IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

COMBINED MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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As explained in HHS's pending dispositive motion, this and several related disputes arose last year when several of PhRMA's members, all large, global pharmaceutical manufacturers, abruptly upended the twenty-five year operation of the 340B Program by restricting access to discounted drugs by participating safety-net healthcare providers that rely on neighborhood pharmacies. Specifically, the PhRMA-member manufacturers announced that no longer will they offer (or offer without manufacturer-imposed, extra-statutory restrictions) access to 340B-discounted drugs for certain statutorily defined healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies." These unlawful restrictions have spawned a raft of litigation across the country brought by manufacturers seeking to thwart 340B Program requirements and HHS's enforcement of the 340B statute against them. In this suit PhRMA seeks to aid its members' campaign by challenging an administrative-dispute resolution regulation mandated by Congress that presents the sole method for safety-net providers to assert directly against manufacturers their statutory right to purchase 340B-discounted drugs, along with a set of nearly quarter-century-old guidelines governing the ways in which manufacturers may audit covered entities. Neither challenge has merit because both the audit guidelines and dispute-resolution rule were issued as lawful exercises of discretion granted by Congress; this suit should therefore be dismissed.

ARGUMENT

I. THE AUDIT GUIDELINES WERE LAWFULLY ESTABLISHED.

Although the ADR Rule promulgated last year by HRSA is the only live issue presented in this case, PhRMA attempts to use litigation over that rule to bootstrap a challenge to decades-old audit guidelines that have operated without challenge since their promulgation in 1996. But the Secretary promulgated those guidelines in accordance with the statutory text and intent of Congress, and in the considered and reasonable exercise of his statutorily conferred discretion. PhRMA's belated challenge should thus be rejected by this Court.

A. The Audit Guidelines Are Consistent with the 340B Statute.

PhRMA does not (and cannot) dispute that Congress instructed that manufacturers auditing covered entities must "act[] in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." 42 U.S.C. § 256b(a)(5)(C). Exercising the discretion granted him to devise those procedures, the Secretary issued guidelines requiring manufacturers to show "reasonable cause" to institute an audit. This sensible requirement is a procedure "relating" to the "number" of audits a manufacturer may conduct in that it limits the number of permissible audits to circumstances where the manufacturer "has documentation which indicates that there is reasonable cause" to "believe that a covered entity may have violated" the duplicate discount and diversion protections of the statute. Mfr. Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Accordingly, this threshold requirement presents no conflict with the statutory text, which delegates to the Secretary authority to establish the specifics of such procedures. PhRMA's attempts to manufacture a conflict with the text of the statute are unpersuasive.

To begin, limiting the "number" of permissible audits to those circumstances where a manufacturer has "reasonable cause" is unquestionably an action that "relat[es] to" the dictionary definition of "number." The Oxford English Dictionary defines "number" as "[i]n senses relating to the result of enumeration, to quantity," or "the precise sum or aggregate of a collection of individual things." *Number*, Oxford English Dictionary, https://www.oed.com/view/Entry/129082?rskey=VDBT7x&result=1&isAdvanced=false#eid; *see also* PhRMA Mot. 29 (citing Merriam-Webster Dictionary, defining number as "a sum of units"). Here, the Secretary's action necessarily limits the "number" of audits allowed to those times a manufacturer has reasonable cause to believe that a covered entity is violating the statute, and thus this requirement relates to the number of audits performed. *Id.*

In response, PhRMA seems to proffer an understanding of the term that would limit the agency to identifying a specific "numerical quantity." PhRMA Mot. 29 (citing OED). In other words, PhRMA seems to believe that the only permissible action would be for the agency to say that its members may conduct, for example, no more than 20 audits in a set timeframe. But neither the

dictionary definition nor the statute compel an interpretation whereby the Secretary is required arbitrarily to specify a universal numerical quantity applicable to all manufacturers, rather than defining the number of audits more flexibly as coextensive with the existence of cause to do so. After all, PhRMA cannot reasonably maintain that a rule limiting audits to "no more than 20" is permitted but a rule that limits audits to "no more than those in which reasonable cause exists for a violation" is contrary to the plain language of the statute.[1] Indeed, to the extent PhRMA's alternative definition of "number" is relevant at all, it would be solely to create ambiguity entitling the agency's interpretation to deference. *See U.S. v. Deaton*, 332 F.3d 698, 710 (4th Cir. 2003) (quoting *Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407 (1992) ("The existence of alternative dictionary definitions … each making some sense … indicate that the [statute] is open to interpretation.").

