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

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As the Government Defendants' reply persuasively explains, AbbVie, Inc. ("Plaintiff" or "AbbVie") offers no plausible reason to deny Defendants' motion to dismiss. *See* ECF 50 at 5–6 (Defs.' Reply).[1] Contrary to AbbVie's arguments, the Health Resources and Services Administration's ("HRSA") August 15 and September 18, 2025, letters (the "Letters") are not final agency action reviewable in this Court. *See* ECF 13 at 12, 15–19 (Defs.' Mot. to Dismiss); ECF 50 at 9–12. Rather, they are merely an interlocutory step in a longer statutory "channeling" process that AbbVie improperly attempts to sidestep. *See* ECF 37 at 27–39 (AbbVie's Opp'n). And where—as here—a statutory scheme reflects a "fairly discernible" congressional intent to route a type of claim through an administrative forum, that scheme displaces district court jurisdiction, at least in the first instance. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207, 212–15 (1994); *see also* 42 U.S.C. § 256b(a)(5)(C), (D), and (d)(3) (establishing exclusive administrative channel for diversion-related disputes). Thus, as the Government Defendants explain, because this Court does not have jurisdiction over AbbVie's claims—which challenge non-final agency action and attempt to circumvent the exclusive administrative channel for diversion-related disputes—Defendants' Motion to Dismiss should be granted.

Intervenor-Defendants agree fully with the Government Defendants' analysis, but offer here a few additional points by way of elaboration and/or emphasis—first on channeling, then on the related issue of finality.

I. This Court Does Not Have Jurisdiction to Review AbbVie's Diversion Claims Because AbbVie Has Not Followed the Mandatory Administrative Process.

AbbVie's failure to complete the statutorily prescribed process deprives the Court of jurisdiction over AbbVie's claims. Where Congress establishes a special statutory review

[1] Citations in this document are to the blue ECF numbers in the Court's header.

scheme—as it has here—that scheme displaces district court jurisdiction over claims arising under the statute. *Thunder Basin*, 510 U.S. at 212–15; *see also Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113–14 (2011). The Supreme Court has stated the governing principle: "when Congress creates procedures 'designed to permit agency expertise to be brought to bear on particular problems,' those procedures 'are to be exclusive'" unless the three *Thunder Basin* conditions apply. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 489 (2010) (quoting *Whitney Nat'l Bank v. Bank of New Orleans & Tr. Co.*, 379 U.S. 411, 420 (1965)). Those conditions apply when "a finding of preclusion could foreclose all meaningful judicial review," the suit is "wholly collateral to a statute's review provisions," and the claims are "outside the agency's expertise." *Id.* (quoting *Thunder Basin*, 510 U.S. at 212–13).

Here, the claim AbbVie presses—what it means to transfer a 340B drug "to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B)—is a diversion inquiry. AbbVie alleges that Barrio and Mt. Sinai have committed diversion because they did not employ AbbVie's preferred definition of the term "patient" when ordering 340B drugs. *See, e.g.*, Compl. ¶¶ 14–15, 74, 131, 138–39, 147, 174. AbbVie's diversion claims must go through the exclusive administrative channel established by Congress. 42 U.S.C. § 256b(a)(5)(C), (D), and (d)(3); *see also Heckler v. Ringer*, 466 U.S. 602, 614 (1984) (a claim so situated is "inextricably intertwined" with the channeled claim and must be "channeled first into the administrative process which Congress has provided"); *Miriyeva v. U.S. Citizenship & Immigr. Servs.*, 9 F.4th 935, 938–43 (D.C. Cir. 2021) (determining Congress channeled claims into an exclusive statutory scheme and the court therefore lacked subject matter jurisdiction over claims outside of that exclusive statutory scheme). And, because AbbVie has *not* gone through the established administrative channel, its claims must be dismissed for lack of jurisdiction.

A. The 340B Statute Sets Up a Mandatory Administrative Process For Diversion Disputes.

As the Supreme Court has explained, congressional intent to channel a dispute need only be "fairly discernible in the statutory scheme." *Thunder Basin*, 510 U.S. at 207 (citation omitted). Here, for three reasons, such intent is unmistakable.

