UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.
Plaintiff,

v.

ROBERT F. KENNEDY, JR., Secretary of Department of Health and Human Services et al.,

Defendants.

Civil Action No. 26-1190 (RDM)

DEFENDANTS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS

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Defendants, Robert F. Kennedy, Jr., in his official capacity as Secretary of the Department of Health and Human Services, Thomas J. Engels, in his official capacity as Administrator of the Health Resources and Services Administration, the Department of Health and Human Services ("HHS"), and the Health Resources and Services Administration ("HRSA"), (collectively "Defendants" or "Agency"), respectfully submit this reply in further support of their motion to dismiss (ECF No. 13, "Defs. Mot.").

INTRODUCTION

Plaintiff AbbVie Inc.'s opposition (ECF No. 37, "Pl.'s Opp'n"), fails to raise any arguments that would warrant denying the Defendants' motion to dismiss. The Defendants' September 18, 2025 letter permitting AbbVie's anticipated audit does not constitute final agency action. Plaintiff's opposition veers towards challenging the Defendants' 1996 guidance that explained how the Defendant interpreted the term patient more than it seeks to challenge the Defendants' letter permitting Plaintiff's audit. At bottom, AbbVie is not challenging any final agency action, and this Court should reject AbbVie's attempt to circumvent the mandatory administrative channel established by Congress in 42 U.S.C. § 256b.

That channel has two elements. *First*, the manufacturer audits the covered entity under Section 256b(a)(5)(C). *Second*, the manufacturer pursues any diversion claim through the administrative dispute resolution ("ADR") process under Section 256b(d)(3). It is the resulting ADR determination that "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." 42 U.S.C. § 256b(d)(3)(C) (emphasis added). That designation—reserved by Congress for the end of the administrative process—confirms that the September 2025 letter is not final agency action.

AbbVie attempts to sidestep this mandatory channel. But it has conducted no audit, filed no ADR claim, and obtained no ADR decision. Rather than challenging a final agency action,

AbbVie asks this Court to supply, in the first instance and on no factual record, the very determination Congress assigned to the agency in Section 256b. AbbVie's attempt to circumvent the exclusive administrative channel established by Congress should therefore be rejected, and AbbVie's complaint should be dismissed on that basis.

In the alternative, the determination AbbVie seeks is committed to the agency's discretion. And that provides an additional, dispositive reason to dismiss AbbVie's complaint.

ARGUMENT

I. AbbVie Seeks Premature Adjudication on Unripe Claims.

AbbVie has not identified a final agency action ripe for review. The ripeness doctrine requires a reviewing court to evaluate "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). AbbVie relies on *Friends of Animals v. United States Bureau of Land Management*, 728 F. Supp 3d 45, 68 (D.D.C. 2024), to argue that the issues presented in this case are "purely legal questions" equivalent to "a question of statutory interpretation" but AbbVie's argument fails. *See* Pl.'s Opp'n (ECF No. 37) at 42 (quoting *id*.). To the contrary, this case does not present a purely legal question of statutory interpretation. AbbVie invokes an interlocutory statement from the government in an effort to convince this Court to adopt a definition of "patient" that neither Congress nor any court has recognized. But this attempt to reshape the audit process to secure its preferred outcome does not convert the Defendant's September 2025 letter into a case presenting solely legal issues or statutory interpretation. To be sure, AbbVie does not challenge the 1996 patient Guidelines directly on constitutional grounds. Rather, AbbVie only challenges the Defendants' 2025 letter permitting the audit. There is no purely legal question ripe for decision.

AbbVie also ignores the second part of the ripeness analysis in *Friends of Animals*, where the court "consider[ed] "whether the agency or the court will benefit from deferring review until

the agency's policies have crystallized and the question arises in some more concrete and final form." *Friends of Animals*, 728 F. Supp. 3d. at 68. (cleaned up). This is important because *Friends of Animals* involved "final agency action that took effect" and plaintiffs were challenging whether the agency had statutory authority to take the final agency action. *See id*. Here, AbbVie is not challenging the Defendants' statutory authority to issue the 1996 guidance or any statutory authority at all. Simply put, there is no policy that has "crystallized." AbbVie is challenging the Defendants' interlocutory statement, allowing the audit to proceed. This audit involves an administrative process which may produce a final agency action reviewable by a court with the benefit of a fully developed administrative record. Premature judicial interference at this stage would unduly interfere with a future administrative process. *See* Defs. Mot. (ECF No. 13) at 14.

