

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., et al.,

Defendants,

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; RYAN WHITE CLIN-
ICS FOR 340B ACCESS; 340B HEALTH; UMASS
MEMORIAL MEDICAL CENTER; GENESIS
HEALTHCARE SYSTEM,

Intervenor-Defendants.

Civil Action No. 26-cv-1190-RDM

PLAINTIFF ABBVIE INC.'S SURREPLY
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

This Court has jurisdiction over AbbVie’s claims. To argue otherwise, Intervenor’s purport to invoke *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994). But the Government itself declined to raise that argument—and for good reason. The theory conflates two different doctrines. Intervenor’s argue (at 5) that this Court lacks jurisdiction to review AbbVie’s claims because AbbVie “has not followed the mandatory administrative process.” In so arguing, they blend two distinct doctrines: (1) the exception to district court jurisdiction recognized in *Thunder Basin*; and (2) the exhaustion of administrative remedies prior to judicial review. Neither doctrine applies.

A. *Thunder Basin* Is Inapplicable. Under the general grant of federal-question jurisdiction, 28 U.S.C. § 1331, federal district courts ordinarily have original jurisdiction over challenges to federal agency action under the APA. In *Thunder Basin*, the Supreme Court recognized that Congress can displace this ordinary rule: By providing for initial agency review, followed by direct review by “the appropriate United States court of appeals,” 510 U.S. at 204, Congress can strip a district court of its ordinary jurisdiction to review questions within the statutory scheme’s reach. But even where Congress has provided for initial review in the court of appeals, the *Thunder Basin* exception is narrow—applying *only* when a statutory scheme displays a “‘fairly discernible’ intent to limit jurisdiction,” and only where the claims at issue “are of the type Congress intended to be reviewed within th[e] statutory scheme.” *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 489 (2010) (alteration in original) (quoting *Thunder Basin*, 510 U.S. at 207, 212). Even if those criteria are met, moreover, courts “presume that Congress does not intend to limit jurisdiction if ‘a finding of preclusion could foreclose all meaningful judicial review’; if the suit is ‘wholly collateral to a statute’s review provisions’; and if the claims are ‘outside the agency’s expertise.’” *Id.* (quoting *Thunder Basin*, 510 U.S. at 212-13). This case fails the test at every step.

The *Thunder Basin* exception applies only where Congress has “substitute[d]” a district

court’s “ordinar[y]” authority—which is based on “28 U.S.C. § 1331’s grant of jurisdiction for claims ‘arising under’ federal law”—with an “alternative scheme” of “review in a court of appeals following the agency’s own review process.” *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023). In *Thunder Basin*, the Federal Mine Act provided for an administrative process that culminated in potential civil penalties imposed by the Federal Mine Safety and Health Review Commission. 510 U.S. at 207-08 (citing 30 U.S.C. §§ 815, 823). The statute then provided that “[m]ine operators may challenge adverse Commission decisions in the appropriate court of appeals, whose jurisdiction ‘shall be exclusive and its judgment and decree shall be final’ except for possible Supreme Court review.” *Id.* at 208 (quoting 30 U.S.C. § 816(a)(1)). Because “the statute establishe[d] that the Commission and the courts of appeals have exclusive jurisdiction over challenges to agency enforcement proceedings,” the statute precluded pre-enforcement claims. *Id.*

The Supreme Court has only “twice held specific claims to fit within a statutory review scheme, based on the *Thunder Basin* factors,” and both cases involved an express statutory provision vesting exclusive judicial review in a court of appeals. *Axon Enter.*, 598 U.S. at 186-87. The first was *Thunder Basin* itself, discussed above. 510 U.S. at 208. The second was *Elgin v. Department of Treasury*, 567 U.S. 1 (2012), where the Civil Service Reform Act similarly vested the Federal Circuit with “‘exclusive jurisdiction’ over appeals from a final decision of the MSPB.” *Id.* at 6 (quoting 28 U.S.C. § 1295(a)(9)). Intervenors’ other cited cases fit the same pattern. *See Sturm, Ruger & Co. v. Chao*, 300 F.3d 867, 873 (D.C. Cir. 2002) (“employers may appeal adverse Commission decisions to the appropriate court of appeals, whose jurisdiction ‘shall be exclusive’”) (quoting 29 U.S.C. § 660(a)); *Arch Coal, Inc. v. Acosta*, 888 F.3d 493, 495 (D.C. Cir. 2018) (“[T]he [statute] assigns exclusive jurisdiction over Arch’s challenges to the Department’s administrative process and then the relevant federal court of appeals.”) (cleaned up); *New York v. Trump*,

181 F.4th 132, 138 (D.C. Cir. 2026) (“aggrieved parties may petition for review in the D.C. Circuit”) (citing 39 U.S.C. § 3663). In each case, the analysis turned on the language of a statute that expressly displaced district court jurisdiction with an exclusive appellate-review mechanism.

Those cases are nothing like this one. Nothing in Section 340B gives a court of appeals exclusive jurisdiction to review agency decision-making. Indeed, Section 340B does not provide for *any* judicial-review mechanism—much less does it displace a district court’s normal grant of federal-question jurisdiction with a mechanism for original review in a court of appeals. No decision has ever applied *Thunder Basin* under those circumstances. *See, e.g., Gilead Scis., Inc. v. AJC Med. Grp., Inc.*, 2022 WL 1642758, at *6 (S.D. Fla. Feb. 10, 2022) (Section 340B “does not bear the hallmarks of a jurisdiction-stripping framework”). Intervenors point (at 7-8) to the 340B statute’s audit provisions, ADR process, and designation of ADR determinations as final agency decisions. But none of these provisions strips jurisdiction from the district court or channels judicial review to an appellate court. Rather, they establish an *administrative* process; they do not create a *jurisdiction-stripping* scheme providing for exclusive appellate judicial review.

