

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Intervenor-Defendants.

No. 1:26-cv-1190-RDM

**JOINT MOTION OF INTERVENOR-DEFENDANTS
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.
AND RYAN WHITE CLINICS FOR 340B ACCESS FOR LEAVE TO FILE
SUR-SUR-REPLY IN SUPPORT OF MOTION TO DISMISS**

Intervenor-Defendants National Association of Community Health Centers, Inc. and Ryan White Clinics for 340B Access (together, “Intervenor-Defendants”) respectfully move this Court, pursuant to Local Civil Rule 7 and the Court’s Standing Order, for leave to file the accompanying [Proposed] Joint Sur-Sur-Reply Brief in Support of the Motion to Dismiss, attached as Exhibit A. In support of this motion, Intervenor-Defendants state as follows:

1. On September 29, 2026, AbbVie Inc. (“AbbVie”) filed a sur-reply in opposition to Defendants’ motion to dismiss. *See* ECF 54. Intervenor-Defendants seek leave to file the attached sur-sur-reply to respond to the arguments and authorities raised by AbbVie for the first time in its sur-reply.

2. Pursuant to Local Rule 7(m), counsel for Intervenor-Defendants conferred with opposing counsel. AbbVie stated that it opposes this motion.

3. This Court’s Standing Order states: “Sur-replies will only be permitted upon a specific showing of good cause.” ECF 6 ¶ 8(c). As the D.C. Circuit has explained, “[t]he district court routinely grants such motions [for sur-reply] when a party is ‘unable to contest matters presented to the court for the first time’ in the last scheduled pleading.” *Ben-Kotel v. Howard Univ.*, 319 F.3d 532, 536 (D.C. Cir. 2003) (quoting *Lewis v. Rumsfeld*, 154 F. Supp. 2d 56, 61 (D.D.C. 2001)). “The decision to grant or deny leave to file a sur-reply is committed to the sound discretion of the Court.” *United States v. Mejia*, 657 F.Supp.3d 123, 130 n.3 (D.D.C. 2023) (citation omitted). In exercising that discretion, a court considers “whether the movant’s reply in fact raises arguments or issues for the first time, whether the non-movant’s proposed surreply would be helpful to the resolution of the pending motion, and whether the movant would be unduly prejudiced were leave to be granted.” *Id.* (citation omitted).

4. There is good cause here to grant Intervenor-Defendants’ motion for a sur-sur-reply.

5. AbbVie’s sur-reply raises new arguments and authorities regarding whether (a) the 340B statute reflects a fairly discernible intent to channel diversion disputes through its administrative processes (ECF 54 at 2–5¹); (b) AbbVie’s claims here are inextricably linked with the diversion disputes confined to the mandatory administrative process (ECF 54 at 5); and (c) Defendants sufficiently raised AbbVie’s failure to exhaust administrative remedies (ECF 54 at 5–6).

6. Intervenor-Defendants’ proposed five-page sur-sur-reply, which is attached as Exhibit A, is confined to answering the new arguments and authorities raised in AbbVie’s sur-reply. And Intervenor-Defendants’ proposed sur-sur-reply would be helpful in resolving its pending motion to dismiss, particularly as it relates to this Court’s subject-matter jurisdiction to hear AbbVie’s claims.

7. AbbVie—as the non-moving party—would not be unduly prejudiced if leave were granted and Intervenor-Defendants were given the last word to rebut AbbVie’s new arguments and authorities. Rather, granting leave to file the attached sur-sur-reply would restore the ordinary order of briefing. This Court has recognized that “[t]he movant . . . gets the last word and a nonmovant . . . cannot continue to file additional pleadings, rearguing matters [it] had an opportunity to address in [its] response to the movant’s motion.” *Harrington v. Sec’y of State*, No. 18-CV-1056 (TSC), 2019 WL 13128386, at *2 (D.D.C. May 14, 2019). Here, AbbVie is the non-movant on the motion to dismiss, yet its sur-reply would leave it with the final submission on

¹ Citations in this document are to the blue ECF numbers in the Court’s header.

that dispositive motion. Permitting Intervenor-Defendants a responsive sur-sur-reply corrects that inversion and ensures that neither side is unfairly deprived of the chance to be heard.