AbbVie's own conduct confirms that there is no immediate hardship warranting early judicial intervention. None of the options AbbVie identifies constitutes hardship—the audit is not futile, proceeding under the 1996 Guidelines is not a legal injury, and abandoning the audit is AbbVie's own choice. *See* Defs. Mot. (ECF No. 13) at 14-15. AbbVie's litigation conduct underscores the point: AbbVie waited seven months after receiving the September 2025 letter before filing this lawsuit. During that time, AbbVie could have moved forward with its audits, yet it chose not to do so. A party that faces no immediate compulsion to act, and that does not act for seven months, cannot credibly claim that withholding judicial review imposes cognizable hardship. *Friedman v. FAA*, 841 F.3d 537 (D.C. Cir. 2016), on which AbbVie relies by analogy, is inapposite. There the agency set deadlines, allowed them to lapse without acting, and left the petitioner with no administrative path forward short of capitulating to the requirement he sought to challenge. *Id.* at 542-43. Here, the Department has affirmatively authorized AbbVie's audit, and AbbVie has an administrative path forward that does not require abandoning its position.

Indeed, that AbbVie must pursue its claims through the administrative process is not hardship at all. AbbVie has previously acknowledged the exclusiveness of the administrative process for resolving diversion-related disputes. On August 7, 2026, in another federal court filing addressing an unrelated issue, AbbVie stated: "[t]he federal 340B statute forbids the 'transfer' of 340B-discounted drugs to anyone but a covered entity's patients. . . . If a manufacturer suspects that such diversion is occurring . . . the only way to enforce such violations is through the federal ADR process (not State or other federal law, or even through private suit)." Compl. (ECF No. 1) ¶ 135, *AbbVie Inc. v. Raoul*, No. Civ. A. No. 26--9523 (N.D. Ill. Aug. 7, 2026). Indeed, in separate filings across the country, AbbVie has referred to the "exclusive" ADR process that Congress explicitly required before courts have jurisdiction to review diversion-related disputes. *See, e.g.*, Br. of Appellants, *AbbVie Inc. v. Neronha*, Appeal No. 25-1940 (1st Cir. Dec. 8, 2025); Br. of Appellants, *AbbVie Inc. v. Brown*, Appeal No. 24-1939 (4th Cir. Dec. 18, 2024); Br. of Appellants, *AbbVie Inc. v. Skrmetti*, Appeal No. 26-5279 (5th Cir. June 10, 2026); Opening Br. of Appellants, *AbbVie Inc. v. Brown*, Appeal No. 26-3709 (9th Cir. July 7, 2026); Opening Br. of Appellants, *AbbVie Inc. v. Weiser*, Appeal No. 25-1439 (10th Cir. Feb. 19, 2026).

On August 7, 2026, moreover, a federal court confirmed the premise AbbVie now resists, holding that Section 256b "require[s] that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings" under § 256b(d)(3)(B)(iv). *AbbVie Inc. v. Jackley*, Civ. A. No. 25-3006, 2026 WL 2280929, at *1 (D.S.D. Aug. 7, 2026). AbbVie cannot transform the Letters into final agency action by sidestepping the required ADR process.

For these reasons, Defendants respectfully request that the complaint be dismissed because AbbVie's claims are not ripe for review.

II. There Is No Final Action for the Court to Review.

Allowing AbbVie's proposed audit work plan to proceed was not final agency action. The Defendants' September 2025 Letter did not mark the "consummation' of the agency's decision-making process" and is not one by which "rights or obligations have been determined," or from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1977). AbbVie's arguments to the contrary fall flat.

Viewing the facts in the light most favorable to the plaintiff, as the Court must, shows the September 2025letter was interlocutory at best. Before Defendants will approve an audit plan, "the manufacturer must provide reasonable cause that the entity is engaging in . . . diversion." Compl. (ECF No. 1) ¶ 11 (quoting 61 Fed. Reg. 65,406–12 (Dec. 12, 1996)); *see also* 42 U.S.C. § 256b(a)(5)(B) (permitting drug manufacturers to audit covered entities when the manufacturer has reasonable cause to believe the covered entity is violating this statutory provision). The Defendants' statement in its August 2025, letter infers AbbVie provided "reasonable cause" for its diversion claims and allowed the audit to proceed by stating "[i]n the event AbbVie chooses to proceed with the audit and pursuant to the manufacturer audit guidelines . . . [.]" *See* (ECF No. 1-9) at 2. Further, the September 2025 letter expressly stated the "[Office of Pharmacy Affairs] is not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan [AbbVie] submitted." *See* (ECF No. 1-5) at 2. The audit can proceed.