Intervenors also point to *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Miriyeva v. USCIS*, 9 F.4th 935 (D.C. Cir. 2021), but both were channeling cases involving express channeling provisions. *Heckler* involved a statute “provid[ing] that [42 U.S.C.] § 405(g), *to the exclusion of 28 U.S.C. § 1331*, is the sole avenue for judicial review for all ‘claims arising under the Medicare Act.’” 466 U.S. at 614-15 (emphasis added) (cleaned up). Again, Section 340B contains nothing comparable barring the normal grant of federal-question jurisdiction under 28 U.S.C. § 1331.

Miriyeva involved an equally explicit channeling provision, requiring certain claims intertwined with denied naturalization applications to be reviewed “before the United States district court for the district in which such person resides.” 8 U.S.C. § 1421(c). Yet notwithstanding

Congress’s decision to “exclusively ... direct the review process of naturalization application denials” in this manner, 9 F.4th at 940, a *California* resident sought to challenge an adverse agency decision in the district court *for the District of Columbia*. *See id.* at 938-40. The Court found that she could not, because the statute “elaborately explain[ed] the procedure for an applicant to follow,” and “[b]oth the text and structure make clear that Congress intended this multistep review scheme to be the *only* path to judicial review for” her claim. *Id.* at 940 (cleaned up). Section 340B contains no similarly “elaborate” mechanism for channeling judicial review in an “exclusive” manner; indeed, it contains no mechanism for channeling judicial review at all.

Thunder Basin is inapplicable for a separate reason: AbbVie raises only a question of statutory interpretation—regarding the best reading of “patient” in 42 U.S.C. § 256b(a)(5)(B)—that is “wholly collateral” to any individual diversion dispute. *Free Enter. Fund*, 561 U.S. at 490 (citation omitted). Intervenor’s argue (at 9-12) that AbbVie’s challenge to the meaning of “patient” is “inextricably intertwined” with a dispute about diversion, which HRSA must resolve. But AbbVie seeks only a declaration of the correct meaning of “patient,” not an order assessing a particular covered entity’s liability or requiring particular remedial measures. Moreover, unlike in *Thunder Basin* and *Elgin*, where the plaintiffs’ rights could be fully adjudicated within the statutory scheme, any ADR claim that AbbVie could bring would apply the very statutory standard that AbbVie challenges. Requiring AbbVie to use a process that presupposes the correctness of the very standard under review “foreclose[s] all meaningful judicial review” of that standard. *Thunder Basin*, 510 U.S. at 212-13.

B. Section 340B Does Not Require Exhaustion. While Intervenor’s do not use the term “exhaustion,” the crux of their argument is that AbbVie should have exhausted the 340B program’s ADR process before filing suit. Citing *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011),

Intervenors argue (at 8-9) that “the Supreme Court has already determined that the 340B statute has an exclusive administrative scheme.” Yet administrative exhaustion is not jurisdictional unless “Congress clearly states that it is,” *Santos-Zacaria v. Garland*, 598 U.S. 411, 416 (2023) (cleaned up), and only the Government may raise exhaustion as a defense, *see Ctr. for Pub. Integrity v. FCC*, 505 F. Supp. 2d 106, 110 n.2 (D.D.C. 2007); *Cutler v. Hayes*, 818 F.2d 879, 891 n.95 (D.C. Cir. 1987).

Regardless, *Astra* did not address exhaustion, jurisdiction, or channeling. The Court rejected a covered entity’s state-law contract claim as a purported third-party beneficiary of the agreement between 340B-participating drug manufacturers and HHS. *Id.* at 113. Nothing in *Astra* precludes APA suits challenging HRSA’s failure to fulfill its *own* statutory duties. And the Court’s primary concern—that “dispersed and uncoordinated lawsuits” between private parties would leave HHS out of the loop, *id.* at 120—has no application to an APA suit against the agency itself.

Indeed, another court in this District has already held that Section 340B *does not* require exhaustion of the ADR process before a participant can challenge final agency action under the APA. Only “express[]” statutory language that “speak[s] in ‘clear, unequivocal terms’” can override the rule that “plaintiffs challenging final agency action need not exhaust administrative remedies.” *Amgen, Inc. v. Kennedy*, 2025 WL 2206948, at *3 (D.D.C. Aug. 4, 2025). Section 340B contains no such language: There is no “statute or rule that requires Plaintiffs to first exhaust the administrative process” under Section 340B before filing an APA suit, “let alone one that says such a requirement is jurisdictional.” *Id.* In other words, “[h]aving conferred jurisdiction in the APA, Congress must speak in ‘clear, unequivocal terms’ to take it away.” *Id.* Here, it did not.

CONCLUSION

The Court should deny Defendants’ motion to dismiss.

Dated: September 29, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with LCvR 5.3, undersigned counsel hereby certifies that the above brief was filed via the Court's electronic filing system.

Dated: September 29, 2026

By: /s/ Allon Kedem
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