Moreover, even if PhRMA were correct about the interpretation of the term "number" in the statute, that still would not mandate the result it seeks. The statute does not require the agency to promulgate a number for audits, but rather requires that the "procedures" developed by the agency "relat[e] to" "the number" of audits. 42 U.S.C. § 256b(a)(5)(C). PhRMA briefly contests this by arguing that the requirement does not relate to the number of audits but instead relates to the manner in which such audits are conducted. PhRMA Mot. 30. To the contrary, 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, and does not give cause for the Court to consider the "furthest stretch of … indeterminacy" that the phrase "relate to" may encompass. *See Retail Industry Leaders Ass'n v. Fielder*, 475 F.3d 180, 191 (4th Cir. 2007) (citing *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

PhRMA argues further that the "reasonable cause" requirement is not a "procedure" within the scope of the Secretary's rulemaking authority under the 340B statute. PhRMA Mot. 30. But that argument proves too much, because PhRMA's reading of the word "procedure" would effectively

[1] And—contrary to PhRMA's portrayal—had the Secretary adopted guidelines limiting manufacturers in advance to a set cap on the number of annual audits, without regard to the factual predicate establishing need to audit additional covered entities, that numerical restriction could be challenged as arbitrary and possibly contrary to statutory intent.

render the term "number" superfluous, as the agency would be unable to define the term number in any manner, including the "numerical value" cap interpretation that PhRMA proposes. According to PhRMA, the reasonable cause requirement is an "evidentiary standard, not a procedure." *Id.* But by that logic a numerical quantity would be a number, not a "procedure" relating to a number, and the Secretary would not be able to determine the number of audits a manufacturer may conduct at all. This argument runs counter to Congress's clearly expressed intent and presents no basis for invalidating the audit guidelines. "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (citation omitted); *see also Lynch v. Jackson*, 853 F.3d 116, 122 (4th Cir. 2017) (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982)) ("Readings of a statute that 'produce absurd results are to be avoided.'"). Indeed, to the extent the argument has any force, it supports the Secretary's decision to adopt a limitation on the number of audits that is case-specific in nature (the requirement of "reasonable cause") rather than a rigid numerical cap.

The "reasonable cause" requirement is also a valid exercise of the Secretary's authority to establish procedures "relating to" the "scope" of audits. Contrary to PhRMA's characterization of this argument as a "post hoc rationalization," PhRMA Mot. 30-31, the audit guidelines themselves state that HRSA will review audit workplans "for reasonable purpose and scope," including whether the audits will target records that "directly pertain to the potential 340B violation(s)." The "reasonable cause" requirement is thus related to the procedures for determining the scope of manufacturer audits, because HRSA has made plain that it will ensure that the scope of audits bears reasonable symmetry to the suspected violations. That the requirement also limits the number of permissible audits does not invalidate its service in defining the scope of the audit, as PhRMA contends. PhRMA Mot. 31 (arguing that the "reasonable cause" requirement only pertains to "whether a manufacturer may conduct an audit in the first instance, not the extent of the audit") (internal quotation omitted). PhRMA provides no reason to believe that HRSA does not consider the extent of cause to initiate an audit in reviewing whether a manufacturer's proposal is appropriate in scope.

In addition to being consistent with the plain text of the statute, the "reasonable cause"

requirement also reflects its context and purpose. *See Mgmt. Grp., LP v. FTI Consulting, Inc.*, 138 S. Ct. 883, 893 (2018) (internal quotation omitted) ("[W]e look to both the language itself [and] the specific context in which that language is used …"). Congress acknowledged a concern that manufacturers may have an incentive to conduct wide-ranging audits by limiting the scope of such audits to the "records of the entity that directly pertain to the entity's compliance" with the statute. 42 U.S.C. § 256b(a)(5)(C). The Secretary's "reasonable cause" requirement is intended to address this same concern—that highly profitable pharmaceutical companies' audits of resource-strapped safety-net providers may unfairly burden providers without any reason to believe that violations of the statute are occurring. And although the statutory limitation on the scope of the records audited is distinct from the Secretary's requirement that manufacturers articulate "reasonable cause" to believe that a statutory violation is occurring, the Secretary's interpretation of the statute is consistent in addressing the same underlying concerns that Congress identified in enacting the statute. PhRMA responds by saying that there was no evidence of "prior misuse" of audit rights. PhRMA Mot. 31. But this is a quibble with Congress, not the agency, which is authorized to regulate with Congress's stated purposes in mind and is under no obligation to allow misuses to occur before adopting rules intended to prevent them.

According to PhRMA, the "reasonable cause" requirement cannot possibly be consistent with the statute because "Congress knows how to prescribe threshold requirements for statutorily authorized activities" and it did not do so here. PhRMA Mot. 32. PhRMA fails to acknowledge, however, that Congress also knows how to confer discretion on agencies, and did so here, by giving the Secretary authority to proscribe procedures relating to the number, scope, and duration of manufacturer audits. As explained, *supra*, the Secretary exercised that authority consistently with the text of the statute, and in accordance with his expertise, as Congress intended. That Congress did not impose the "reasonable cause" requirement itself has no bearing on whether the Secretary properly exercised the authority delegated to him by Congress. To argue otherwise would be to suggest that Congress can never delegate to the Secretary that which it has authority to enact as law, and would therefore be contrary to the modern administrative state.

