Nos. 21-3128 & 21-3405

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
Honorable Sarah Evans Barker

APPELLANTS' SUPPLEMENTAL JURISDICTIONAL MEMORANDUM

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Pursuant to this Court's November 1, 2022 Order, Appellants Eli Lilly and Company and Lilly USA (together, "Lilly") submit this memorandum addressing the Court's jurisdictional and related questions. The Court has jurisdiction and should decide the merits of this appeal.

BACKGROUND

I. The 340B Statute

Under the 340B Drug Pricing Program, drug manufacturers that participate in Medicaid and Medicare Part B must offer their prescription drugs at steep discounts to non-profit "covered entities." 42 U.S.C. §256b(a)(1). The Department of Health and Human Services (with its component agency, the Health Resources and Services Administration) oversees the program. The 340B statute vests the agency with authority to (i) establish administrative-dispute resolution procedures for resolving claims *between* the private-party 340B participating entities (covered entities and manufacturers) before an agency tribunal, and (ii) enforce the statute directly *against* participants.

As to disputes between covered entities and manufacturers, the statute directed the Secretary of Health and Human Services to promulgate regulations establishing administrative-dispute-resolution procedures to govern resolution "of claims by covered entities that they have been overcharged," as well as "claims by manufacturers" that covered entities have violated statutory restrictions on duplicate discounts and diversion. *Id.* §256b(d)(3)(A); *see id.* §256b(d)(3)(B)(i) (directing establishment of a "decision-making body" within the agency to "finally resolv[e] claims by covered entities … and claims by manufacturers").

Apart from those provisions addressing claims between covered entities and manufacturers, the statute also vests the agency with the authority to enforce the 340B statute directly against manufacturers, separate from and without implicating the administrative-dispute-resolution process created for private-party participants. The agency asserts it can require manufacturers to reimburse covered entities for alleged overcharges; terminate manufacturers' participation in the 340B program (and with it, eligibility to participate in Medicaid and Medicare); and impose civil monetary penalties on "any manufacturer" that "knowingly and intentionally" overcharges a covered entity. *Id.* §256b(d)(1)(B)(vi); *see also Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115–16 (2011); Agency Suppl. Br. at 3.

II. Lilly's 340B Initiative and the Agency's Response

As described in more detail in Lilly's opening brief (at 12–15), the 340B program is a private-wealth transfer program that has been transformed over the last several years from a small cost-savings program for safety-net providers (enacted to restore discounts that the Medicaid rebate amendments had the unintentional effect of eliminating) into the second-largest federal drug program and a massive arbitrage scheme that generates hundreds of millions of dollars for entities Congress never contemplated—for-profit chain pharmacies (*e.g.*, CVS and Walgreens). This commandeering, which the Government Accountability Office has documented in recent years, *see, e.g.*, GAO, GAO-18-480, at 44–45 (June 2018), https://bit.ly/3OY0Fj9, has occurred principally through the development and implementation of a so-called "replenishment" accounting model.

This is not how the 340B program operated for most of its history. Historically,

when covered entities distributed discount drugs directly to their patients, the risk of abuse was relatively low. The covered entity would typically provide drugs only to its own patients, and it could readily ensure that the drugs were not diverted to non-patients, that no duplicate discounts were charged, and that the money it saved through the statutory discounts benefited its patients (directly or indirectly). The explosion of contract pharmacies changed all of that and substantially reduced any accountability—to the point where the agency no longer takes enforcement action against covered entities based on pharmacy violations. *See* GAO, GAO-21-107, at 15–16 (Dec. 2020), https://bit.ly/3wl7UcA.