8. Courts in this district routinely allow both sides to file sur-replies in these circumstances, considering “the sur-replies filed by both parties” where doing so aids resolution of the motion. *Mejia*, 657 F. Supp. 3d at 130 n.3. This is not a bid merely to have the last word on arguments already made; it is a request to answer genuinely new matter in AbbVie’s brief—the circumstance in which leave is routinely granted. *See Stevens v. Sodexo, Inc.*, 846 F. Supp. 2d 119, 130 (D.D.C. 2012).

9. Finally, the requested relief imposes no burden on AbbVie or the Court. The proposed sur-sur-reply is short—five pages, which matches AbbVie sur-reply, ECF 54—and is narrowly directed at the new arguments in AbbVie’s brief. It requires no change to any schedule and no further briefing. AbbVie cannot claim unfair surprise or prejudice from a filing that simply answers the arguments AbbVie chose to raise in its sur-reply. *See Mejia*, 657 F. Supp. 3d at 130 n.3.

10. For these reasons, Intervenor-Defendants respectfully request that the Court grant them leave to file the attached [Proposed] Joint Sur-Sur-reply in Support of the Motion to Dismiss.

11. A proposed order is filed with this motion.

Dated: September 30, 2026

Respectfully submitted,

/s/ Gene C. Schaerr

Gene C. Schaerr (D.C. Bar No. 416368)
Stephanie L. Freudenberg (D.C. Bar No. 1656482)
Justin A. Miller (D.C. Bar No. 90022870)
SCHAERR | JAFFE LLP
1717 K Street NW, Suite 900
Washington, DC 20006
(202) 787-1060
gschaerr@schaerr-jaffe.com
sfreudenberg@schaerr-jaffe.com
jmillers@schaerr-jaffe.com

*Counsel for Intervenor-Defendant
National Association of Community
Health Centers, Inc.*

/s/ Barbara Straub Williams

William H. von Oehsen (D.C. Bar No. 423381)
Barbara Straub Williams (D.C. Bar No. 396582)
Ronald S. Connelly (D.C. Bar No. 488298)
POWERS PYLES SUTTER & VERVILLE PC
1250 Connecticut Ave, NW, Eighth Floor
Washington, DC 20036
(202) 466-6550
William.vonOehsen@PowersLaw.com
Barbara.Williams@PowersLaw.com
Ron.Connelly@PowersLaw.com

*Counsel for Intervenor-Defendant
Ryan White Clinics for 340B Access*

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Intervenor-Defendants.

No. 1:26-cv-1190-RDM

**[PROPOSED] JOINT SUR-SUR-REPLY BRIEF OF INTERVENOR-DEFENDANTS
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.
AND RYAN WHITE CLINICS FOR 340B ACCESS
IN SUPPORT OF MOTION TO DISMISS**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
ARGUMENT	1
I. The 340B Statute Reflects a “Fairly Discernible” Intent to Route Diversion Claims Through Administrative Channels.....	1
II. This Court Lacks Subject Matter Jurisdiction Because Congress Confined Diversion Disputes, Including the Meaning of “Patient,” to 340B Administrative Processes.....	3
III. AbbVie’s Failure to Exhaust Provides an Alternative Basis to Dismiss Its Complaint.....	5
CONCLUSION.....	5

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Amgen, Inc. v. Kennedy</i> , 2025 WL 2206948 (D.D.C. Aug. 4, 2025)	5
<i>Astra USA, Inc. v. Santa Clara County</i> , 563 U.S. 110 (2011).....	3
<i>Axon Enter., Inc. v. Fed. Trade Comm’n</i> , 598 U.S. 175 (2023).....	1
<i>Fed. Law Enf’t Officers Ass’n v. Ahuja</i> , 62 F.4th 551 (D.C. Cir. 2023).....	4
<i>Gilead Scis., Inc. v. AJC Med. Grp., Inc.</i> , 2022 WL 1642758 (S.D. Fla. Feb. 10, 2022)	2
<i>Heckler v. Ringer</i> , 466 U.S. 602 (1984).....	1, 2, 4
<i>Miriyeva v. U.S. Citizenship & Immigr. Servs.</i> , 9 F.4th 935 (D.C. Cir. 2021).....	1, 2, 4
<i>Patten v. District of Columbia</i> , 9 F.4th 921 (D.C. Cir. 2021).....	2, 3
<i>Sanofi Aventis U.S. LLC v. HHS</i> , 58 F.4th 696 (3d Cir. 2023).	4
<i>Shalala v. Ill. Council on Long Term Care, Inc.</i> , 529 U.S. 1 (2000).....	4
<i>Thunder Basin Coal Co. v. Reich</i> , 510 U.S. 200 (1994).....	1, 4
Statutes	
42 U.S.C. § 256b.....	3, 4
8 U.S.C. § 1421.....	2