The independent auditor requirement is equally consistent with the text of the statute. PhRMA readily acknowledges that manufacturers must employ someone to conduct audits of covered entities, and there is no textual basis to conclude that Congress *required* the Secretary to permit manufacturers to deputize their own, internal employees to comb through covered entities' records, rather than the sensible requirement that manufacturers engage neutral, professional auditors to perform that task on their behalf. The independence requirement serves to ensure that the audits are conducted fairly and without bias---a requirement that would have no meaning if manufacturers' employees were conducting the audits. Moreover, the designation of who may conduct the audit is necessarily a "procedure" that is "related" to the "scope" of such audit, in that the auditor is responsible for conducting and defining the scope of the audit. PhRMA may disagree with the substance of the requirement, but it cannot reasonably dispute its statutory basis.

B. The Audit Guidelines Are a Reasonable Exercise of the Secretary's Discretion, and Should be Awarded Deference.

To the extent the Court concludes that the statute is ambiguous as to the procedures which the Secretary may adopt, the Court should defer to the Secretary's reasonable interpretation, as PhRMA has identified no basis to justify the Court "substituting its judgment for that of the agency." *People for the Ethical Treatment of Animals ("PETA") v. USDA*, 861 F.3d 502, 510 (4th Cir. 2017). That highly deferential standard requires a court to "defer" "to an administrative agency's … reasonable interpretations of governing law." *Crutchfield v. Cty. Of Hanover, VA.*, 325 F.3d 211, 218 (4th Cir. 2003).

The Secretary explained that the "reasonable cause" requirement exists to ensure that "audits are performed where there are valid business concerns and are conducted with the least possible disruption to the covered entity." 61 Fed. Reg. at 65,406. Recognizing that the statute requires audits to "pertain directly to the entity's compliance" with the prohibitions against diversion and duplicate discounting, the Secretary also concluded that it was "appropriate to require manufacturers" to establish "reasonable cause" to ensure that audits are tailored to ensure compliance with those statutory requirements. *Id.*

PhRMA strains credulity by claiming that manufacturers "have the same interest" as covered

entities in conducting audits and that the "reasonable cause" requirement is inconsistent with covered entities' ability to audit their own contract pharmacies and HRSA's random auditing of covered-entity arrangements. PhRMA Mot. 34-35. This argument ignores the very basis for congressional and regulatory action in the first place, which is that manufacturers' interests are *not* aligned with those of covered entities and, although it is undoubtedly true that both manufacturers and covered entities share a goal of reducing diversion and duplicate discounting, it does not make sense to equate audits conducted by covered entities and HRSA with those conducted by manufacturers.

For one, as the agency explained, covered entities are fully "responsible for ensuring that the system of distribution chosen fully meets statutory obligations," and "remain[] responsible at all times for the disposition of covered outpatient drugs [they] purchase[]." Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Serv., 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010). Covered entities may therefore audit the contract pharmacies that they choose to have a relationship with in order to ensure compliance with *the covered entities'* responsibility to meet their own statutory obligations. In other words, covered entities must have the right to audit the contract pharmacies with which they do business because non-compliance with statutory obligations risks forfeiture by the covered entities of *their* right to participate in the 340B Program. Because the duty to ensure adherence with the prohibitions on duplicate discounts and diversion always remains on the covered entity, they can only comply with those duties through audits of their contract pharmacies (which, unlike covered entities, have no statutory right to participate in the program). Manufacturers' relationships with covered entities are fundamentally distinct—as the manufacturers have a vested interest in limiting the amount of deeply discounted sales—and there is no basis in the statute to conclude that Congress intended them to have similar internal auditing rights as the covered entities that choose to utilize contract pharmacies.

Additionally, PhRMA's argument ignores the Secretary's sensible determination that the "reasonable cause" requirement is necessary to give effect to the statute's requirement that the scope of manufacturers' audits be properly limited. Although PhRMA suggests that the Secretary could have chosen another mechanism to give effect to this statutory requirement, the Court must "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). This Court may not "substitute [its] own construction … for a reasonable interpretation made by" the agency, but instead "must uphold the agency's interpretation if it is 'rational and consistent with the statute.'" *Yi v. Fed. Bureau of Prisons*, 412 F.3d 526, 534 (4th Cir. 2005) (citation omitted). Here, PhRMA provides no persuasive ground to upset the Secretary's determination that the "reasonable cause" requirement fulfills Congress's goal of ensuring that manufacturer audits do not unduly burden covered entities. *See* H.R. Rep. No. 102-384, pt. 2, at 17 (1992) (conf. report) ("The Committee expects that, in developing these procedures, 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."). The Secretary's interpretation of the statute in requiring manufacturers to make a threshold showing of cause is thus reasonable under the statute. And PhRMA's attempt to equate its members' auditing rights to those of HRSA is nonsensical. HRSA is the regulator and administrator of the 340B statute, charged with ensuring the program's proper operation. That HRSA itself, the agency charged with statutory enforcement, possesses more-flexible audit powers than manufacturers—themselves regulated entities—is unsurprising and commonplace. No reasonable observer would conclude that manufacturers' ability to audit covered entities should be coextensive with that of the agency.

