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' MOTION TO DISMISS AND**
**MEMORANDUM IN SUPPORT THEREOF**

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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 Servies ("HHS"), and the Health Resources and Services Administration ("HRSA"), (collectively "Defendants" or the "Department" or the "Agency"), respectfully move to dismiss the complaint filed in this action by Plaintiff AbbVie Inc. ("AbbVie") under Federal Rules of Civil Procedure ("Rules") 12(b)(1) and 12(b)(6) for a lack of subject-matter jurisdiction and a failure to state a claim, respectively,

**INTRODUCTION**

This case presents an attempt by a highly profitable pharmaceutical company to upend the long-settled operation of the statutory 340B Program that provides discounted medication to healthcare providers and their patients. By alleging violations of the Administrative Procedure Act ("APA"), AbbVie seeks an impermissible advisory opinion from this Court regarding the definition of the term "patient," by inviting the Court to adjudicate what amounts to an interlocutory statement by the Department at best. Specifically, AbbVie petitions the Court to set aside a letter from the Department that informed AbbVie that it may proceed to audit two 340B healthcare providers, and to the extent that any corrective action may be warranted, the Department could only act in a manner consistent with the statute. *See* Compl. (ECF No. 1) at 70.

AbbVie's claims should be dismissed for four independent reasons.[1] First, the Court lacks jurisdiction to hear Plaintiff's APA claims because those claims are not ripe for review. Second,

[1] Defendants seek to dismiss the complaint on threshold jurisdictional grounds based on the allegations in the complaint and not the administrative record. Accordingly, Defendants request that the Court waive their compliance with Local Civil Rule 7(n). *See Thein Win Htet v. Trump*, Civ. A. No. 24-1446 (RC), 2025 WL 522033, at *9 (D.D.C. Feb. 18, 2025) (quoting *Janay v. Blinken*, 743 F. Supp. 3d 96, 105 (D.D.C. 2024)) ("'[T]he administrative record is unnecessary to decide the threshold legal questions presented by the pending motion to dismiss.'"). Courts in this

even if the claims were ripe, AbbVie's APA claims fail because the Department's letter permitting AbbVie to move forward with its proposed audits does not constitute final agency action. Third, AbbVie lacks Article III standing because even if a favorable ruling from this Court would redress its alleged injury—the enforcement outcome AbbVie ultimately seeks remains committed to agency discretion regardless of how the definitional questions are resolved. Fourth, and independently, the enforcement determination AbbVie seeks is committed to agency discretion by law and is therefore unreviewable under the APA. Moreover, the Department's letter is consistent with the Department's thirty-year-old guidance.

## BACKGROUND

### I. Statutory Background.

In 1992, Congress created a program by which certain hospitals, community health centers and other federally-funded entities serving low-income patients – referred to as "covered entities"- could receive outpatient drug discounts. The program is commonly known as the 340B Program, because it was created by section 340B of the Public Health Service Act ("Section 340B"). Section 340B requires participating drug manufacturers to offer to covered entities covered outpatient drugs for purchase at or below a "maximum" or "ceiling price," which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). Drug manufacturers must offer their drugs for sale

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District have repeatedly exercised their discretion to waive the requirement to file an administrative-record index at this stage and defer those obligations only if a claim proceeds to record-based merits review. *See, e.g.*, *Abdullahi v. Blinken*, Civ. A. No. 23-3900 (RC), 2024 U.S. Dist. LEXIS 213561, at *26 (D.D.C. Nov. 25, 2024) (denying motion to compel certified administrative record under Rule 7(n) because "the administrative record is not necessary to decide Defendant's motion to dismiss"); *People for the Ethical Treatment of Animals, Inc. ("PETA") v. Fish & Wildlife Serv.*, 59 F. Supp. 3d 91, 94 n.2 (D.D.C. 2014) (granting relief from the requirements of Local Civil Rule 7(n) where agency moved to dismiss and the certified record list was immaterial).

through the 340B Program in order to have their drugs covered through the separate Medicaid and Medicare Part B programs. 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a).

Section 340B places several restrictions on 340B covered entities. For instance, Section 340B prohibits a covered entity from requesting payment under Medicaid for a drug that was subject to a 340B discount. 42 U.S.C. § 256b(a)(5)(A). This is known as the prohibition on duplicate discounts and is not relevant to the present case. In addition, covered entities are prohibited from reselling or otherwise transferring a 340B drug to an individual who is not a patient of the covered entity. 42 U.S.C. § 256b(a)(5)(B). This is known as the prohibition on diversion.