AbbVie dedicates much of its discussion to parsing and distinguishing caselaw in an attempt to characterize Defendants' September 2025 Letter as final. *See* Pl.'s Opp'n (ECF No. 37) at 29-39. But "when assessing the nature of an agency action (including whether it is final), courts

should resist the temptation to define action by comparing superficially similar actions in the caselaw. Rather, courts should take as their NorthStar the unique constellation of statutes and regulations that govern the action at issue." *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 631 (D.C. Cir. 2019). Here the relevant statute deems the September 2025L letter non-final because any final agency action must occur "*after* audit" and "*after* notice and hearing[.]" 42 U.S.C. § 256b(a)(5)(D), (C). (emphasis added). Only the resulting determination "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 "constellation of the statute and regulations" make it clear that the Defendants' 2025 letter allowing the audit to proceed is not the consummation of the agency's decision making but only one step in the multi-step process of determining whether Mt. Sinai or Barrio committed diversion. 934 F.3d at 631.

AbbVie's opposition invokes *Darby v. Cisneros*, 509 U.S. 137 (1993), for the proposition that no further administrative step may be required of it. Pl.'s Opp'n (ECF No. 37) at 24-25. But that reliance misconceives what *Darby* decided and disregards the channel Congress mandated for this category of dispute. *Darby* holds that where an agency action is already "final for the purposes of" 5 U.S.C. § 704, a court may not impose a judge-made exhaustion requirement as a condition of review unless a statute or rule requires an administrative appeal. 509 U.S. at 144–47. In other words, *Darby* presupposes final agency action. It says nothing about whether Congress has assigned a category of dispute to an administrative forum in the first instance, and it cannot itself manufacture the finality it presupposes. Moreover, *Darby* itself refutes the conflation AbbVie asks the Court to make: As the Court put it there, "the judicial doctrine of exhaustion of administrative remedies is conceptually distinct from the doctrine of finality." *Id.* at 144 (quoting *Williamson County Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 193 (1985)).

Read whole, Section 704 confirms the point. Its first sentence extends APA review only to final agency action "for which there is no other adequate remedy in a court," a limitation *Darby* explained was meant "to avoid duplicating previously established special statutory procedures for review of agency actions." 509 U.S. at 146 (discussing *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988)). Congress established such a procedure here, from the audit prerequisite, § 256b(d)(3)(B)(iv); 42 C.F.R. § 10.21(a)(2), through a binding final agency decision reviewable in court, § 256b(d)(3)(C). That provision, which designates ADR decisions as "final agency decision[s]" reviewable by courts, identifies exactly what final agency action looks like in this statutory scheme. The September 2025 letter at issue here looks nothing like it. AbbVie cannot make that mandatory administrative process optional by pointing to the September 2025 letter.

AbbVie's attempt to distinguish *Oregon Health & Science University v. Engels*, Civ. A. Nos. 24-2184, 24-2563, 24-2187, 24-2268 (RC), 2025 WL 1707630 (D.D.C. June 17, 2025), is similarly unavailing. The *Oregon* court's reasoning for its conclusion applies with equal force here: the compliance question has not been definitively resolved by anyone, let alone HRSA; the administrative process remains available and would produce the final agency decision that Section 256b(d)(3)(c) contemplates and that is currently absent; and the legal consequences AbbVie identifies are contingent on future agency determinations that have not yet been made and may never be made. Whether AbbVie ultimately prevails in that process, including on appeal to a federal court following an ADR final decision, is precisely the kind of merits question that belongs to that process with a developed record, not to this Court on no record at all. AbbVie faces no new legal obligations as a result of the Agency's audit approval. No amount of artful pleading changes that.

To the extent AbbVie relies on the August 2025 letter as an alternative source of finality, that letter fares no better under the *Bennett* analysis. The August 2025 letter expressly invited AbbVie to revise its workplans, requested removal of certain document requests, and stated that HRSA would review any revised plan and advise on next steps. An agency communication that invites further revision and promises continued engagement is, by definition, not the consummation of the agency's decision-making process. The August 2025 letter is more clearly interlocutory than the September 2025 letter, and provides no stronger basis for a finding of finality.

At bottom, AbbVie cannot point to any final agency action within the meaning of the APA.

III. There is No Injury for the Court to Redress.

Abbie fails to point to an injury redressable by this Court. AbbVie alleges it has standing by designating itself the "object of the action." *See* Pl.'s Opp'n (ECF No. 37) at 39, 41 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992)). Defendants have demonstrated that there is no final action, but to the extent that there is any action at all, the covered entity would be the object of such action and not Plaintiff. The purpose of AbbVie's audit and the subsequent ADR process is to determine if the covered entities Mt. Sinai or Barrio engaged in diversion. *See id*. § 256b (a)(5), d(2)(A), d(3)(A). AbbVie is not the object of the action, but instead its "asserted injury arises from the government's alleged[ ] . . . lack of regulation of *someone else*" if the government does not use AbbVie's definition in any subsequent action after the audit. *Lujan*, 504 U.S. at 562.