According to PhRMA, manufacturers are in a "Catch-22" because they need covered entities' records to justify an audit of the covered entity in the first place. PhRMA Mot. 35. But the Secretary was clear in the audit guidelines that these records are not necessary to establish reasonable cause. The audit guidelines state that "reasonable cause" means "that a reasonable person could believe that a covered entity may have violated" the statute. 61 Fed. Reg. at 65,409. "Significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity," neither of which requires records from a covered entity, "may be a basis for establishing reasonable cause." *Id.* at 65,406. Not only does PhRMA fail to explain why it is

impossible to establish reasonable cause in this manner, it fails to acknowledge this text of the audit guidelines in its entirety.

PhRMA also accuses the Secretary of imposing the "reasonable cause" requirement without evidence that manufactures have misused audits. PhRMA Mot. 35. But, once again, Congress did not require the Secretary to defer the reasonable judgment that, in light of the competing interests of manufacturers and covered entities, abuse may occur until manufacturers have the opportunity to overburden resourced-strapped safety-net providers. Finally, the fact that manufacturers have infrequently used the auditing process does not provide a basis to invalidate the Secretary's interpretation of the 340B statute. On the contrary, the infrequent use of manufacturer audits would more naturally suggest that manufacturers lack reasonable cause to suspect widespread noncompliance, since audits must be linked to noncompliance with covered entities' statutory obligations. The audit guidelines provide a blueprint for manufacturers to use the auditing process, and it is up to them whether or not to do so.

With respect to the requirement that manufacturers use independent public accountants to perform audits, the Secretary emphasized that conducting audits consistently with the Government Auditing Standards is important to ensure 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 65, 407. The Secretary also explained that the requirement is important to "ensure audit uniformity and consistency and adequacy of documentation to permit independent review in cases where disputes arise." *Id.*

PhRMA's only arguments against the Secretary's reasonable conclusion are that hiring outside auditors renders the audits "financially infeasible," and that Government Auditing Standards provide for the use of internal auditors, neither of which is persuasive. PhRMA Mot. 36-37. In the first instance, the idea that large, highly profitable pharmaceutical manufacturers find hiring third-party auditors "financially infeasible" strains credulity, particularly in light of their apparent willingness to devote significant internal resources to the same task. And PhRMA's assertion that audits are "financially infeasible in most instances," PhRMA Mot. 36, is belied by the fact that its pharmaceutical-

manufacturer members have continued to conduct such audits under the guidelines that have been in place during the last twenty-plus years.

While PhRMA is correct that the Government Auditing Standards do allow for internal auditors to audit external parties in some limited circumstances, the same standards are also clear that this exception does not apply if independence is "impaired." GAO, *Government Auditing Standards* ¶ 3.58 (2018 rev.), available at https://www.gao.gov/assets/gao-21-368g.pdf. One such "impairment" is if the audit would "create the appearance that the auditor's integrity, objectivity, or professional skepticism may be compromised." *Id.* at ¶ 3.61. There is no question that a manufacturer's non-independent internal auditor delving into the business records of a covered entity whose financial interest runs contrary to the manufacturers could "create the appearance" of a bias. Thus, the Secretary's determination to require an independent third-party auditor is entirely rational, and a reasonable interpretation of the statute deferring to the Secretary's expertise in creating the procedures for manufacturer audits.

Because the audit guidelines reflect the Secretary's reasonable interpretation of the statute, this Court is "bound to uphold [the] agency['s] interpretation." *Serono Labs., Inc.*, 158 F.3d at 1321. The Court should therefore grant HHS's motion for summary judgment on this claim.

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

A. The ADR Rule Complies with the APA.

PhRMA claims that the ADR Rule is arbitrary and capricious, *see* 5 U.S.C. § 706(2)(A), because HHS promulgated the rule without adequately addressing (i) public comments recommending that the agency revise its audit guidelines and (ii) the contents of a rulemaking petition submitted by PhRMA long after the comment period had closed, which also requests revised audit guidelines and new agency guidance for determining who is a covered entity's "patient." As already explained, *see* HHS Mot. 17–20, HHS was not obligated to consider, much less respond to, these comments or PhRMA's rulemaking petition because they raised issues that were neither relevant nor important to the

proposed rulemaking.[2] *See N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 769 (4th Cir. 2012); *see also Defs. of Wildlife v. U.S. Dep't of Interior*, 931 F.3d 339, 345 (4th Cir. 2019) (citations omitted); *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."). PhRMA's counterarguments are unavailing.