ARGUMENT

Nothing in AbbVie’s sur-reply (ECF 54) alters the conclusion that this Court lacks subject-matter jurisdiction over AbbVie’s claims because the 340B statute reflects a “fairly discernible” congressional intent to channel diversion disputes through its administrative process. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207, 212–15 (1994).

I. The 340B Statute Reflects a “Fairly Discernible” Intent to Route Diversion Claims Through Administrative Channels.

AbbVie first argues—wrongly—that “the *Thunder Basin* exception applies only” where a statute vests “review in a court of appeals following the agency’s own review process.” ECF 54 at 2–3 (quoting *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 185 (2023)). AbbVie therefore contends that *Thunder Basin* does not apply because the 340B statute does not “give[] a court of appeals exclusive jurisdiction to review agency decision-making.” *Id.* at 4. But AbbVie misreads *Axon Enterprise* and the other authorities on which it relies.

1. In *Axon Enterprise*, the Supreme Court stated only that direct court of appeals review of agency action is “[t]he method Congress *typically* chooses” to route claims through administrative channels. 598 U.S. at 185 (emphasis added). The Supreme Court did not state or hold that direct court of appeals review is the *exclusive* method Congress may use to channel claims and thus deprive district courts of jurisdiction to review them in the first instance. *See id.*

AbbVie’s sur-reply cites two cases *confirming* that statutory schemes other than direct appellate review may channel claims through the administrative process. *See* ECF 54 at 4–5. In *Heckler v. Ringer*, the Supreme Court interpreted the Medicare Act to displace initial district court jurisdiction over claims “arising under” that Act. 466 U.S. 602, 614–15 (1984). And in *Miriyeva v. U.S. Citizenship & Immigration Servs.*, the D.C. Circuit interpreted the Immigration and Nationality Act (“INA”) to reflect a “fairly discernible” intent to “preclude judicial review outside a special statutory review scheme.” 9 F.4th 935, 939–40 (D.C. Cir. 2021).

Like the 340B statute, neither the Medicare Act nor the INA provides for direct court of appeals review of agency action. *See Heckler*, 466 U.S. at 614–15, *Miriyeva*, 9 F.4th at 940. Yet both the *Heckler* and *Miriyeva* courts held that the channeling methods Congress had adopted there precluded district court review in the first instance, and this court should do the same.

2. Moreover, contrary to AbbVie’s argument, ECF 54 at 4–5, the INA does not *expressly* invoke channeling. It provides only that an applicant whose naturalization application is denied after an administrative hearing “may seek review of such denial before the United States district court for the district in which such person resides.” 8 U.S.C. § 1421(c). The D.C. Circuit nonetheless held in *Miriyeva* that § 1421(c) “implicitly forecloses parallel district court jurisdiction” because the INA’s review provisions are “elaborate” and naturalization claims are of the type Congress intended to be reviewed within that structure. 9 F.4th at 939–43. The 340B statute’s audit, notice-and-hearing, and ADR sequence, followed by review of the final agency decision, is at least as elaborate and likewise precludes district-court jurisdiction over diversion claims in the first instance. *See* ECF No. 52 at 7–8.

3. To challenge the application of *Thunder Basin* to the 340B statute, AbbVie points to *dicta* in an unpublished, out-of-district case. *Cf.* ECF 54 at 4 (citing *Gilead Scis., Inc. v. AJC Med. Grp., Inc.*, 2022 WL 1642758, at *6 (S.D. Fla. Feb. 10, 2022)). But *Gilead* is of little help. The court declined to “resolve the question of whether Congress intended to strip district courts of jurisdiction” because suit was filed before the final administrative dispute resolution (“ADR”) rule was published. *Gilead*, 2022 WL 1642758, at *5–*7. And the court did not consider even in *dicta* whether the *structure* of the 340B statutory scheme reflected Congress’s intent to channel diversion claims through its administrative processes. *See id.* at *5–6.