First, the 340B statute makes a manufacturer or agency audit the mandatory antecedent to any determination of a diversion violation. It provides: "If the Secretary finds, *after audit* as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of" subparagraph (B), "the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug." 42 U.S.C. § 256b(a)(5)(D) (emphasis added). Congress therefore expressly required the development of this factual record to precede the legal determination of a diversion prohibition violation. But AbbVie asks this Court to invert that sequence and pronounce the legal standard *before* an audit creates a factual record.

Second, the 340B statute directs the Secretary to promulgate binding regulations establishing an administrative dispute resolution process, 42 U.S.C. § 256b(d)(3)(A), and requires the Secretary to "designate or establish a decision-making official or decision-making body within the Department of Health and Human Services" to hear and resolve claims. *Id.* § 256b(d)(3)(B)(i). Among the claims Congress expressly routed to that body are "claims by manufacturers" and "for the resolution of claims by covered entities that . . . have been overcharged for drugs purchased under this section." *Id.* § 256b(d)(3)(A). And the implementing regulations include "[c]laims by manufacturers of 340B drugs . . . that a covered entity may have violated the prohibitions against duplicate discounts or diversion." 42 C.F.R. § 10.3(2). That claim is precisely what AbbVie's audits were designed to develop and precisely the claim underlying this suit.

Third, the 340B statute specifies that an ADR 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." 42 U.S.C. § 256b(d)(3)(C). And it is settled that, when Congress designates a particular administrative decision as the "final agency action" subject to judicial invalidation, it has identified the point of entry into court and has expressly excluded earlier ones. *See, e.g.,* 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 894 (1990) ("Except where Congress explicitly provides for our correction of the administrative process at a higher level of generality, we intervene in the administration of the laws only when, and to the extent that, a specific 'final agency action' has an actual or immediately threatened effect."); *Mullin v. Doe*, 146 S.Ct. 2121, 2136 (2026) ("In APA cases, an agency's subsidiary decisions merge into the final agency action, which is then subject to review.").

Accordingly, when read together with § 256b(a)(5)(D)'s requirement of a Secretarial finding after notice and hearing, the 340B statute describes a closed administrative circuit that begins with an audit and ends with a reviewable final agency decision. Nothing in that circuit contemplates a manufacturer's mid-stream detour to district court over a diversion dispute, including aspects of the diversion prohibition that are "inextricably intertwined" with that dispute. *See Miriyeva*, 9 F.4th at 942–43; *Heckler*, 466 U.S. at 614.

Moreover, the Supreme Court has already determined that the 340B statute has an exclusive administrative scheme. In *Astra USA, Inc. v. Santa Clara County*, the Court emphasized that allowing parties to bypass that administrative framework and proceed directly to court would undermine Congress's choice to centralize enforcement of the program in the agency. 563 U.S. at

120. The Court held that "Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions," and that a private action seeking to enforce a particular view on the eligibility of prescriptions to be filled with 340B drugs is "in essence a suit to enforce the statute itself"—regardless of "the clothing in which [the plaintiff] dress[es] [its] claims." *Id.* at 114, 118 (citation omitted).

So too here. AbbVie brought this case in an effort to enforce its own definition of "patient," and allowing this case to proceed would result in other manufacturers bringing lawsuits to enforce their own understandings of "patient." This would lead to the "multitude of dispersed and uncoordinated lawsuits" that the Supreme Court determined was contrary to the dictates of the 340B statute. *See id*. at 120.

Those lawsuits, if successful, would also put HRSA at risk of having to enforce various interpretations of "patient," as this Court implicitly recognized in its decision granting intervention. ECF 45 at 2 (noting that AbbVie's lawsuit seeks to "allow Plaintiff to require the agency to enforce Plaintiff's preferred definition of 'patient' under 42 U.S.C. § 256b(a)(5)(B) in any future audits"). But the D.C. Circuit recently reaffirmed the premise that HRSA is the sole enforcer of 340B compliance requirements, holding that the 340B statute places "the Secretary, not the manufacturers, in the driver's seat of this important program." *Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027, 1035 (D.C. Cir. 2026).