In August 1995, HRSA issued a Federal Register notice that described its proposed approach to the statutory requirement that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 60 Fed. Reg. 39,762 (Aug. 3, 1995). The guidance was finalized in 1996. 61 Fed. Reg. 55,156 (Oct. 24, 1996). The guidance sought to "explain how the Department intends to administer the 340B program" by "clarifying the meaning given by the Department to particular words of phrases." *Id.* at 55,156. The guidance merely "explain[ed] the statutory language"—it was not meant to "create … new law [or] new rights or duties" and in HRSA's view it did not "exceed the purpose of 340B or conflict with any of its provisions." *Id.* Because the prohibition on diversion turns on who, exactly, is a "patient of the entity," this guidance became known as the "patient definition" or "patient-eligibility guidelines."

More specifically, the 1996 guidance states that an individual is a 340B patient for purposes of the 340B statute if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

> 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding . . . has been provided to the entity.

*See id*. The 1996 guidance remains in effect to this day.

The Agency's Office of Pharmacy Affairs administers the 340B Program under authority delegated by the Secretary of the Department of Health and Human Services ("HHS"). The Agency is authorized under the statute to audit covered entities. 42 U.S.C. § 256b(a)(5)(C). So, too, are participating drug manufacturers. *Id.* Covered entities must comply with the statute's audit requirements to remain eligible to participate in the program. *Id.* § 256b(a)(4), (a)(5). "A covered entity shall permit" a manufacturer to audit "the records of the entity that directly pertain to the entity's compliance with" the prohibitions on diversion and duplicate discounts "with respect to drugs of the manufacturer," so long as the manufacturer "act[s] in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." *Id.* The audit is "at the manufacturer's expense." *Id.* § 256b(a)(5)(C).

In 1996, following public notice and comment, the Agency published a final notice in the Federal Register entitled "Manufacturer Audit Guidelines and Dispute Resolution Process." 61 Fed. Reg. 65,406 (Dec. 12, 1996). This document implements the statutory instruction to "establish[]" "procedures" for 340B manufacturer audits. Under the guidance, "audits must pertain directly to the entity's compliance with the prohibitions against drug diversion and the generation of duplicate drug rebates and discounts with respect to drugs of the manufacturer"; thus, "[s]ignificant changes in quantities of specific drugs ordered by a covered entity . . . may be a basis for establishing reasonable cause [for an audit]." *Id.* at 65,406.

The manufacturer must first "notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B. The manufacturer and the covered entity

shall have at least thirty days from the date of notification to attempt in good faith to resolve the matter." *Id.* at 65,410. Next, "[i]f the matter is not resolved and the manufacturer desires to perform an audit, the manufacturer must file an audit work plan with" the Agency. *Id.* The work plan must include a description of the "audit objectives," the "skill and knowledge" of audit personnel, the tests to be used to "assess the covered entity's system of internal controls," and protections for patient confidentiality and proprietary information. *Id.* Furthermore, the covered entity must be given a minimum of fifteen days to prepare for the audit. *Id.* The 1996 notice includes "suggested audit steps" that manufacturers can use for preparing their work plan, and the manufacturer-submitted documentation must also explain that there is "reasonable cause . . . to believe that a covered entity may have violated" the statutory prohibition on diversion or duplicate discounts. *Id.* at 65,409–10.

The Agency reviews the manufacturer's work plan for "reasonable purpose and scope"; furthermore, "only one audit of a covered entity will be permitted at any one time" and "[n]ormally, audits shall be limited to an audit period of one year and shall be performed in the minimum time necessary with the minimum intrusion on the covered entity's operations." *Id.* If the Agency has concerns about the work plan, it works with the manufacturer "to incorporate mutually agreed-upon revisions to the plan." *Id.* at 65,410. If, after review of the work plan, the Agency determines that reasonable cause for the audit exists, "the Department will not intervene" in the manufacturer's audit of the covered entity. *Id.* After the audit is complete, the auditors must prepare an audit report, which is provided to the Agency and the covered entity. *Id.* The covered entity has thirty days to provide its response to the report's findings and recommendations, including any planned actions to address the findings. *Id.* After an audit and review of the findings (if any), the Agency may take enforcement action against the covered entity, which can include ordering the covered