The agency's original 1996 guidance, which permitted covered entities to use one—and only one—contract pharmacy, but which required covered entities to maintain title to the drugs (and accountability for the pharmacy's conduct), lowered the potential for abuse. *See* Lilly Opening Br. at 10. Pharmacies with discrete, close arrangements with covered entities generally kept 340B drugs in separate inventories, and they generally dispensed those drugs to customers that presented a prescription from a 340B provider. *See* Asay Decl. ¶4, R.129-3; HHS-OIG, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://bit.ly/3eWKmBQ (Admin.Rec.7968). But following the agency's 2010 guidance, which permitted an unlimited number of contract-pharmacy arrangements—with chain pharmacies anywhere in the country—for-profit pharmacies acted to maximize their own profits. A "pre-purchased" inventory model, *id.*, gave way to a scalable "replenishment" model, which reduced what little transparency and accountability that had existed to effectuate a

massive private wealth transfer from manufacturers to contract pharmacies.

Under the replenishment model, contract pharmacies fill all prescriptions (including those of covered-entity patients) out of their general inventory and bill the customer or the customer's insurer at full price—usually without knowing whether the customer is a patient of a covered entity at the time of dispensing. Pharmacies (or third-party-administrator affiliates of those pharmacies) then use opaque and manipulable computer algorithms to supposedly identify *post hoc* which of those customers *may* have been 340B patients. At that point, the contract pharmacy (or affiliate) places an order—purportedly on a covered entity's account—to "replenish" those alleged 340B purchases. The contract pharmacy, third-party administrator, and covered entity then divvy up the margin between the sale price and the 340B discounted price. This system plainly increases the risk of abuse, resulting in inconsistent approaches to identifying who might have once been a patient of a covered entity, to justify a post-hoc determination without the consent of manufacturers. *See* Lilly Opening Br. at 12–15 (collecting citations); Pharm. Rsch. & Mfrs. of Am. Amicus Br. at 19–24; Asay Decl., R.129-3; Pedley Decl., R.125-2; HHS-OIG, OEI-05-13-00431, at 1–5 (Admin.Rec.7964–68). This is all *sui generis*: No other Lilly customers are permitted to use unaffiliated, third-party contract pharmacies and no other customers use the replenishment model.

In 2020, Lilly responded to the abuses of the replenishment model by attempting to restore some accountability and limiting its delivery of discounted drugs in the same way that the agency itself articulated in 1996. *See* Lilly Opening

Br. at 10. Under its 340B initiative, Lilly would offer and deliver discounted drugs to all covered entities, but it would not deliver them to contract pharmacies unless (1) a covered entity lacked an in-house pharmacy, in which case the entity could designate one contract pharmacy, or (2) the contract pharmacy was wholly owned by, or shared a corporate parent with, a covered entity.[1]

The agency took three distinct actions in response. First, the agency finally promulgated its long-overdue administrative-dispute-resolution rule to permit covered entities to seek relief against manufacturers.[2] *See* Order, R.81.11–14. Second, the agency issued an Advisory Opinion that purported to require manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies anywhere on earth (or even beyond). *See* A.5–12; *cf.* A.7. Third, the agency issued violation letters to every manufacturer that imposed *any conditions whatsoever* on the delivery of drugs to contract pharmacies.

Lilly received the Violation Letter on May 17, 2021. *See* A.2–3. Although the agency did not give Lilly any opportunity to review or respond to the allegations against it, the agency specifically determined that Lilly had violated the 340B statute. The agency wrote: "After a review of [Lilly's] policy and an analysis of the complaints [the agency] has received from covered entities, [the agency] has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B

[1] Lilly will also deliver penny-priced insulin to unlimited contract pharmacies as long as the covered entity agrees, among other things, that *patients* will receive the full 340B discount.

[2] Although the statute directed the establishment of procedures by September 2010, *id.* §256b(d)(3)(A), the agency did not attempt to finalize a rule until 2020.

statute." A.2.[3] The agency then ordered Lilly to "immediately" begin honoring contract-pharmacy relationships and to "credit or refund all covered entities for overcharges" caused by Lilly's policy. A.3. The agency concluded by threatening severe and accumulating civil monetary penalties. *See* A.3.

III. Procedural History

Lilly challenged all three actions. As to the first, the district court preliminarily enjoined the administrative-dispute-resolution rule because the agency violated the Administrative Procedure Act's notice-and-comment requirements. SA.2 n.1. The agency did not appeal, and cross-motions for summary judgment remain pending.