B. AbbVie Cannot Sidestep the Mandatory Administrative Process Because the Meaning of "Patient" is Inextricably Intertwined With its Diversion Dispute.

AbbVie tries (ECF 37 at 28–29, 33–34) to sidestep these dispositive jurisdictional deficiencies by characterizing its suit as a freestanding legal challenge to an agency interpretation, severable from any concrete diversion dispute. But for multiple reasons, that effort is wrong.

First, that characterization cannot survive the statutory text. Diversion under the 340B statute consists of a covered entity's resale or transfer of a covered outpatient drug "to a person who is not a *patient* of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). The definition of "patient" is therefore not a collateral question that happens to bear on diversion. Rather, it is the crux of the diversion prohibition itself. Accordingly, to decide what "patient" means is to decide the scope of the very violation that Congress assigned to the Secretary to find "after audit . . . and after notice and hearing." *Id.* § 256b(a)(5)(D).

Second, AbbVie's effort is foreclosed by *Thunder Basin*, which applies the same rule in the pre-enforcement posture AbbVie occupies. The plaintiff there sought a district court declaration of its rights and duties before any administrative proceeding had begun. The Court held that claims which "at root require interpretation of the parties' rights and duties" under the statute and implementing regulations "fall squarely within the [agency's] expertise" and must proceed through the statutory channel. *Thunder Basin*, 510 U.S. at 214–15. AbbVie's claim here is the same as the claim in *Thunder Basin*: a request for an authoritative interpretation of the parties' respective rights and duties concerning who qualifies as a patient of a covered entity.

Further, the D.C. Circuit applies the *Thunder Basin* factors as "general guideposts" rather than "a strict mathematical formula." *Jarkesy v. SEC*, 803 F.3d 9, 17 (D.C. Cir. 2015). And, like in *Jarkesy*, "each of the guideposts points in the same direction" here, *id.* at 17: (1) "[M]eaningful judicial review" is preserved, not foreclosed, *see id.* at 17–19; (2) Congress expressly provided for judicial invalidation of an ADR determination in "a court of competent jurisdiction," 42 U.S.C. § 256b(d)(3)(C); *see also Jarkesy*, 803 F.3d at 19; and (3) AbbVie may obtain review of the patient definition—on a developed record, in a concrete dispute, *after* the agency has brought its expertise

to bear, *see Jarkesy*, 803 F.3d at 21–22. AbbVie's ability to obtain review is thus not foreclosed, but merely delayed. Delay is not deprivation. *See Thunder Basin*, 510 U.S. at 207 & n.8, 216.

Third, AbbVie's effort is foreclosed by other binding case law. For example, in *Elgin v. Department of the Treasury*, 567 U.S. 1, 10–23 (2012), the Supreme Court confirmed that a detailed, integrated statutory review path can channel a claim away from district court when it provides eventual Article III review. Likewise, in *Heckler v. Ringer*, the Supreme Court held that if a claim is "inextricably intertwined" with a claim Congress routed through an agency, it must be "channeled first into the administrative process which Congress has provided." 466 U.S. at 614. The Court emphasized that the inquiry looks to the substance of the relief sought, not the label the plaintiff attaches: A claim that "at bottom" seeks to establish entitlement under the statute belongs in the channel however it is pleaded. *Id.*

Here, AbbVie seeks to alter the substantive standard governing diversion—whether a recipient is a "patient of the entity." That is the central issue Congress required the audit and ADR process to address first. AbbVie cannot sidestep that mandatory administrative process.