entity to reimburse the manufacturer for the amount of price reduction that the covered entity received in connection with the diversion or duplicate discount, 42 U.S.C. § 256b(a)(5)(D), (d)(2)(B)(v)(I), or, in cases where a violation was "systematic and egregious, as well as knowing and intentional," the covered entity's removal from the 340B Program, *id.* 256b (d)(2)(B)(v)(II). Any enforcement action would depend on the audit's findings, the covered entity's response, as well as the Agency's final, independent determination that enforcement is warranted—determinations that remain within the Agency's discretion at every stage of the process. The statute provides no mandatory enforcement standard compelling the Agency to act on any particular audit finding or to pursue corrective action in any particular case.

## II. Allegations in the Complaint.

For purposes of this motion only, the Defendants assume the truth of the allegations in the complaint. Defendants reserve the right to contest the allegations in any future proceedings.

AbbVie is a biopharmaceutical company and purports to be "a longtime participant in the 340B program." Compl. ¶ 3, 25. Barrio is a healthcare provider and 340B participant. *See id*. ¶ 118. Mount Sinai Health System ("Mt. Sinai") is comprised of healthcare providers and 340B participants. *See id*. ¶ 152. After a back-and-forth exchange with Barrio regarding Barrio's 340B purchases, on or about June 27, 2025, AbbVie submitted an audit work plan to the Department seeking to audit Barrio. *See* Compl. ¶ 139. After a back-and-forth exchange with Mt. Sinai, on or about, July 2, 2025, AbbVie submitted an audit work plan to the Department seeking to audit Mt. Sinai. *See id*. ¶ 163.

Although audit work plans are not required to define "patient," AbbVie chose to include its own interpretation of the term as used in the 340B statute in its audit work plan submitted to HRSA. *See id*. ¶¶ 140, 163-165; *see also* Manufacturer Audit Guidelines and Dispute Resolution Process." 61 Fed. Reg. 65,406 (Dec. 12, 1996). On or about August 15, 2025, the Department

advised AbbVie that AbbVie's definition and criteria for determining when an individual is a patient for 340B purposes, outlined in AbbVie's audit work plans, went beyond the Department's guidance, which was adopted consistent with the statute, for determining when an individual is a patient under 340B. *See* ECF No. 1-3. The Department further elaborated that "[i]f AbbVie proceed[ed] to conduct the audit using a different standard, OPA will not be able to enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id*. This letter referred AbbVie to the Department's 1996 guidance. *See id*.

On or about September 4, 2025, AbbVie advised the Department that it intended to proceed with the audit using AbbVie's definition of patient. *See* ECF No 1-4. On or about September 18, 2025, the Department responded to AbbVie's September 4, 2025 letter. *See* ECF No. 1-5. The Department again advised AbbVie that AbbVie's criteria for the term patient went beyond the Department's 1996 Guidelines, adopted in accordance with the statute. *See id*. The Department expressly stated the "[Office of Pharmacy Affairs] is not denying AbbVie the opportunity to audit Mt. Sinai or Barrio." *Id*. The Department further informed AbbVie if "findings result from AbbVie's application of a patient definition that is inconsistent with the longstanding 1996 Guidelines and the 340B statute, [the Office of Pharmacy Affairs] will not be able to impose corrective actions." *Id*. At no point did the Department prohibit AbbVie from proceeding with its audits.

More than six months later, AbbVie initiated this lawsuit. AbbVie argues the Department refused to enforce yet to be determined findings related to AbbVie's proposed audits in violation of the section 706(2)(A) of the APA. Compl. ¶¶ 197, 204. AbbVie seeks an order from this Court (1) determining the Department's 1996 guidance on defining patient under 340B as outlined in the

Department's letter dated September 18, 2025 is unlawful; (2) setting aside the September 18, 2025 letter; (3) enjoining the Department from implementing or enforcing its 1996 guidance; (4) declaring AbbVie's interpretation of the term "patient of the entity" is the "best meaning"; and (5) authorizing AbbVie to audit Barrio and Mt. Sinai using AbbVie's "statutory understanding" of patient. *See id.* at 70.