The district court next entered a partial final judgment that resolved Lilly's challenges to the Advisory Opinion and the Violation Letter. The court ruled for Lilly on the Advisory Opinion (which the agency also withdrew) but issued a split decision on the Violation Letter. It vacated it as arbitrary and capricious but refused to find it contrary to law, instead affirmatively holding "the statute, correctly construed, *does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements*." SA.59 (emphasis added); *see* SA.71. The court also found under Federal Rule of Civil Procedure 54(b) that "there is no just reason for delay," and it ordered that "partial final judgment shall issue … to allow the parties to decide whether to seek expedited appellate review of these issues." SA.62; *see* SA.70.

[3] Lilly provided evidence in the district court rebutting many of those complaints. *See, e.g.*, Dixson Decl., R129-2.

Both parties appealed the decisions on the Violation Letter. Consistent with this Court's orders, both filed multiple jurisdictional briefs and statements. Docs.5, 8, 9, 49, 57. The parties have consistently agreed that this appeal is justiciable.

ARGUMENT

I. The District Court Issued a Proper Rule 54(b) Judgment.

Rule 54(b) permits a court to "direct entry of a final judgment as to one or more, but fewer than all claims" if "the court expressly determines that there is no just reason for delay." To determine whether a district court entered a proper Rule 54(b) judgment, this Court considers first whether the decision is "truly a final judgment" without "too much factual overlap with claims remaining in the district court," and second, "whether the district court abused its discretion in finding no just reason to delay." *Peerless Network, Inc. v. MCI Commc'ns Servs., Inc.*, 917 F.3d 538, 543 (7th Cir. 2019). The judgment below satisfies both requirements.

The district court's judgment is "truly a final judgment" because the administrative-dispute-resolution claims pending below and the Violation-Letter claims on appeal are neither factually nor legally intertwined. *Id.*; *see also Marseilles Hydro Power, LLC v. Marseilles Land & Water Co.*, 518 F.3d 459, 463–64 (7th Cir. 2008). What remains below are Lilly's five claims challenging the administrative-dispute-resolution rule as unconstitutional under Articles II and III, contrary to the 340B statute, in violation of notice-and-comment requirements, and arbitrary and capricious. *See* Compl. ¶¶233–275, R.103. Lilly's claims on appeal, by contrast, challenge the Violation Letter as contrary to law and arbitrary and capricious. *See also* Lilly Statement of Jur. at 3–4, Doc.5.

As a factual matter, the two sets of claims involve entirely distinct agency actions. The Violation Letter provides the agency's final determination about the legality of Lilly's 340B initiative, while the administrative-dispute-resolution rule promulgates a process for resolving "claims by covered entities that they have been overcharged for drugs" and "claims by manufacturers" that covered entities have violated certain statutory restrictions. 42 U.S.C. §256b(d)(3)(A). The Violation Letter is not the product of the administrative-dispute-resolution process, nor can Lilly challenge it through that process. Indeed, that process has nothing to do with disputes between the agency and manufacturers (or between the agency and covered entities). The agency made exactly this point when questioned by the district court:

> THE DISTRICT COURT: So let me ask you a question about the enforcement process. So the enforcement letter basically asserts [the agency's] view of the violation. So how does Lilly contest that if it chooses to disagree?
>
> [AGENCY COUNSEL]: Exactly as it has done, Your Honor. We have not moved to dismiss on the violation letter. We've only moved for summary judgment. So we're not arguing that it's not justiciable. So this process is playing out exactly as Congress intended. The agency charged with enforcement has found a violation. It has issued the equivalent of a cease and desist letter, and Lilly can challenge it in this court. So this is as Congress designed, and it's directly analogous to other agency enforcement scenarios as well.
>
> THE COURT: So the opposition to the quote, cease and desist order, end quote, is through judicial action?
>
> [AGENCY COUNSEL]: Yes, Your Honor.
>
> THE COURT: Okay. So this would not be something – we're not going to talk today about ADR [administrative dispute resolution] too much, but *it would not be something that would come within the ADR [administrative-dispute-resolution]* –
>
> [AGENCY COUNSEL]: *No, Your Honor*.
>
> THE COURT: – process?
>
> [AGENCY COUNSEL]: No, Your Honor. The ADR [administrative-

> dispute-resolution] process allows covered entities and manufacturers to sue each other before the agency. It doesn't determine the agency's enforcement and it doesn't allow Lilly to challenge the agency's view.