First, PhRMA contends that the relevance or importance of an issue "must be measured by" the statute that governs the rulemaking. *See* PhRMA Mot. 41. But this cuts sharply *against* its claim. The 340B statute, in subsection (d)(3)(B), outlines the particular requirements, procedures, and deadlines that compose the ADR regulations. *See* 42 U.S.C. § 256b(d)(3)(B)(i)–(vi). One such requirement, as PhRMA points out, is that a manufacturer conduct an audit as a prerequisite to filing an ADR claim, *see id.* § 256b(d)(3)(B)(iv)—a requirement the ADR Rule expressly addresses, *see* AR 16; *see also* 42 C.F.R. 10.21(c)(2). But nowhere does the statute direct the Secretary to develop new or revised audit procedures as a component of, or in conjunction with, the ADR rulemaking, and the audit guidelines PhRMA challenges had been in place for *nearly fifteen years* when Congress directed the Secretary to create an ADR process. Moreover, the Secretary's obligation and authority to establish audit procedures derive from a different statutory subsection, *see id.* § 256b(a)(5)(C), separate from those provisions governing the ADR regulations.[3] And similarly, nothing in § 256b(d)(3) directs the Secretary, in promulgating these *procedural* regulations, to issue new or revised *substantive* interpretations of each statutory term (*e.g.*, "patient") that a decision-making official may need to apply in resolving

[2] Nothing in the record supports PhRMA's assertion that HHS "concede[s]" that it did not "consider[]" comments pertaining to the audit guidelines. *See* PhRMA Mot. 37. It is irrefutable that HHS considered and responded to these comments, *see* AR 13, as PhRMA itself acknowledges, *see* Compl. ¶ 78.

[3] Because the Secretary's obligation and authority to establish audit procedures is governed by § 256b(a)(5)(C), PhRMA's attempt to read a duplicative obligation into § 256b(d)(3)(B)(ii)—which directs the Secretary to establish "deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously"—should be rejected. After all, the Secretary "enjoys broad discretion in determining how best to handle [the] related, yet discrete," audit guidelines promulgated under § 256b(a)(5)(C) "in terms of procedures[] and priorities." *See Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 231 (1991). It thus proper for this Court to afford the Secretary "significant latitude as to the manner, timing, content, and coordination of [the agency's] regulations." *See Massachusetts v. EPA*, 549 U.S. 497, 533 (2007).

an ADR dispute. It is therefore "evident on the face" of the 340B statute that revised audit procedures and a revised "patient" definition were not issues important or relevant to the rulemaking mandated by § 256b(d)(3). *See Catholic Legal Immigr. Network, Inc. v. Exec. Off. for Immigr. Review*, 2021 WL 184359, at *11–12 (D.D.C. Jan. 18, 2021).

Second, PhRMA insists that the final ADR Rule failed to sufficiently expound on public comments requesting revised audit guidelines because the agency had invited these comments in the ANPRM, thus demonstrating that HHS viewed new audit procedures to be "inextricably linked" with the ADR rulemaking. *See* PhRMA Mot. 38. But the record belies this argument. For one, HHS was clear in the ANPRM that any potential revisions to the audit guidelines, should they be deemed necessary, would occur "*prior* to" (and thus separate from) implementation of the final ADR rule. AR 3 (emphasis added). Two, the ANPRM asked whether revisions to the audit guidelines were even "*appropriate* or *necessary*," *see id.* (emphasis added), reflecting HHS's unsettled view on the subject, *see id.* at 1 ("HRSA is issuing this ANPRM to gather comments prior to committing to a particular regulatory path."). *See also, e.g.*, *P & V Enterprises v. U.S Army Corps of Engineers*, 516 F.3d 1021, 1026 (D.C. Cir. 2008) ("The plain text of the *ANPRM* indicated that the [agency] was considering its options and seeking information to assist it in deciding on the *possibility* of a *future* proposed rule … ."), *abrogated on other grounds by United States v. Kwai Fun Wong*, 575 U.S. 402 (2015); *see also* HHS Mot. 19-20 (collecting cases discussing the role of an advance notice of proposed rulemaking in the informal-rulemaking process). And most telling was HHS's decision, after receiving comments on the ANPRM, *not* to propose in the subsequent NPRM (or in a separate, concomitant rulemaking) new audit procedures. After all, an ANPRM, as "a generalized and tentative undertaking," is not intended to constitute a binding statement of agency intent, and an agency's decision to deviate from an ANPRM should be reviewed according to a "highly respectful" standard of review. *Consumer Fed'n of Am. v. Consumer Prod. Safety Comm'n*, 990 F.2d 1298, 1304-05 (D.C. Cir. 1993).

PhRMA's argument on this score also lacks legal support. It relies principally on *Cigar Association of America v. FDA*, 480 F. Supp. 3d 256 (D.D.C. 2020), where the court, having found that an agency "placed [certain] issues on the table" by inviting comments on those issues in a *notice of*

proposed rulemaking, faulted the agency for then not responding to those comments, *id.* at 280. But here, the NPRM requested no comments and made no proposals regarding revisions to the audit guideline, making it clear that HHS "placed th[at] issue[] o[ff] the table," *see Cigar Ass'n of Am.*, 480 F. Supp. at 280. The agency thus had no reason to respond to comments raising this irrelevant issue. *See N.C. Growers' Ass'n, Inc.*, 702 F.3d at 769; *City of Portland v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007); *Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 549 (D.C. Cir. 1997).[4]