## LEGAL STANDARDS

### I. Rule 12(b)(1).

Under Rule 12(b)(1), a plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). A court considering a Rule 12(b)(1) motion must "assume the truth of all material factual allegations in the complaint and 'construe the complaint liberally, granting plaintiff the benefit of all inferences that can be derived from the facts alleged.'" *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting *Thomas v. Principi*, 394 F.3d 970, 972 (D.C. Cir. 2005)). A court may examine materials outside the pleadings as it deems appropriate to resolve the question of its jurisdiction. *See Herbert v. Nat'l Acad. of Scis*., 974 F.2d 192, 197 (D.C. Cir. 1992).

### II. Rule 12(b0(6).

Under Rule 12(b)(6), the Court may dismiss a Complaint where a plaintiff fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When resolving a motion to dismiss pursuant to Rule 12(b)(6), the pleadings are construed broadly so that all facts pleaded therein are accepted as true, and all inferences are viewed in a light most favorable to the plaintiff. *See Iqbal*, 556 U.S. at 678. However, a court is not required to accept as true conclusory allegations or unwarranted

factual deductions. *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. Likewise, a court need not "accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Ultimately, the focus is on the language in the complaint and whether the complaint sets forth sufficient factual allegations to support a plaintiff's claims for relief.

## ARGUMENT

### I. AbbVie's Challenges to the Preliminary Audit Letters Are Not Ripe and Therefore the Court Lacks Subject Matte Jurisdiction.

This Court lacks subject matter jurisdiction over AbbVie's claims, which are not yet ripe for review. The ripeness doctrine requires that a litigant's claims be "constitutionally and prudentially ripe," so as to protect: (1) "the agency's interest in crystallizing its policy before that policy is subjected to judicial review," (2) "the court's interests in avoiding unnecessary adjudication and in deciding issues in a concrete setting," and (3) "the petitioner's interest in prompt consideration of allegedly unlawful agency action." *Asante v. Azar*, 436 F. Supp. 3d 215, 224 (D.D.C. 2020) (quoting *Nevada v. Dep't of Energy*, 457 F.3d 78, 83–84 (D.C. Cir. 2006)). "Ripeness is a justiciability doctrine designed to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807–08 (2003) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967)). Here, AbbVie fails to demonstrate that its claims are prudentially ripe.

To satisfy the prudential elements of ripeness, courts consider "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l*

*Park Hosp. Ass'n*, 538 U.S. at 808. In actions against government agencies, the inquiry focuses on: "(1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented." *Nevada*, 457 F.3d at 84 (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998)).

The ripeness inquiry is forward-looking: it asks whether the dispute is ready for judicial resolution given what has yet to occur. Here it is not. AbbVie's feared harm, that the Department will decline to enforce audit findings based on its patient definition, depends on a chain of contingencies that may never materialize. The audit may find no violations. If violations are found, the Department may determine they are actionable under the 1996 Guidelines regardless of which patient definition is applied. If AbbVie initiates an alternative dispute resolution proceeding, that process may resolve in AbbVie's favor. At each step, the legal question AbbVie presses this Court to decide may become unnecessary. Judicial intervention now, before any of these contingencies have resolved, is precisely the kind of premature adjudication the ripeness doctrine is designed to prevent. *See Oregonians for Floodplain Prot. v. Dep't of Com.*, 334 F. Supp. 3d 66, 73-74 (D.D.C. 2018) (dismissing on ripeness grounds in part to not interfere with the administrative process); *Food & Water Watch v. EPA*, 5 F. Supp. 3d 62, 80-81 (D.D.C. 2013) (same).

Withholding review also causes AbbVie no cognizable hardship. AbbVie is free to proceed with its audit today, at its own expense as the statute contemplates. *See* 42 U.S.C. § 256b(a)(5)(C). AbbVie contends it faces a Hobson's choice among three options: conduct a futile audit, revise its audit work plan to conform to the 1996 Guidelines, or abandon the audit. ECF No. 1, at 65-66. None constitutes cognizable hardship. The first option is not futile because the audit may produce findings the Department could enforce under the 1996 Guidelines. The second is not a legal injury;

it is how the program has operated for thirty years. The third is AbbVie's own choice, not a consequence the Department has imposed. Any "theoretical possibility of future hardship arising from the Court's decision to withhold review until the agency's position is settled does not overcome the finding that the case is not yet 'fit' for judicial resolution." *Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 41 (D.D.C. 2012).