7/30/21 Hr'g Tr. at 18–19, R.139 (emphases added). And the agency reiterated that point just a few days ago in its supplemental brief before this Court. *See* Agency Suppl. Br. at 3–6; *see also* Oral Arg. Audio at 35:45–35:55, *Eli Lilly v. Becerra*, No. 21-3128 (7th Cir. Oct. 31, 2022), https://bit.ly/3hHm6J0 (agency counsel stating, "[T]he agency can *sua sponte* initiate an enforcement action as it could do … before the regulation … that governs the administrative dispute process").[4]

The same point can be made another way: Lilly's challenges to the administrative-dispute-resolution rule and the Violation Letter could each exist independent of the other. If the agency had never issued its Violation Letter (and never provided the factual basis for the claims on appeal), Lilly could still assert the same claims against the administrative-dispute-resolution rule that remain pending below. Likewise, if the agency had never finalized the administrative-dispute-resolution rule (and never provided the factual basis for the claims pending below), Lilly could still bring the same Violation-Letter claims that are on appeal.

The two sets of claims also bear no legal relation to each other. If this court resolves the merits of Lilly's Violation-Letter challenge, it would not be addressing

[4] The agency's position is that its determination would be binding in any subsequent proceedings before the Department of Health and Human Services, and that Lilly cannot challenge that determination in such proceedings. *See* 7/30/21 Hr'g Tr. at 18–19, R.139. That does not mean, however, that principles of *collateral estoppel* attach to the Violation Letter. Collateral estoppel applies only when an issue is actually litigated, and Lilly was never given an opportunity to review or respond to the allegations. *See B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148 (2015).

the legality of the administrative-dispute-resolution rule. Lilly's challenges to that rule turn on wholly distinct issues: constitutional questions surrounding how the agency appoints adjudicators, the lawfulness of the remedies those (non-Article III) decisionmakers may impose, and *that rule's* compliance with the Administrative Procedure Act. The claims on appeal, by contrast, turn on whether the Violation Letter's extra-statutory prohibition of any and all manufacturer conditions is contrary to law and arbitrary and capricious.

Finally, neither this Court nor the parties have ever suggested that the district court "abused its discretion in finding no just reason to delay the appeal of the claim[s] that w[ere] finally decided." *Peerless Network, Inc.*, 917 F.3d at 543. There is no reason to delay resolving the Violation-Letter claims so that the district court can resolve what are undisputedly "entirely separate" challenges to the administrative-dispute-resolution rule. *Id.* at 545. After all, any delay comes at a price. Lilly faces, in the agency's view, the threat of severe and accruing penalties for failing to comply with the Violation Letter. A Rule 54(b) judgment is more than appropriate here.

II. There Is No Finality Bar To This Court's Review.

The Administrative Procedure Act provides a cause of action for persons aggrieved by final agency action. *See* 5 U.S.C. §702; *id.* §704. As an initial matter, the Court need not address whether the Violation Letter is final because the agency affirmatively waived any argument that it is not. But if the Court does reach the question, it should conclude that the Violation Letter is final agency action.

A. The Agency Affirmatively Waived Finality.

The agency has repeatedly, knowingly, and intelligently waived finality (also

forfeiting, and now affirmatively waiving, any such argument on appeal). Because the finality requirement derives from the Administrative Procedure Act and not a "jurisdiction-conferring statute," the requirement can be waived. *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 183–84 (D.C. Cir. 2006); *Air Courier Conf. of Am. v. Am. Postal Workers Union AFL-CIO*, 498 U.S. 517, 523 n.3 (1991). As this Court recently put it, "a litigant-specific final decision is not a jurisdictional requirement," and a court is "not require[d] … to dismiss [a] suit when the agency has acquiesced in immediate review." *Builders Bank v. Fed. Deposit Ins. Corp.*, 846 F.3d 272, 275 (7th Cir. 2017); *cf. Sprague v. King*, 23 F.3d 185, 188 (7th Cir. 1994).