Third, with respect to its rulemaking petition, PhRMA suggests that the petition raised "new evidence" that HHS was required to consider before promulgating the ADR Rule. PhRMA Mot. 42–45 (emphasis removed). This evidence, according to PhRMA, relates to purported compliance issues in the 340B Program and an increase in the number of contract pharmacies used by covered entities. *Id.* at 44 (emphasis removed). And in PhRMA's view, this evidence was "material" to the ADR Rulemaking because (and only because) it "underscored the need" for revised audit procedures and a revised "patient" definition. *Id.* at 43. But as explained above, neither issue was a relevant component of the proposed rulemaking mandated by § 256b(d)(3), *see also* HHS Mot. 18–20, so HHS was under no obligation to reopen the rulemaking to consider it.

Finally, because PhRMA submitted its petition long after close of the comment period and a mere three weeks before publication of the final ADR Rule,[5] HHS was not obligated to respond in the course of HHS's ADR rulemaking. Indeed, as PhRMA's petition acknowledges, the final rule was already before the White House Office of Management and Budget, Office of Information and Regulatory Affairs. *See* Compl., Ex. A at 3. Whether styled as a letter submitting "public comments" or a rulemaking petition, "agencies are free to ignore [such] late filings" made during informal rulemaking. *See Reytblatt v. U.S. Nuclear Regul. Comm'n*, 105 F.3d 715, 723 (D.C. Cir. 1997). As the D.C. Circuit explained in *Reytblatt*, there is "no basis" in the APA "for obliging an agency to specifically

[4] PhRMA's reliance on *Ohio Valley Env't Coal. v. U.S. Army Corps of Eng'rs*, No. 3:08–0979, 2013 WL 1305732 (S.D. W. Va. Mar. 28, 2013), is similarly misplaced. There, unlike here, the agency failed to respond to relevant and significant public comments that it had solicited in a public notice for a § 404 permit under the Clean Water Act. *Id.* at *6–12.

[5] As PhRMA's petition acknowledges, the final rule was already before the White House Office of Management and Budget, Office of Information and Regulatory Affairs. *See* Compl., Ex. A at 3.

address" untimely submissions on a proposed rule. *Id.* In *Reytblatt*, the plaintiff had sent a letter to the agency to raise concerns with a proposed rule and to rebut the agency's response to certain public comments. *Id.*; *see also* Brief for Respondents, *Reytblatt v. U.S. Nuclear Regulatory Comm'n*, No. 95–1578, 1996 WL 34483549, at *18–19 (D.C. Cir. July 22, 1996). The court considered the letter, regardless of its form, to be an "untimely comment" that the agency could simply ignore because it was sent months after the comment period had closed. *Id.* So too here. And, even aside from timeliness, PhRMA's argument ignores that denial of (or failure to act upon) a petition for rulemaking is *an entirely separate agency action* from promulgation of the ADR Final Rule and thus not properly reviewed through the vehicle of this challenge to the ADR Rule. *Cf. Consumer Fed.*, 990 F.2d at 1304 (describing "decision not to *initiate* a rulemaking" as "so discretionary that it qualifies for our most deferential review").

Indeed, a contrary rule would effectively immobilize HHS's effort to implement the mandatory rulemaking under § 256b(d)(3) by requiring the agency to respond to every belated complaint from a stakeholder. That is why "[t]he Supreme Court has cautioned against upsetting well-considered agency decisions based on scanty new evidence of alleged problems," *Glass Packaging Inst. v. Regan*, 737 F.2d 1083, 1094 (D.C. Cir. 1984), and why it is "well settled that an agency need not reopen administrative proceedings merely because some new piece of evidence has come to light that was not before the agency at the time it made its decision," *See Am. Mining Congress v. Marshall*, 671 F.2d 1251, 1257 (10th Cir. 1982). This principle, as the Supreme Court has explained in a related context, is necessary due to the nature of administrative rulemaking: "Administrative consideration of evidence always creates a gap between the time the record is closed and the time the administrative decision is promulgated … [If] litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated … ." *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 554–55 (1978) (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944)). PhRMA's rulemaking petition deserves no different treatment.

B. *ARTHREX* CONFIRMS THAT ADR BOARD MEMBERS ARE LAWFULLY APPOINTED INFERIOR OFFICERS

Ten days after HHS filed its motion for summary judgment in this matter, the Supreme Court issued additional guidance on the constitutional constraints governing the appointment of adjudicatory officers, holding that administrative judges operating under statutory restrictions on *both* review of their decisions *and* removal from their office exceeded the power that properly may be vested in inferior officers. *United States v. Arthrex, Inc.*, 594 U.S. __ , slip op. 19-1434 (June 21, 2021). *Arthrex* concerned Administrative Patent Judges (APJs) appointed by the Secretary of Commerce and empowered, when assigned to three-judge panels, to hear challenges to previously issued patents in an adversarial proceeding "which resembles civil litigation in many respects." *Id.* 1, 3-4. Although a dissatisfied litigant could request rehearing by a panel, under the statutory scheme "[n]either the Secretary nor Director," the supervising principal officer, "had the authority to review [APJs'] decisions or to remove them at will"; the APJs' decisions were final for the Executive Branch and could be appealed only to the Court of Appeals for the Federal Circuit. *Id.* at 4-6. The Court determined that this novel structure, where "Congress has assigned APJs 'significant authority' in adjudicating the public rights of private parties[] while also insulating their decisions from review and their offices from removal," was inconsistent with the Appointments Clause. *Id.* at 19.