That this dispute may present a purely legal question about statutory interpretation does not change the analysis. This Circuit has held that courts should refrain from intervening "even if the issue presented is 'purely legal' and 'otherwise fit for review.'" *Id.* at 39. The ripeness defect is independently sufficient to require dismissal.

## II. The Department's Preliminary Audit Letters Do Not Constitute Final Agency Action.

Even if AbbVie's claims were ripe, which they are not, they would still fail because the September 18 letter is not final agency action under the APA. Unlike the ripeness inquiry, which asks whether the dispute is ready for judicial resolution, the finality inquiry asks whether the agency action being challenged has the legal character that Congress made a prerequisite to APA review. The APA's definition of "final agency action" expressly carves out "preliminary, procedural, or intermediate agency action." 5 U.S.C. § 704. Judicial review may be obtained under the APA only if the agency action is considered "final." *Atl. States Legal Found. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003). To be final, agency action must be definitive, with a direct and immediate effect on the day-to-day business of the challenging party. *Reliable Automatic Sprinkler Co., Inc. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003). An agency action is "'final for the purposes of [the APA]' only after a plaintiff has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Holistic Candlers &*

*Consumers Ass'n v. FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011), *aff'd*, 664 F.3d 940, 945 (D.C. Cir. 2012).

In *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997), the Supreme Court established a two-part test for determining whether an agency action qualifies as final to be subject to judicial review: "First, the action must mark the consummation of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Both *Bennett* prongs must be met to make agency action final. *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018). Because the Department's letter allowing the audit to proceed is only "interlocutory" in nature and did not consummate the Department's decision-making process, AbbVie's challenge fails the first prong of the *Bennett* test. And even if it did not, it nevertheless fails on the second prong because the decision to allow the audit to proceed does not itself have legal consequences for AbbVie.

As to the first prong, deciding that an audit can proceed is not final agency action because it is only a "threshold determination that further inquiry is warranted." *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241 (1980). Here, the Department has expressly permitted AbbVie to proceed with its audits of Barrio and Mt. Sinai's use of the 340B Program. *See* ECF No. 1-5. Additional steps are required before the Department can take any action regarding Barrio or Mt. Sinai's participation in the 340B Program or any other action based on the audits. *See* 61 Fed. Reg. 65,410. This includes whether any reimbursement may be due to AbbVie for unqualified 340B purchases. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(2)(B)(v)(I). Specifically, the auditor must prepare a report, AbbVie must send the report to Barrio and Mt. Sinai, and Barrio and Mt. Sinai must provide a response within thirty days. 61 Fed. Reg. 65,410. If Barrio and Mt. Sinai agree with the findings,

then they must provide a "description of the actions planned or taken to address the audit findings and recommendation." *Id.* If Barrio and Mt. Sinai disagree with AbbVie's audit findings, then they must submit their rationale for the disagreement to AbbVie. *Id.* AbbVie could then elect to use the audit findings to bring a proceeding against Barrio or Mt. Sinai under the 340B Program's administrative dispute resolution process. *See* 42 U.S.C. § 256b(d)(3). Only after the Department has decided whether to take enforcement action, would there be legal consequences for AbbVie, and the agency's decision be subject to judicial review. *See id.* § 256b(d)(3)(C). AbbVie has not yet conducted the audits. No findings exist for the Department to review, or for Barrio or Mt. Sinai to respond to. And the Department cannot take any adverse action or provide any decision adverse to AbbVie based on audits and reports that do not yet exist.

Thus, the Department's September 18, 2025 letter allowing the audits to proceed is not final agency action because it is not "the culmination of [the Department's] consideration of an issue." *Soundboard Ass'n*, 888 F.3d at 1267; *see also Automatic Sprinkler*, 324 F.3d at 734 (series of agency actions non-final, as "the agency has not yet done that which the statutory scheme requires for its conduct to constitute final agency action"—namely, reach a final decision after an administrative proceeding); *Winter v. Cal. Med. Rev., Inc.*, 900 F.2d 1322, 1325–26 (9th Cir. 1990) (since agency's conclusions could change with additional information, "appellant's claim that the investigation itself represented final agency action lacks merit . . . . This court must give the agency an opportunity to formulate a final position."). Because additional proceedings must occur before the Department can issue any final decision concerning the proposed audits, the Department's letter allowing the proposed audits to proceed is interlocutory at best and is not a reviewable final agency action. Therefore, AbbVie fails to satisfy the first *Bennett* prong.