Not only did the agency waive any argument that the Violation Letter is not final, it *affirmatively argued* that the letter *is* final agency action both before the district court and now this Court. The agency told the district court that this case is "justiciable" and that Lilly "can challenge [the Violation Letter] in this court." 7/30/21 Hr'g Tr. at 18–19, R.139; *see also* Agency's Mot. for Summ. J. Br. at 12, R.125 (referring to the Violation Letter as the "culminat[ion]" of the agency's decision-making and arguing that the "dispute between the parties—whether Lilly is, in fact, in violation of its statutory obligation—now is squarely presented in the 340B Violation Letter"). The agency was even more blunt in its supplemental brief before this Court. There, it argued succinctly that if this Court reaches the issue, "it should hold that the [Violation Letter] was a final agency action." Agency Suppl. Br. at 9. In short, the agency has intentionally relinquished a known right, *i.e.*, the right to contest the finality of the Violation Letter, and it affirmatively encouraged the district

court and now this Court to address the merits of its determination.

The agency's waiver is binding. This Court need not and should not raise a finality defense over the agency's knowing and intelligent waiver. The Supreme Court has cautioned against such a departure from "the principle of party presentation basic to our adversary system." *Wood v. Milyard*, 566 U.S. 463, 472 (2012); *see also United States v. Sineneng-Smith*, 140 S. Ct. 1575, 1579 (2020). *Wood* is instructive. There, a district court denied habeas relief on the merits after the State of Colorado twice informed the district court that it would not challenge the timeliness of a habeas petition. The Tenth Circuit, however, "resurrect[ed] the limitations issue" and affirmed solely on the ground that the petition was untimely. *Wood*, 566 U.S. at 466. The Supreme Court reversed, holding that "[a] court is not at liberty … to bypass, override, or excuse a State's deliberate waiver." *Id.* The Court emphasized that "[w]hen a court of appeals raises a procedural impediment to disposition on the merits, and disposes of the case on that ground, the district court's labor is discounted and the appellate court acts not as a court of review but as one of first view." *Id.* at 474. Here too the agency, "after expressing its clear and accurate understanding of the [finality] issue, deliberately steered the District Court" and now this Court "away from the question and towards the merits." *Id.* (citation omitted). At this point, the Court should reach the merits.

B. The Violation Letter is Final Agency Action.

In any event, the parties are correct that the Violation Letter is final, and the Supreme Court's decision in *U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590 (2016), which was discussed at argument, confirms this. An agency action must

satisfy two conditions to be final. First, "the action must mark the consummation of the agency's decisionmaking process"; it cannot be "merely tentative or interlocutory." *Id.* at 597. Second, "the action must be one by which rights or obligations have been determined, *or* from which legal consequences will flow." *Id.* (emphasis added). The Violation Letter satisfies all of the above. *See also* Oral Arg. Audio at 13:25–13:31, 14:30–15:01, *Novartis v. Johnson*, No. 21-5299 (D.C. Cir. argued Oct. 24, 2022), https://bit.ly/3DQBQRl (Judge Katsas stating there "probably is final agency action" and agency counsel arguing that "the Court can rule on th[e] question" whether a nearly identical violation letter is lawful).