As a remedy, the Court concluded that the will of Congress could best be effectuated in that particular scheme by severing the statutory restriction on review of APJs' decisions by the Director, rather than the statutory restriction on removal from office at will. "In every respect save the insulation of their decisions from review within the Executive Branch, APJs appear to be inferior officers—an understanding consistent with their appointment" by a Head of Department, the Court concluded, so the most-sound result was to render the statute "unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the [APJs] on his own." *Id.* at 21-22. It mattered not that no formal mechanism for appeal to the Director would then exist, because vesting the Director with the discretionary power to review APJs' decisions "would follow the almost-universal model of adjudication in the Executive Branch." *Id.* "To be clear, the Director need not

review every decision," because "[w]hat matters is that the Director *have the discretion to review* decisions rendered by APJs." *Id.* at 23 (emphasis added).

Arthrex confirms that the ADR Rule challenged here is consistent with the Appointments Clause. The statutory scheme at issue here (which PhRMA does *not* challenge, as opposed to the Rule promulgated under it) contains no restraint on the Secretary's ability to direct and supervise the ADR Board through review of panel decisions or removal from office at will. To be sure, the statute directs the Secretary to "establish a decision-making official or decision-making body … to be responsible for reviewing and finally resolving claims." 42 U.S.C. § 256b(d)(3)(B)(i). But that language instructs the Secretary *to delegate* authority to issue final agency actions reviewable in district court; it does not resemble the language at issue in *Arthrex*, where "Congress unambiguously specified" in *prohibitory* terms that the Director could not alter a decision. *See* slip op. at 10; *see also* 35 U.S.C. § 6(c) (specifying that "[o]nly the … Board may grant rehearings"); *Arthrex* at 12 (confirming § 6(c) represents "a statutory prohibition on review"). Here, the absence of any statutory constraint on discretionary review by the Secretary of final decisions of his subordinates makes the ADR Rule analogous to the *Arthrex* Court's statutory *fix*—not the initial constitutional *violation*.[6]

Under both the ADR Rule and the statute, the Secretary freely may exercise discretionary review of panel decisions; it makes no difference that no formal mechanism for appeal to the Secretary is set forth in the regulation. Indeed, the *Arthrex* Court confirmed that an express grant of power to direct and review the decisions of subordinates is unnecessary, so long as no express *restriction* on that power is found in the statutory scheme. Notably for the present case, not only was there no need for express statutory authorization for the Director's review of APJs' decisions, the Court also made clear that the Director need not promulgate regulations establishing a formal mechanism to facilitate his review. Simply severing the statutory prohibition on review of APJs' decisions "does not result in an incomplete or unworkable statutory scheme," since "[w]hat matters is that the Director have the

[6] Even if this Court concluded that the statute was unclear as to whether it preserves the Secretary's authority to review Board decisions, principles of constitutional avoidance counsel in favor of construing the statute to allow for such review.

discretion to review decisions rendered by APJs." *Arthrex*, slip op. at 21, 23; *see also id.* at 15 ("For the most part, Congress left the structure of administrative adjudication up to agency heads, who prescribed internal procedures (and thus exercised direction and control) as they saw fit."); *id.* (confirming "authority to review" "decisions of [] subordinates despite congressional silence on the matter"). This principle was well established even before *Arthrex*; since "[a]s a general proposition of administrative law, the head of an administrative agency has the power to review and revise the acts of subordinates where … the powers in question are vested in the subordinate under the supervision and direction of the superior." *Morrow v. Clayton*, 326 F.2d 36, 45-46 (10th Cir. 1963). *Accord Chevron Oil Co. v. Andrus*, 588 F.2d 1383, 1387-88 (5th Cir. 1979) (confirming officer who delegates authority does not divest himself of the power to exercise that authority to review and overrule subordinate absent express restriction in delegation). Because Congress has placed no restrictions on the Secretary's authority to review and revise ADR panel decisions, ADR Board members serve as properly appointed inferior officers. PhRMA's argument (made without statutory support) that "ADR Board rulings may not be reversed, modified, or otherwise reviewed within the Executive Branch," PhRMA Mot. 24, fails as a matter of law because neither the statute nor the Rule purport to prohibit the Secretary from exercising discretion to overturn a panel decision with which he disagrees.[7]