AbbVie also fails the second *Bennett* prong because it cannot demonstrate that the Department's letter allowing the audit to proceed is a decision in which "rights or obligations have been determined." In evaluating the second prong, courts consider whether the action has "direct and appreciable legal consequences," *Army Corps. of Eng'rs v. Hawkes Co., Inc.*, 578 U.S. 590, 598 (2016), including by imposing an obligation, denying a right, or fixing some legal relationship. *Role Models Am., Inc. v. White*, 317 F.3d 327, 331–32 (D.C. Cir. 2003). Such consequences may occur when, among other things, an agency's definitive position has a direct and immediate effect on day-to-day operations of the party seeking review and if immediate compliance with the agency terms is expected. *Automatic Sprinkler Co*., 324 F.3d 726, 731 (finality is indicated by something that is "definitive" and has a "'direct and immediate . . . effect on the day-to-day business' of the party challenging the agency action" (quoting *Standard Oil*, 449 U.S. at 239)).

This analysis is entirely consistent with the court's recent decision in *Oregon Health & Science University v. Engels*, Civ. A. Nos. 24-2184, 24-2563, 24-2187, 24-2268 (RC) 2025 WL 1707630, at *1 (D.D.C. June 17, 2025). There, covered entities sued alleging violations of the APA because the Department merely approved a drug manufacturer's audit work plan, allowing a drug manufacturer's audit to proceed. *Id.* at *1. The defendants moved to dismiss, arguing that the Department's approval of the work plan did not constitute final agency action. The court agreed, finding that the plaintiffs failed to satisfy either of the *Bennett* prongs and dismissed the complaint. *Id.* at *7-8. There, the court emphasized that only "final agency action" is reviewable under the APA, and that intermediate steps, such as audit approvals, do not constitute the "consummation" of a decision-making process and do not alter the parties' statutory obligations or impose new legal duties because the Department made no findings as to whether or not the covered entities violated the prohibitions against duplicate discounts or diversions. *Id.* at *8. AbbVie's dispute is in the

same procedural posture. No audits have occurred. AbbVie's complaint challenges HRSA's interpretation and handling of its audit work plans but does not and cannot identify any final agency action that determines rights or obligations or from which legal consequences flow. Therefore, the complaint must be dismissed as it was in *Oregon Health & Science University.*

While the Department's letter advised AbbVie that its patient criteria went beyond the Department's 1996 guidance, nothing in the letter prohibits AbbVie from proceeding with its audits. *See* ECF No. 1-5. Indeed, the letter explicitly states 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 id*. While AbbVie characterizes this letter as an "effective denial" on its face, the letter demonstrates that this characterization lacks merit. *See* Compl. ¶ 1. AbbVie cannot rely on the Department's warning related to Abbvie's audit work plan or any prospective audit findings as final agency action. *See id*. ¶¶ 18, 146, 185. The Department warned that it will not be able to take corrective action against Barrio or Mt. Sinai based on any aspect of AbbVie's patient definition criteria that is inconsistent with the 1996 Guidelines or the 340B statute—not that the Department will not take any action at all. *See* ECF No. 1-5. To be sure, the audit proceedings anticipate the Department's independent review of the anticipated audit report. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(2)(B)(v)(I), (d)(2)(B)(v)(II), (d)(3). Not only is AbbVie free to move forward with its audits, but AbbVie could also submit audit reports consistent with the Department's 1996 guidance. AbbVie may find violations under the Department's 1996 guidance, or it may find no violations at all. Any argument based on the denial of any future enforcement petition is too speculative to be considered final agency action. *See* Compl. ¶ 190.

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

## III. AbbVie Lacks Standing Because Its Alleged Injury Is Not Redressable.

AbbVie's claims independently fall for lack of standing. To establish Article III standing, a plaintiff must demonstrate, among other things, that its alleged injury is "likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). If the alleged injury is not redressable, the court lacks jurisdiction. *Seed v. EPA*, 100 F. 4th at 260 (D.C. Cir. 2024). Where redress depends on the independent discretionary action of the government, standing is lacking. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

The disconnect between the relief AbbVie requests and the injury it alleges is most apparent in the Complaint's own prayer for relief. AbbVie asks this Court to "authorize AbbVie to audit Barrio and Mount Sinai." ECF No. 1, at 70. But the Department has already done exactly that. ECF No. 5-1. A court order authorizing AbbVie to take a step the Department has already expressly permitted it to take would redress nothing. AbbVie cannot satisfy the redressability requirement.