Miriyeva v. U.S. Citizenship & Immigration Services, provides an additional structural parallel that forecloses AbbVie's argument. *See* 9 F.4th at 938–43. In that case, the Immigration and Nationality Act required a naturalization applicant to proceed from an agency examination and initial decision, to a hearing before an immigration officer, and then to de novo review in the district where the applicant resides. 8 U.S.C. §§ 1421(c), 1446, 1447(a). The plaintiff framed her suit as an APA and constitutional challenge to a policy concerning how military-discharge classifications are characterized for purposes of obtaining naturalization, but the D.C. Circuit held that the claim was not wholly collateral because it was "at bottom" an effort to reverse the denial of her naturalization application. *Miriyeva*, 9 F.4th at 942–43. The court reasoned that even if the

plaintiff's "claim challenges the 'procedure' the agency used to reach its decision," the "claim is not wholly collateral" where it is "'inextricably intertwined' with the claim referenced in the review scheme"—there, the denial of a naturalization application. *Id.* Likewise, AbbVie may cast its dispute about the definition of "patient" as an abstract legal question, but it is inextricably intertwined with AbbVie's diversion claim, because AbbVie's preferred definition of "patient" would "at bottom" establish the substantive standard for whether specific transactions constitute diversion.[2]

Fourth, AbbVie's own description of the relief it seeks confirms that its claim is a diversion claim in the dress of statutory interpretation. AbbVie claims that *its* proposed definition "accords with the best reading of that term in the 340B statute." ECF 1 ¶ 140 (Compl.). And it now asks this Court to fix its proposed definition as the meaning of "patient" before any covered entity has been audited and before the ADR Panel has heard anything because, in AbbVie's view, the "dispute must be resolved based solely on [the] 'best reading' of the statute." ECF 37 at 42. AbbVie then states what that reading is for: It claims it has "established reasonable cause to believe that Barrio and Mount Sinai have engaged in conduct that constitutes diversion under the best reading of 'patient' but that the 1996 Guidelines permit." *Id.* at 44. That is a request for a judicial declaration that two named covered entities are diverting. And that claim must go through the statutorily mandated channeling process before it is ripe for judicial review.

[2] The D.C. Circuit's decision in *Sturm, Ruger & Co. v. Chao*, 300 F.3d 867 (D.C. Cir. 2002), further supports deferral of court review until after a dispute goes through the mandatory administrative process. There, the Court held that the Occupational Safety and Health Act "creates a comprehensive review process" and that the plaintiff's claims "'are of the type Congress intended to be reviewed within this statutory structure.'" *Id.* at 873 (second quote to *Thunder Basin*, 510 U.S. at 212). It therefore rejected plaintiff's attempt to "make an end run around" the mandatory administrative "process by going directly to district court." *Id.* at 876. AbbVie's requested patient definition is a similar end run around the prescribed review process in the 340B statute, and should therefore be rejected.

Fifth, contrary to AbbVie's suggestion (ECF 37 at 9–10, 14, 34, 42, 49), *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), cannot save this dispute from dismissal for lack of subject matter jurisdiction. *Loper Bright* simply governs the standard of review a court applies to an agency's construction of a statute. *Id.* at 412–13. It says nothing about which agency forum reviews that construction, or when. It does not confer jurisdiction, create finality, ripen a claim, or remove Congress's power to legislate mandatory administrative channels over disputes in the first instance.

That is apparent from the D.C. Circuit's explanation in *New York v. Trump*, that *Loper Bright* does not eliminate the agency-expertise consideration mandated by *Thunder Basin*. 181 F.4th 132, 142 (D.C. Cir. 2026). Courts independently resolve legal questions on final review, but the agency's distinctive knowledge and regular administration of the relevant statutory function remain pertinent to initial channeling. *Id.* at 139–41. HHS's expertise is similarly central to issues related to the 340B statute because it administers 340B's diversion restriction, audit authority, and ADR process. Moreover, as the D.C. Circuit has previously explained, the mere fact that a plaintiff is challenging the agency's statutory interpretation does not give it license "to short-circuit the administrative process." *See Arch Coal, Inc. v. Acosta*, 888 F.3d 493, 501 (D.C. Cir. 2018) (rejecting a direct attack on agency sub-regulatory guidance as foreclosed by the administrative statutory review scheme); *see also Fed. L. Enf't Officers Ass'n v. Ahuja*, 62 F.4th 551, 556–60 (D.C. Cir. 2023) (similar).

