate or necessary to modify" the audit guidelines as one of the issues where comments would be "particularly helpful." AR2-3. That was because, as HRSA explained, the ADR provisions of the statute transformed the "rarely utilized" guidelines into a *required* step for manufacturer-initiated ADR. AR3. Defendants' various efforts to walk back HRSA's clear recognition that the audit guidelines were relevant to the ADR Rule are groundless.

Defendants note that different subsections of the statute govern issuance of the guidelines and the ADR Rule. Defs. Opp. 11. But as HRSA itself recognized, the statute directly links the audit guidelines and the ADR process. Indeed, subsection (d)(3)(B) explicitly incorporates subsection (a)(5)(C) by cross-reference, requiring not only that manufacturers first conduct audits, but that they do so "*pursuant to subsection (a)(5)(C).*" 42 U.S.C. § 256b(d)(3)(B)(iv) (emphasis added). "It can hardly have been Congress's intention to include this cross-reference and thereby incorporate the otherwise inapplicable [audit guidelines], only to have [HRSA] disregard [them]" in designing the ADR process. *Port Auth. of N.Y. & N.J. v. Dep't of Transp.*, 479 F.3d 21, 32 (D.C. Cir. 2007).

Defendants argue that nothing in the statute "direct[ed]" HRSA to develop new

or revised audit rules for the ADR process, and that HRSA has broad discretion to decide such questions. Defs. Opp. 11 & n.3. But in challenging the Rule as arbitrary and capricious, PhRMA need not show that HRSA violated a directive in § 256b, and the issues relevant to a rulemaking are not limited to steps directly outlined in the statute. Here, HRSA conceded (as it had to) that guidelines governing a precondition to manufacturer claims were relevant to the ADR process, and it solicited and received comments urging changes to the guidelines. If it believed the comments it had asked for were mistaken, it had to explain why. It could not dismiss them out of hand.[4]

Nor does it matter that HRSA conceded the relevance of the guidelines in an advance notice of proposed rulemaking (ANPRM) rather than a notice of proposed rulemaking (NPRM). Defs. Opp. 12-13. The guidelines are relevant to the ADR Rule because the statute requires manufacturers to complete an audit to bring a claim, and manufacturers rarely conducted audits because the guidelines are burdensome. These facts did not change between the 2010 ANPRM and the 2016 NPRM.

In all events, HRSA stated in the NPRM that it had requested comments on the guidelines (among other topics), had received 14 comments, and had considered them in

[4] By contrast, in *Tindal*, Congress "narrowly defined the factors" the agency had to consider, rendering comments on other topics irrelevant. 717 F.2d at 880. Similarly, where a law required an agency to adopt the most stringent water treatment option feasible "regardless of cost-benefit analysis," comments concerning cost-benefit analysis were irrelevant. *City of Portland v. EPA*, 507 F.3d 706, 714-15 (D.C. Cir. 2007). *See also Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 525, 549 (D.C. Cir. 1997) (where agency overhauled existing safety regulations under statutory "no less protection" standard, it reasonably dismissed comments seeking new regulations as "beyond the scope of the rulemaking").

developing the proposed rule. AR5. And, in connection with consolidated claims by manufacturers, HRSA "recognize[d] the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity," and sought comment on how manufacturers "can satisfy the audit requirement" for such claims. AR7. Thus, far from taking the issue "off the table," the statements in the NPRM indicated that the issue remained salient, which is why many commenters addressed it again. *See* AR196-97, AR208-09, AR 232-33, AR292-93, AR307-13, AR345-46, AR354-56.

Defendants' remaining cases undermine their defense of HRSA's dismissal of these comments. In *Mobil Oil Exploration & Producing Southeast Inc. v. United Distribution Companies*, 498 U.S. 211 (1991), the agency responded to comments about take-or-pay gas contracts and "articulated rational grounds for" why it would address them in a later proceeding. *Id.* at 229-31. In *Consumer Federation of America v. Consumer Product Safety Commission*, 990 F.2d 1298 (D.C. Cir. 1993), the ANPRM did not propose a ban on sales of all-terrain vehicles to youth, or seek comment on the idea, *id.* at 1305, but the agency still offered a "rational" explanation for not imposing such a ban—waiting to see if a judicial consent decree that required age recommendations proved effective, *id.* at 1303, 1306-07.[5]

Here, by stark contrast, HRSA solicited comments on revising the audit guidelines,

[5] In *P&V Enterprises v. U.S. Army Corps of Engineers*, 516 F.3d 1021 (D.C. Cir. 2008), *abrogated on other grounds by United States v. Kwai Fun Wong*, 135 S. Ct. 1625 (2015) the Court did not address whether an agency should have responded to comments. *P&V Enters.*, 516 F.3d at 1026. There, the agency issued an ANPRM to gather information to assess whether it should modify a regulatory definition in light of a Supreme Court decision—a step it ultimately chose not to take. *See id.* at 1022-23. Here, HRSA's ANPRM was the beginning of a rulemaking it was required to undertake and that resulted in a final rule.