Even setting aside that the Department has already authorized the audit AbbVie seeks, a favorable ruling from the Court would do no more than return AbbVie to the beginning of an administrative process whose outcome remains entirely within the Department's discretion. To achieve the outcome it actually wants, enforcement action against Barrio and Mt. Sinai, AbbVie must first conduct the audits, the audits must produce findings of violations, the covered entities must have the opportunity to respond and contest the findings, any alternative dispute resolution proceeding must be resolved in AbbVie's favor, and the Department must then determine any necessary corrective or enforcement action. Each of these steps requires the exercise of discretion that this Court cannot compel. Where redress depends on such a chain of contingent future events, the redressability requirement is not satisfied. *See Lujan*, 504 U.S. at 560-561. Dismissal is therefore warranted on this independent ground as well.

## IV. AbbVie's Challenge to the Department's Enforcement Posture is Unreviewable Because Enforcement Decisions are Committed to Agency Discretion by Law.

Even if the Court determines that AbbVie's claims are ripe, that the Department's September 18 letter constitutes final agency action, and AbbVie has standing, AbbVie's challenge still fails because the enforcement determination it ultimately seeks (a particular enforcement outcome) is committed to agency discretion by law and is therefore unreviewable under the APA. The APA authorizes judicial review of agency action except where "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). In *Heckler v. Chaney*, 470 U.S. 821, 833 (1985), the Supreme Court held that an agency's decision whether to take enforcement action is presumptively unreviewable under this provision. This is because enforcement decisions "involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," such as "whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id*. at 831.

The presumption established in *Heckler* applies here. Whether to enforce manufacturer audit findings involves a number of factors that are within the Department's expertise and is committed to the Department's discretion. *See Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.,* Civ. Ac. No. 20-08806, 2021 WL 616323, at *8 (N.D. Cal. Feb. 17, 2021) (applying *Heckler* and granting motion to dismiss because "whether to enforce or prosecute violations under the 340B Program are committed to agency discretion"). The Complaint's prayer for relief explicitly requests a declaration that the Department's "refusal to enforce findings" from AbbVie's proposed work plans is unlawful. ECF No. 1, at 70. That request asks this Court to compel an enforcement determination that *Heckler* places squarely beyond judicial reach.

The presumption of unreviewability may only be rebutted where the substantive statute provides guidelines for the agency to follow in exercising its enforcement powers. *See Heckler*, 470 U.S. at 833. Here it does not. The 340B statute is silent on the standards governing the Secretary's enforcement discretion. The 340B statute does not mandate that the Secretary initiate enforcement proceedings upon receipt of a manufacturer's audit results, nor does it set any standard compelling the Secretary to act on a manufacturer's audit claim. *See* 42 U.S.C. § 256b(a)(5). The statute merely authorizes manufacturers to conduct audits and permits them to submit claims through the administrative dispute resolution process after doing so. *Id.* Where Congress has provided no law to apply, *Heckler*'s presumption of unreviewability controls, and judicial intervention is unavailable.

This case presents an even more attenuated basis for review than the typical *Heckler* case, which involves an agency's refusal to pursue enforcement after a violation has been identified. Here, no violation has been identified. If courts may not compel enforcement after findings are made, and under *Heckler* they may not, they certainly may not predetermine an outcome by compelling enforcement commitments before findings exist. The *Heckler* presumption applies at least as strongly here as in the paradigmatic case, and the Department's enforcement posture is therefore unreviewable.

* * *

## CONCLUSION

For these reasons, the Court should dismiss the complaint in its entirety.

Dated: June 16, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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| ABBVIE INC.<br>Plaintiff,<br><br>v.<br><br>ROBERT F. KENNEDY, JR., Secretary of Department of Health and Human Services et al.,<br><br>Defendants. | Civil Action No. 26-1190 (RDM) |

**[PROPOSED] ORDER**

UPON CONSIDERATION of Defendants' motion to dismiss, and the entire record herein, it is hereby

ORDERED that Defendants' motion is GRANTED, and it is further

ORDERED that this case is DISMISSED.

SO ORDERED:

_____
Date

_____
Randolph D. Moss
United States District Judge