In sum, AbbVie cannot sidestep the mandatory administrative process. The relief it seeks—"the invalidation of the Secretary's current policy and a 'substantive' declaration" in its favor—is "inextricably intertwined" with its underlying diversion claim. *Heckler*, 466 U.S. at 614. And

every aspect of AbbVie's diversion claim must "be channeled first into the administrative process which Congress has provided." *Id.*

II. The Challenged Letters Do Not Constitute Final Agency Action.

In any event, Defendants' motion should be granted on the alternative ground that the Letters are not final agency action. AbbVie's argument on this point (ECF 37 at 27–39) is wrong because the Letters did not announce a new interpretation, did not change the governing standard, and did not compel or forbid anything. *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004). Rather, the August 15, 2025, letter merely stated that it "should not be viewed as an approval of AbbVie's interpretation of the term 'patient.'" ECF 1-3 at 2. And that letter further: (1) advised AbbVie that its workplan definition "goes beyond HRSA's 1996 Guidelines, which . . . [are] the currently operative standard"; and (2) stated that HRSA would not "enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id.* And the September 18, 2025, letter confirmed that HRSA was "not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan submitted." ECF 1-4 at 2.

On the finality issue, *Independent Equipment Dealers v. EPA*, 372 F.3d 420 (D.C. Cir. 2004), is controlling. There, an EPA office director sent a letter restating the agency's longstanding reading of its regulations, and the D.C. Circuit held the letter unreviewable: "The Letter neither announced a new interpretation of the regulations nor effected a change in the regulations themselves. . . . Compelling no one to do anything, the letter had no binding effect whatsoever[.]" *Id*. at 427. The D.C. Circuit further explained: "By *restating* EPA's established interpretation . . . , the EPA Letter tread no new ground. It left the world just as it found it." *Id.* As the D.C. Circuit advised, "it is silly to permit parties to challenge an established regulatory interpretation each time it is repeated." *Id.* at 428. It "would quickly muzzle any informal communications between

agencies and their regulated communities—communications that are vital to the smooth operation of both government and business." *Id.*

AbbVie's attempt to escape this conclusion by relying on *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218 (D.C. Cir. 2026), is misplaced. *Cf.* ECF 37 at 27. There, the D.C. Circuit held the challenged document *nonfinal*, reemphasizing that "an agency action does not impose binding duties—and therefore causes no 'legal consequences'—when it merely clarifies existing duties under a statute." *Centro de Trabajadores Unidos*, 167 F.4th at 1236 (quoting *Del. Valley Reg'l Ctr., LLC v. U.S. Dep't of Homeland Sec.*, 106 F.4th 1195, 1204 (D.C. Cir. 2024)) (cleaned up). Because the document "merely explain[ed] how [the agency] w[ould] administer a process established by statute and [made] explicit existing requirements," it was "a nonbinding, nonfinal agency action." *Id.* (cleaned up). That also describes the Letters AbbVie challenges here, which advise that the 1996 Guidelines are "the currently operative standard." ECF 1-3 at 2, 1-4 at 2.

Sackett v. EPA, 566 U.S. 120 (2012), on which AbbVie heavily relies, ECF 37 at 22, also favors dismissal of AbbVie's claims. The Sacketts were Idaho landowners who received an EPA administrative compliance order declaring their residential lot to be protected wetlands and directing them to restore it. And when they asked the agency for a hearing, EPA refused. They were therefore left facing liability and with an order "not subject to further Agency review." *Sackett*, 566 U.S. at 127. But here, AbbVie stands in the opposite position: it is subject to no order, accrues no liability, and can itself initiate the proceeding Congress built for resolving its claim.

AbbVie also cannot transform the Letters into final agency action simply because they were signed by the Director of the Office of Pharmacy Affairs. *Cf.* ECF 37 at 30. As the D.C. Circuit explained in *Soundboard Association v. FTC*: "[t]he decisionmaking processes set out in an agency's governing statutes and regulations are key to determining whether an action is

properly attributable to the agency itself." 888 F.3d 1261, 1267 (D.C. Cir. 2018). And here, the relevant statutes and regulations show that the Letters are not final agency action. Specifically, the 340B statute conditions liability on a finding by "the Secretary . . . *after* audit as described in subparagraph (C) and *after* notice and hearing," 42 U.S.C. § 256b(a)(5)(D) (emphasis added), and the challenged Letters merely implement that command. But no audit and no notice and hearing have taken place, and no such finding exists. And where, as here, "[t]he Act and the agency's regulations clearly prescribe a scheme whereby the agency must hold a formal, on-the-record adjudication before it can make any determination that is legally binding," a subordinate official's preliminary correspondence is not final agency action. *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 732–33 (D.C. Cir. 2003).