4. The D.C. Circuit also held in *Patten v. D.C.*, 9 F.4th 921 (D.C. Cir. 2021), that the Randolph-Sheppard Act (“RSA”)—which “creates state-administered programs for blind

individuals to operate vending facilities on federal property”—reflects “fairly discernible” intent under *Thunder Basin* because its “administrative-review scheme” is “detailed, precise, and comprehensive.” *Patten*, 9 F.4th at 923, 927. As the D.C. Circuit put it, “the RSA grievance scheme channels claims into the district court . . . once the administrative process has run its course.” *Id.* at 928.

Because the 340B statute’s administrative scheme is similarly comprehensive, *see supra* at 2, it also reflects a “fairly discernible” intent to route diversion disputes through those channels. Indeed, AbbVie agreed with such administrative exclusivity when it told another court that “the only way to enforce [340B] violations is through the federal ADR process (not State or other federal law, or even through private suit).” ECF 50 at 4 (quoting Compl. ¶ 135, *AbbVie Inc. v. Raoul*, No. 26-cv-9523 (N.D. Ill. Aug. 7, 2026)). This Court should follow that same principle.

5. AbbVie also fails to rebut (ECF 54 at 5–6) the applicability of *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). There, the Supreme Court held that Congress “centralized enforcement [of Section 340B disputes] in the government,” and private suits “would undermine the agency’s efforts to administer . . . § 340B harmoniously and on a uniform, nationwide basis.” *Id.* at 119–20. Congress instead “ma[d]e the new [340B ADR] adjudicative framework the proper remedy for . . . violations of the discounted pricing requirements,” *id.* at 122—a framework that governs diversion claims too. 42 U.S.C. § 256b(d)(3)(A). Under *Astra*, drug manufacturers bringing diversion claims, like covered entities bringing overcharge claims, must abide by the 340B statute’s “unitary” administrative enforcement scheme. *See* 563 U.S. at 120, 122. That is no less true to diversion claims than the dispute at issue in *Astra*.

II. This Court Lacks Subject Matter Jurisdiction Because Congress Confined Diversion Disputes, Including the Meaning of “Patient,” to 340B Administrative Processes.

AbbVie also argues that its claims are “‘wholly collateral’ to any individual diversion dispute.” ECF 54 at 5. But a claim is not collateral where, as here, it is “‘at bottom’ an attempt to

accomplish what’s contemplated by the review scheme,” *Miriyeva*, 9 F.4th at 941 (citing *Heckler*, 466 U.S. at 614), or when it “aim[s] to obtain the same relief [it] could seek” through the administrative process. *Fed. Law Enf’t Officers Ass’n v. Ahuja*, 62 F.4th 551, 561 (D.C. Cir. 2023).

1. Here, AbbVie seeks a declaration endorsing its definition of “patient” so that HRSA must “allow AbbVie to audit these covered entities against that definition and to enforce audit findings from those audits.” ECF 37 at 8. Because this is precisely the relief the ADR process exists to award, AbbVie’s claims are not “wholly collateral” to its diversion disputes.

AbbVie has made this very point in prior filings. In opposing Louisiana’s contract-pharmacy law regulating drug delivery, AbbVie argued that “federal law establishes an *exclusive* administrative enforcement mechanism for claims of overcharges”; that any “separate enforcement scheme that purports to overlap, even in part, with HRSA’s *mandatory* and *exclusive* ADR procedure raises a conflict with Congress’s choices”; and that “pricing and distribution are *inextricably linked*; [and hence] there is no ‘340B drug’ without the ‘340B price.’” Opp’n MSJ at 1, 10, 13, *AbbVie Inc. v. Murrill*, No. 6:23-cv-01307 (W.D. La. Apr. 5, 2024), ECF 70 (emphasis added). AbbVie took that position even though the 340B statute “is silent about delivery.” *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023). Using AbbVie’s own framing, then, there is no “340B diversion” without a “340B patient”; they are inextricably intertwined.

2. AbbVie is also wrong that requiring it to channel its claims through the ADR process will “foreclose[] all meaningful judicial review” of the definition of “patient.” *Cf.* ECF 54 at 5 (quoting *Thunder Basin*, 510 U.S. at 212–13). As the Supreme Court put it, a reviewing court “has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide.” *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000). AbbVie, then, will have every opportunity for “meaningful judicial review” once it has completed the channeling process Congress built into the 340B statute. *See* 42 U.S.C. § 256b(d)(3)(C).