AbbVie fails to identify any injury that is anything more than speculative. It puts the cart before the horse by asking the Court to permit audits of Mt. Sinai and Barrio "using the correct statutory understanding of patient," relying on a definition it created itself and that no authority has adopted. *See* Pl.'s Opp'n (ECF No. 37) at 40 (citing Compl. ¶ 70). As Defendants explained

in their moving papers, any alleged injury is speculative because an audit may reveal no diversion at all—or, if diversion is found, it may be resolved in AbbVie's favor, resulting in no injury. *See* Defs.' Mot. (ECF No. 13) at 14, 20. And if the audit or ADR process ultimately yields a decision AbbVie seeks to challenge, it may pursue judicial review at that time, with the benefit of a fully developed record. But that has not yet occurred.

IV. Any Future Enforcement Decision is Committed to Agency Discretion by Law.

Even if AbbVie's claims survived the threshold grounds set forth above, the enforcement determination it ultimately seeks is committed to agency discretion by law and is therefore unreviewable under the APA. Indeed, to the extent AbbVie challenges HRSA's statement that it would not "enforce corrective actions" premised on a patient definition exceeding the operative standard, (Pl.'s Opp'n ECF No. 37 at 28), AbbVie is challenging a non-enforcement decision that is at least presumptively unreviewable because Congress has not provided meaningful standards for doing so. 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). And AbbVie offers no persuasive reason to apply the exception permitting review of an "abdication of statutory responsibilities." *Heckler*, 470 U.S. at 833 n.4. An agency's decision whether to pursue enforcement is presumptively unreviewable unless Congress has circumscribed that discretion through meaningful standards. *Id*. at 830–35. Section 256b does not do so. Accordingly, AbbVie's request for a specific enforcement action is committed to agency discretion by law. 5 U.S.C. § 701(a)(2).

AbbVie's reliance on *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808 (D.C. Cir. 1998), for the position that HRSA's letters constitute a reviewable general enforcement polivy fares no better. OSG Bulk Ships holds only that "an agency's adoption of a general enforcement policy is subject to review," as opposed to a "single-shot nonenforcement decision." 132 F.3d at 812. But here, Defendants adopted no new policy in notifying AbbVie the audit may proceed; it identified

the standard already on the books. And the D.C. Circuit's decision in *Hi-Tech Furnace Systems, Inc. v. FCC*, 224 F.3d 781, 788 (D.C. Cir. 2000), addresses the general "no law to apply" inquiry, not a separate presumption governing nonenforcement. Defendants simply stated the 1996 Guidelines are the operative standard, HRSA will apply them, and AbbVie may audit and pursue the statutory process. An agency's statement that it will enforce the current standard on the books rather than a standard a regulated party wrote for itself is the exercise of enforcement discretion, not its abandonment.

AbbVie's remaining authority is equally inapposite. *Weyerhaeuser Co. v. U.S. Fish & Wildlife Service*, 586 U.S. 9 (2018), involved "the sort of routine dispute that federal courts regularly review: An agency issues an order affecting the rights of a private party, and the private party objects that the agency did not properly justify its determination under a standard set forth in the statute." Pl.'s Opp'n (ECF No. 37) at 48-49 (quoting *Weyerhaeuser* 586 U.S. at 23–24). Here, by contrast, Defendants issued no order, and § 256b prescribes no standard governing when they must pursue corrective action. Section 256b(a)(5)(D) states that liability attaches only "[i]f the Secretary finds, after audit [...] that a covered entity is in violation" of the diversion or duplicate discounting prohibitions. 42 U.S.C. § 256b(a)(5)(D). The word "shall" in that provision governs the legal consequence that follows once a violation has been found by the Agency. It says nothing about how the Agency is to determine whether a violation exists in the first place, including what definition of "patient" applies, whether the evidence gathered during an audit is sufficient, or whether an audit should proceed on a given theory. Those antecedent determinations are precisely what AbbVie asks this Court to resolve in its favor, and precisely what remains committed to agency discretion. But nothing in Section 256b indicates that Congress meant to displace the Agency's judgment over how to define an undefined statutory term merely because a different,

later provision uses mandatory language to describe the consequence of a finding that has not yet been made.

CONCLUSION

For these reasons, and those stated in the Defendants' underlying motion to dismiss, the Court should dismiss Plaintiff's complaint in its entirety.

Dated: August 31, 2026

Respectfully submitted,

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