First, the text of the Violation Letter demonstrates that it marks the consummation of the agency's decision-making process as to Lilly's 340B initiative. Compare the language of the Violation Letter with that of the letter held to be final in *Western Illinois Home Health Care, Inc. v. Herman*, 150 F.3d 659 (7th Cir. 1998). There, a Department of Labor employee sent a letter "stress[ing]" that, although the agency would be "closing [its] investigation with no further action," it was nonetheless "the [agency's] position" that the plaintiffs' overtime policies violated the Fair Labor Standards Act. *Id.* at 661. The employee further wrote that he "inten[ded] to consider a follow-up investigation at some later date," and he noted that the plaintiffs could face civil monetary penalties in the future for failing to comply with the agency's statutory interpretation. *Id.* at 661. On appeal, this Court concluded that the first finality requirement was satisfied because "the language of the letter itself" was "declarative" and neither "tentative [n]or interlocutory in nature." *Id.* at 662–63.

The same is true here. The Violation Letter explains that the agency had performed "an analysis of the complaints [the agency] has received from covered entities," "completed its review," and "*determined* that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." A.2 (emphasis added); *see also Sackett v. EPA*, 566 U.S. 120, 129 (2012) ("[T]he text … of the compliance order makes clear [that] the … 'deliberation over whether the Sacketts are in violation of the Act is at an end.'"). The Violation Letter does not contemplate nor permit any further factfinding or process before the Department of Health and Human Services. *Contra Hawk v. Burr*, 2022 WL 4364740, at *1 (7th Cir. Sept. 21, 2022) (no final agency action where a notice of trespass "by its own terms" contemplated further proceedings). Indeed, the agency has averred that its "comprehensive review of Lilly's policy culminated in a new agency action in the form of a 340B-violation letter." Agency Mot. for Summ. J. at 2, R.125.

The reasoning in *Hawkes*, which applied the principles in *Sackett*, further demonstrates that the Violation Letter satisfies the first prong, as it is not "tentative or interlocutory." 578 U.S. at 597. In *Hawkes*, the Supreme Court concluded that the issuance of an "approved jurisdictional determination"—which "definitively" stated the presence or absence of "waters of the United States" on a particular parcel of land and impacted future permitting decisions—was a final agency action. *Id.* at 595, 597. Although the agency in *Hawkes* could still revise its jurisdictional determinations after five years or based on "new information," the Court observed that such determinations followed agency "factfinding," were "typically not revisited if the

permitting process move[d] forward," and were described by the agency itself as "final agency action." *Id.* at 597–98. The Court therefore held that the determination in *Hawkes* was final agency action because the agency "for all practical purposes ha[d] ruled definitively." *Id.* at 598. Similarly, the agency here insists it has completed its factfinding, has "ruled definitively" that Lilly is violating the 340B statute, and contemplates no further agency proceedings as to that determination. *Id.*[5]

Second, the Violation Letter is an agency decision "by which rights or obligations have been determined," as well as one "from which legal consequences will flow." *Id.* at 597. As to "rights or obligations," the Violation Letter announces the agency's sweeping, categorical position that imposing any delivery restrictions at all violates the 340B statute. A.2-3.[6] And the Violation Letter orders Lilly to

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[5] It makes no difference for purposes of finality that the agency's "factfinding" was superficial (at best) and that the agency failed to give Lilly any opportunity to respond. That was the agency's choice, which it made clear by declaring that it had completed its "review" and "determined" that Lilly had violated the statute.

[6] The agency has repeatedly suggested that Lilly, not the agency, has taken an extreme or "categorical" position. *See, e.g.*, Agency Supp. Br. at 6. That is exactly backwards. It is the agency that has taken the "categorical" position that all conditions on a manufacturer's offer to sell discounted drugs violates the 340B statute. *See, e.g.*, Oral Arg. Audio at 1:24–1:58, *Novartis*, No. 21-5299, https://bit.ly/3DQBQRl (Judge Katsas describing the agency's position as "awfully hard to accept"); *id.* at 5:42–6:06 (Judge Rao describing "the government's primary position" as "because the statute doesn't *permit* conditions, … any conditions are prohibited"). Indeed, the agency has sent substantively identical violation letters to several other manufacturers, regardless of the distinct delivery conditions each imposed, because, in the government's view, any conditions at all violate the statute.