For all these reasons, this court lacks subject matter jurisdiction.

III. AbbVie’s Failure to Exhaust Provides an Alternative Basis to Dismiss Its Complaint.

AbbVie is also wrong that Intervenor-Defendants “conflate” channeling under *Thunder Basin* with administrative exhaustion. *Cf.* ECF 54 at 2. Administrative exhaustion is an *alternative* doctrine warranting dismissal here.

Contrary to AbbVie’s suggestion (ECF 54 at 6), moreover, Government Defendants *did* raise exhaustion as a defense. In their opening brief, Defendants showed that AbbVie’s diversion claims must first go through the 340B statute’s mandatory administrative process. *See* ECF 13 at 20. AbbVie responded to this point in its opposition (ECF 37 at 27–39), acknowledging Defendants’ contention “that AbbVie must first complete the audit, file ADR claims, and *exhaust* a multi-step administrative process before a court may weigh in.” *Id.* at 43 (emphasis added). Defendants’ reply brief then responded to AbbVie’s arguments for skipping the mandatory administrative process (*see* ECF 50 at 5–9), including by pointing to the many times AbbVie “acknowledged the exclusiveness of the administrative process for resolving diversion-related disputes.” *Id.* at 8. This exchange more than adequately presented the exhaustion point.

AbbVie further errs (ECF 54 at 6) in relying on *Amgen, Inc. v. Kennedy*, 2025 WL 2206948 (D.D.C. Aug. 4, 2025). The drug manufacturers in *Amgen* were challenging final agency action: they alleged that the HHS Secretary’s decisions to certify and recertify certain clinics as eligible for the 340B program were “arbitrary and capricious.” *Id.* at *1–3. Because AbbVie is not challenging final agency action here, *see* ECF 13 at 15–19, ECF 50 at 9–12, ECF 52 at 14–17, *Amgen* provides no excuse for AbbVie’s failure to exhaust.

CONCLUSION

The Court should dismiss AbbVie’s claims because AbbVie improperly seeks to sidestep the mandatory administrative channels that the 340B statute established.

Dated: September 30, 2026

Respectfully submitted,

/s/ Gene C. Schaerr

Gene C. Schaerr (D.C. Bar No. 416368)
Stephanie L. Freudenberg (D.C. Bar No. 1656482)
Justin A. Miller (D.C. Bar No. 90022870)
SCHAERR | JAFFE LLP
1717 K Street NW, Suite 900
Washington, DC 20006
(202) 787-1060
gschaerr@schaerr-jaffe.com
sfreudenberg@schaerr-jaffe.com
jmiller@schaerr-jaffe.com

*Counsel for Intervenor-Defendant
National Association of Community
Health Centers, Inc.*

/s/ Barbara Straub Williams

William H. von Oehsen (D.C. Bar No. 423381)
Barbara Straub Williams (D.C. Bar No. 396582)
Ronald S. Connelly (D.C. Bar No. 488298)
POWERS PYLES SUTTER & VERVILLE PC
1250 Connecticut Ave, NW, Eighth Floor
Washington, DC 20036
(202) 466-6550
William.vonOehsen@PowersLaw.com
Barbara.Williams@PowersLaw.com
Ron.Connelly@PowersLaw.com

*Counsel for Intervenor-Defendant
Ryan White Clinics for 340B Access*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

No. 1:26-cv-1190-RDM

**[PROPOSED] ORDER GRANTING NATIONAL ASSOCIATION OF
COMMUNITY HEALTH CENTERS, INC. AND RYAN WHITE CLINICS
FOR 340B ACCESS' JOINT MOTION TO FILE SUR-SUR-REPLY**

Having considered Intervenor-Defendants National Association of Community Health Centers, Inc. ("NACHC") and Ryan White Clinics for 340B Access ("RWC-340B")'s Joint Motion for Leave to File Proposed Sur-Sur-Reply, and finding good cause to grant it, it is hereby ORDERED that:

1. The Motion is **GRANTED**.
2. The proposed sur-sur-reply attached as Exhibit A to the Motion shall be filed on the docket.

SO ORDERED.

ENTERED this ____ day of _____, 2026

HON. RANDOLPH D. MOSS
United States District Judge