So too here: 42 C.F.R. Part 10 commits the determination of whether "a violation . . . has occurred" to the agency's 340B ADR Panel, 42 C.F.R. § 10.23(a), and makes the Panel's decision "the final agency decision," subject to reconsideration by the HRSA Administrator or review by the Secretary. *Id.* § 10.23(c). In contrast, the Office of Pharmacy Affairs' role at intake is expressly ministerial, with OPA reviewing a claim only for completeness. *Id.* § 10.21(d); *see also* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28643 (Apr. 19, 2024) (codified at 42 C.F.R. pt. 10 ("OPA will review a claim only for completeness, and not make any determinations whether a claim is substantiated. That determination will be reserved for the 340B ADR Panel."). And the OPA Director's role on the back end is implementation, not decision: "The OPA Director will determine any necessary corrective [or enforcement] action . . . based on the final agency decision." 42 C.F.R. § 10.23(d); *id.* § 10.24(f). An official whose sole regulatory functions are to process the claim and to execute the decision is not the official who makes that decision.

The Secretary, moreover, retains plenary review authority. 42 C.F.R. § 10.20(c) ("The Secretary has the authority to review and reverse, alter, or uphold any 340B ADR Panel or reconsideration decision."). And the HRSA Administrator separately retains reconsideration authority. *Id.* § 10.24(c). Where, as here, the agency head retains authority to step in as the final decision-maker, a subordinate's action is not the agency's last word. *See Diamond v. Atwood*, 43 F.3d 1538, 1540–41 (D.C. Cir. 1995).

The authority on which AbbVie relies also cuts against it. *National Automatic Laundry & Cleaning Council v. Shultz*, treats an interpretive ruling as presumptively final *only* where it is "signed by the head of [the] agency" and has "crystallized following reflective examination in the course of the agency's interpretative process." 443 F.2d 689, 702 (D.C. Cir. 1971). The Letters here satisfy neither condition. They issued from an office three levels below the Secretary. And they crystallized nothing, because they merely restated a standard HRSA published in 1996.

And AbbVie is simply incorrect in describing the consequences of the Letters. *Cf.* ECF 37 at 35–38. Contrary to AbbVie, the Letters do not preclude manufacturer recovery under § 256b(a)(5)(D), civil monetary penalties under § 256b(d)(2)(B)(v)(I), or removal from the program under § 256b(d)(2)(B)(v)(II). AbbVie ignores that each asserted consequence requires an antecedent adjudication—one that has not yet occurred. Liability under § 256b(a)(5)(D) expressly requires a Secretarial finding "*after* audit, . . . notice[,] and hearing." *See* 42 U.S.C. § 256b(a)(5)(D). And the penalty and removal provisions likewise operate on findings. *See id.* §§ 256b(d)(2)(B)(v)(I) (knowing and intentional violations), 256b(d)(2)(B)(v)(II) (systematic and egregious violations). As explained earlier, the Letters themselves simply describe the process and relevant *existing* standards, leaving AbbVie free to audit and to bring an ADR claim if the audit develops any evidence of diversion. The Letters therefore do not constitute final agency action.

CONCLUSION

AbbVie offers no persuasive reason to deny Defendants' Motion. It cannot transform HRSA's letter into final agency action by circumventing the exclusive administrative channel established by Congress. Rather than following the prescribed steps, AbbVie asks this Court to write the governing standard for it, on no record, ten months after being told it was free to audit, and to do so in a proceeding from which many covered entities who would bear the consequences are absent. This Court should therefore grant Defendants' Motion to Dismiss.

Dated: September 8, 2026

Respectfully submitted,

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