Lilly, by contrast, is merely arguing that the statutory obligation is narrow and specifically defined. Congress was aware that commercial transactions have multiple terms, and it imposed only one requirement to *offer* discounted drugs to covered entities *at the ceiling price to a covered entity*. Thus, imposing *some* conditions separate from the price is lawful so long as the offer remains an "offer"—*i.e.*, a meaningful, bona fide offer. *See* Lilly Opening Br. at 32. Lilly has never categorically

"immediately" begin honoring all contract-pharmacy arrangements and to "credit or refund all covered entities for overcharges" caused by Lilly's policy. A.3. That definitive determination of Lilly's "obligations" to covered entities is sufficient to establish finality. *Herman*, 150 F.3d at 663.

If more were needed, however, legal consequences also "flow" from the Violation Letter. The Violation Letter threatens accruing civil monetary penalties of up to $6,323 for each instance of overcharging (in addition to the obligation to repay alleged overcharges) if Lilly does not immediately change its behavior now and accede to the agency's requirements. A.3. True, the Violation Letter does not liquidate the precise amount of civil monetary penalties Lilly could owe. But assuming, as this Court must, that "the consequences [are] what the Government asserts," *Sackett*, 566 U.S. at 126 n.2; *see also id.* at 126 n.3, the Violation Letter "exposes" Lilly to crippling "penalties in a *future* enforcement proceeding," *id.* at 126 (emphasis added). And the Supreme Court made clear in *Sackett* that regulated entities need not "wait for [an] [a]gency to drop the hammer" while "each day … they accrue, by the Government's telling," significant "potential liability" from civil penalties. *Id.* at 127.

Herman is again illustrative. This Court held that the letter from the Department of Labor employee was final because the employee "threatened a follow-

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refused to deliver discounted drugs to contract pharmacies. Nor does it categorically refuse to deal with covered entities with contract-pharmacy relationships. Lilly has simply imposed reasonable delivery conditions that reflect the limitations in the agency's own 1996 guidance in an effort to limit the abusive effects of the kabuki effectuated by for-profit-pharmacies' replenishment model—a model that is unique to the 340B program. Lilly's position is hardly "categorical."

up investigation to confirm" the plaintiffs' compliance and "warned" that they would be subject to severe fines "if they failed in the future to comply with the legal ruling contained in the letter." *Herman*, 150 F.3d at 663. Here too the Violation Letter asserts that Lilly "face[s] steeper penalties," *id.*, (not to mention the obligation to repay covered entities ever greater sums) in future enforcement proceedings.

In addition, as the agency explains, the Violation Letter created a type of safe harbor by declaring that Lilly could avoid civil monetary penalties by promptly complying with the agency's demands. *See* Agency Suppl. Br. at 10. Put differently, the Violation Letter determined that Lilly could not avail itself of a safe harbor unless it immediately changed its behavior and ceased imposing delivery restrictions. That too is enough to establish finality, as *Hawkes* demonstrates. There, the Supreme Court recognized that the denial of even a temporary safe harbor from enforcement proceedings is a "legal consequence[]." 578 U.S. at 599. Thus, the Violation Letter is final under the "pragmatic" approach courts have "long taken to finality." *Id.*

Lastly, courts have sometimes said that the finality question is related to the doctrine of prudential ripeness, which historically had been invoked on rare occasions to decline to exercise jurisdiction based on "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 149 (1967). The Supreme Court has since cast doubt on that exception to a court's "virtually unflagging" "obligation to hear and decide cases within its jurisdiction." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014); *cf. Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253, 261 (4th Cir. 2022). But

to the extent the doctrine survives, it is inapplicable here. As the agency explains in its supplemental brief (at 10–12), the issues on appeal are "purely legal and will not be clarified by further factual development." *Susan B. Anthony List*, 573 U.S. at 167. And "denying prompt judicial review would impose a substantial hardship" on Lilly, who faces the threat of accruing penalties and alleged repayment obligations. *Id.* at 167–68. This Court should reach the merits.