gave an unexplained conclusion for dismissing those comments, and did not suggest it would address the problem in another proceeding or point to an alternative proposal or other "meaningful action" that would. *See id.* at 1305. No deference is owed to HRSA's *ipse dixit* dismissal of relevant comments it explicitly solicited. To the contrary, *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007), holds that an agency's failure to "provide[] some reasonable explanation" for its "inaction" on an issue violates the APA. *See also N.C. Growers' Ass'n v. United Farm Workers*, 702 F.3d 755, 769-70 (4th Cir. 2012) (refusal to consider comments on issues "integral to the proposed agency action and the conditions that such action sought to alleviate" violated APA); *Defs. of Wildlife v. U.S. Dep't of Interior*, 931 F.3d 339, 351-52 (4th Cir. 2019) (failure to consider relevant evidence gathered by the agency itself violated APA). HRSA's unexplained refusal to address whether the audit guidelines were appropriate for its new ADR Rule was arbitrary and capricious.

B. HRSA Entirely Failed to Address PhRMA's Petition Demonstrating that the Record Is Stale.

It was also arbitrary and capricious for HRSA to act on an out-of-date record rather than consider the evidence submitted in PhRMA's rulemaking petition. Contrary to defendants' assertions, Defs. Opp. 13, the issues raised by the petition were plainly relevant and merited a response.

The petition showed that rampant problems with diversion and duplicate discounts, facilitated by the growth of contract pharmacy arrangements, had arisen since 2016. Compl. Ex. A, at 4-10. It argued that manufacturer-initiated ADR claims are essential to combat these problems, and that both the burdensome audit guidelines and

HRSA's failure to adequately define who is a "patient" of a covered entity would render the new ADR process ineffective by "restrict[ing]" manufacturers' access to those procedures. *Id.* at 11-12; *cf.* Defs. Opp. 11.

The fact that the petition was submitted four years after the close of the comment period, *see* Defs. Opp. 13, is not dispositive. By its very nature, a claim that the record should be reopened to consider new evidence can only be raised after the original comment period has closed. Nor is this a case where PhRMA submitted a belated letter that simply argued with HRSA's conclusions or offered "scanty new evidence of alleged problems." *Id.* at 14 (quoting *Glass Packaging Inst. v. Regan*, 737 F.2d 1083, 1094 (D.C. Cir. 1984)). PhRMA cited numerous reports, many issued by the government itself, showing significant problems of diversion and duplicate discounts that HRSA is failing to address. The petition thus demonstrated a change in "a significant factual predicate" for the proposed rule; to proceed on the existing record in the face of PhRMA's showing, HRSA had to explain "the factual and policy bases for [the] decision" in sufficient detail to permit judicial review. *Am. Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 5-6 (D.C. Cir. 1987) (citation omitted); *see also Mobil Oil Corp. v. EPA*, 35 F.3d 579, 584-85 (D.C. Cir. 1994); *Geller v. FCC*, 610 F.2d 973, 978 (D.C. Cir. 1979) (per curiam). It plainly failed to do so.[6]

Nor can defendants fault PhRMA for submitting the petition "three weeks before

[6] Defendants suggest that PhRMA cannot challenge the adoption of the ADR Rule and the petition's denial. Defs. Opp. 14. In this case, however—where HRSA effectively denied the petition *by* adopting the Rule—there is only one decision at issue. PhRMA's Complaint challenges both the failure to consider the petition and the issuance of the Rule, Compl. ¶¶ 74-83, and PhRMA is entitled to pursue both on summary judgment.

publication of the final ADR Rule." Defs. Opp. 13. HRSA *publicly abandoned* the proposed ADR Rule in August 2017 due to "concerns raised by commenters" and the Rule's "associated burdens," AR1982, and stated as late as March 2020 that it had no intention of reviving it. *See* PhRMA Br. 14-15. Months later, however, HRSA rushed to finalize the proposed ADR Rule in response to lawsuits by covered entities. *Id.* at 15. The only public notice of HRSA's intended action was a notation that the proposed Rule had been transmitted for review by the Office of Management and Budget on November 17, 2020. *See id.* .PhRMA filed its petition *one week later*. *Id* at 15-16. After years of inaction, HRSA left only a four-week gap between resurrecting the abandoned Rule and finalizing it based on a stale record. It cannot now complain that PhRMA's request to reopen comment came too late. Its failure to provide a reasoned response to the petition renders the ADR Rule arbitrary and capricious.

CONCLUSION

For these reasons and the reasons set forth in PhRMA's opening brief, the Court should grant PhRMA's cross-motion for summary judgment, and deny defendants' cross-motion and motion to dismiss.

Date: October 12, 2021

Respectfully submitted,

/s/ Sujit Raman
Sujit Raman (Bar No. 28907)
Joseph R. Guerra (*pro hac vice*)
Erika L. Maley (*pro hac vice*)
sujit.raman@sidley.com
jguerra@sidley.com
emaley@sidely.com
Sidley Austin LLP
1501 K Street, N.W.

Washington, D.C. 20005
Telephone: 202-736-8000
Facsimile: 202-736-8711

Attorneys for Plaintiff Pharmaceutical Research and Manufacturers of America