Attempting to escape these principles, PhRMA points to a provision in the Rule establishing the finality of agency decisions and argues that this regulatory provision binds the Secretary's hand. *See* PhRMA Mot. 24. Not so. The finality provision, which largely mirrors the statutory language in 42 U.S.C. § 256b(d)(3)(C), confirms only that the ADR process will result in final agency actions reviewable in district court under the APA (as is common practice for agency adjudications) and its

[7] Even were there ambiguity on whether the statute itself constrains the Secretary's review of ADR decisions, PhRMA would not be entitled to relief on the theory that *the statute*, as opposed to the Rule, violates the Constitution. That is because PhRMA has not pleaded any claim that the scheme devised by Congress violates Article II and has not asked this Court for any relief as to the statute. ECF No. 1, Compl., Prayer for Relief (seeking declaration that the ADR Rule violates the APA and the Constitution). And *even if* PhRMA repleaded to mount a facial challenge to the 340B statute *and* prevailed, *Arthrex* teaches that the proper remedy would be merely to render unenforceable any constraint on the Secretary's review—not to strike down the entire adjudicatory process.

treatment in future agency adjudications: "The 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." 42 C.F.R. § 10.24(d). Unlike the language at issue in *Arthrex*, which expressly *prohibited* review by the Director, by specifying that "*[o]nly* the [APJs] may grant rehearings," 35 U.S.C. § 6 (emphasis added), here neither the statute nor the Rule contain any express restriction on the Secretary's ability to reverse an ADR decision as part of the "administrative resolution of a claim." Stated differently, the cited provision provides for review by a court after conclusion of the administrative process—but does not, as PhRMA posits, constrain the Secretary's ability to control that process by reviewing decisions. *Arthrex*, slip op. at 15 (confirming "authority to review" "decisions of [] subordinates despite congressional silence on the matter").[8]

But there is more that distinguishes the ADR Rule from *Arthrex*: Not only may the Secretary review ADR decisions, he also may freely remove ADR Board members at will. In arguing otherwise, PhRMA does not point to any constraint on the Secretary's ability to remove Board members at any time, for any reason (or no reason). *See* PhRMA Mot. 27-28. Instead, PhRMA criticizes *the Rule* (not the statute) for failing to spell out provisions whereby the Secretary may revoke Board members' appointments. This complaint is groundless; HHS need not "infer[] a power for the Secretary to remove members," as PhRMA charges (Mot. 27), in light of "[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 (1983); *see also Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 509 (2010) ("removal is incident to the power of appointment"). Here neither the Rule nor the statute contain any restraint on the Secretary's ability to remove ADR Board members, thus demonstrating that this "powerful tool for control," *Edmond v. United States*, 520 U.S. 651, 664 (1997), remains fully with the Secretary.

[8] PhRMA also criticizes the agency for having "explicitly rejected comments calling for … 'an appeals process'". PhRMA Mot. 24. But as in *Arthrex*, no regulation is needed to allow for discretionary review by a principal officer, so long as no statutory constraint exists. Slip op. at 21, 23.

PhRMA next points to a provision allowing for reassignment of panel members "for cause," including where a conflict of interest is shown. PhRMA Mot. 27 (citing 42 C.F.R. § 10.20(a)(1)(ii)). But PhRMA neglects to mention that this provision contains a partial delegation of authority to the HRSA Administrator—allowing her to share in supervision of the ADR process by reassigning panel members in certain circumstances—not a constraint on *the Secretary's* ability to revoke appointments. Contrary to PhRMA's portrayal, § 10.20(a)(1)(ii) is a sensible delegation of partial authority without constitutional significance, since the Appointments Clause concerns the *appointment* of federal officers—not the interim *panel assignments* on which those officers are tasked to work. In other words, under the ADR Rule, a federal employee becomes an officer when s/he receives an *appointment* by the Secretary to the ADR Board, not when s/he is selected from that Board by the HRSA Administrator to hear any particular petition, and it is removal from one's office—not reassignment from the task at hand—that has constitutional significance. *See Arthrex*, slip op. at 12 (explaining Director's ability to "reassign[] an APJ to a different task going forward" is not relevant constitutional consideration since statute limited "removal from federal service entirely" for cause).[9]

Because there are no "statutory restrictions on the [Secretary] that insulate the decisions of [ADR Board members] from his direction and supervision," *Arthrex*, slip op. at 23, Board members receive a proper appointment under the ADR Rule. Board members also may be removed from their appointment at will by the Secretary at any time, further demonstrating their status as inferior officers. PhRMA's Article II challenge fails.

CONCLUSION

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

[9] PhRMA suggests in passing that perhaps Board members are protected from removal by the general competitive-service statute that governs many civil servants, 5 U.S.C. § 7513. *See* PhRMA Mot. 27-28. But PhRMA neglects to mention that Congress had explicitly incorporated that statute to apply to the APJs in *Arthrex*. *See* slip op. at 22 (explaining that "5 U.S.C. § 7513(a) … applies through 35 U.S.C. § 3(c)"). And regardless of civil-service protections, it is plain that Congress has not included in the 340B statute any restriction on the Secretary's authority to revoke appointments *to the ADR Board*.

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