III. Lilly Has Appellate Standing.

Although the Court's November 1, 2022 Order did not specifically reference Lilly's appellate standing, Lilly addresses the issue for completeness and because the Court raised it at oral argument. Lilly has appellate standing to pursue its own appeal, and because the agency cross-appealed, it may defend the district court's judgment on any ground supported by the record.

Lilly has standing to appeal the district court's entry of a declaration that Lilly is currently violating the 340B statute, as well as its denial of the broader relief Lilly sought—*i.e.*, a declaration that the Violation Letter is contrary to law because the agency lacks the authority to order Lilly to deliver 340B drugs without the ability to impose any conditions whatsoever. As Lilly has previously observed, *see* Lilly Jur. Mem. at 16–19, Doc.9, the Supreme Court has held that an otherwise prevailing party may appeal "so long as that party retains a stake in the appeal satisfying the requirements of Art. III," *Deposit Guaranty Nat'l Bank v. Roper*, 445 U.S. 326, 334 (1980). Here, the district court *denied* Lilly its requested broader relief and, more than that, affirmatively declared that the statute "does not permit drug manufacturers, such as [Lilly], to impose unilateral extra-statutory restrictions on

their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." SA.71; *contra Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021) ("The statute's plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies."). "[A] prevailing party is aggrieved and ordinarily can appeal a decision granting in part and denying in part the remedy requested." *Amazon, Inc. v. Dirt Camp, Inc.*, 273 F.3d 1271, 1275 (10th Cir. 2001). That is what the court did here. And unless this Court reverses the decision below, Lilly faces the prospect of ongoing enforcement proceedings that seek to impose penalties and other sanctions if it does not immediately change its behavior. Indeed, the agency has relied on the district court's declaration to argue just that. *See* Lilly Jur. Mem. at 17–18, Doc.9.

In any event, even if this Court disagrees, the agency's cross-appeal cures any defect. Lilly is entitled to "defend its judgment on any ground preserved in the district court." *Richardson v. Koch L. Firm, P.C.*, 768 F.3d 732, 734 (7th Cir. 2014). And if the Court still disagrees, it should at least vacate the portions of the district court's decision adverse to Lilly because if Lilly lacks appellate standing then any adverse statements lack legal effect and the agency should not be permitted to rely on them.

IV. *Talevski* Will Not Affect This Case.

Finally, the Supreme Court's decision in *Health & Hospital Corp. of Marion County v. Talevski*, 142 S. Ct. 2673 (2022), will not affect this appeal. *Talevski* presents the questions (i) whether Spending Clause legislation gives rise to private rights that are enforceable under 42 U.S.C. §1983 against States that receive federal

funds, and (ii) if so, whether a particular statute creates such rights. Lilly, however, is not a third-party beneficiary seeking to obtain relief from a State through an implied private right of action under §1983. Lilly is instead the target of an enforcement action that seeks to force Lilly to alter its behavior (both prospectively and retrospectively) on pain of severe civil monetary penalties. Regardless of whether the Supreme Court holds that third-party beneficiaries of Spending Clause legislation may sue fund-receiving States under §1983, Lilly may seek relief against the agency because the Administrative Procedure Act expressly grants a private right of action to enforce federal rights against federal agencies. *See* 5 U.S.C. §702. And no argument in *Talevski*, either for the petitioners or the respondent, casts any doubt on Lilly's ability to obtain relief from unlawful agency action.

It bears emphasizing that, although *Talevski* could limit claims that third-party beneficiaries could bring against entities (particularly States) receiving funds pursuant to Spending Clause legislation, that has no bearing on whether a party wishing to *participate* in a Spending Clause program may assert that participation conditions *imposed by the federal government itself* (whether Congress or an agency) violate the unconstitutional-conditions doctrine, as Lilly argues here. *See, e.g.*, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013); Lilly Opening Br. at 47–53; Lilly Reply at 34–38.

CONCLUSION

For these reasons, the Court should reach the merits and reverse in relevant part.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this supplemental brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) and 7th Circuit Rule 32 because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 12-point Century Schoolbook font.

s/ John C. O'Quinn, P.C.
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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2022, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

s/ John C. O'Quinn, P.C.
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