U.S. Department of Justice
Civil Division

VIA CM/ECF

October 8, 2026

Christopher G. Conway, Clerk of Court
United States Court of Appeals for the Seventh Circuit
Everett McKinley Dirksen United States Courthouse
219 S. Dearborn Street, Room 2722
Chicago, IL 60604

RE: *Eli Lilly v. Kennedy* (No. 23-1301) (oral argument held on September 24, 2026)
Supplemental Letter Brief for the Government

Dear Mr. Conway:

We respectfully submit this response to this Court's order directing the parties to address appellate jurisdiction, including "not only how appeals by private parties from remands to agencies have been treated in the Seventh Circuit but also how such appeals have been analyzed in the Supreme Court and other courts of appeals." September 24, 2026, Order 1. As explained below, under the correct understanding of governing principles, recognized by all of the other courts of appeals, a private party such as Eli Lilly cannot appeal a district court's order remanding to an agency.

1. The Supreme Court has not determined whether private parties may appeal remand orders under the Administrative Procedure Act. In two cases, the Court has permitted appeals of orders remanding to the Social Security Administration under the special statutory scheme that governs Social Security cases. *See Sullivan v. Finkelstein*, 496 U.S. 617 (1990); *Forney v. Apfel*, 524 U.S. 266 (1998). In the first case, the Court allowed the government to appeal such an order. The Court relied on a Social Security Act provision identifying as "final" any judgment that "remand[s] the [case] for a rehearing" by the Commissioner of Social Security. *Sullivan*, 496 U.S. at 625 (quoting 42 U.S.C. § 405(g)). In the second case, the Court concluded that "[n]othing in the language" of the statute "suggests that such an order could be 'final' for purposes of appeal only when the Government seeks to appeal but not when the claimant seeks to do so." *Forney*, 524

U.S. at 270. The Court again grounded its analysis in language specific to the Social Security Act. *Id.*

Although the Supreme Court has declined to decide "whether remands to administrative agencies are . . . immediately appealable" outside the Social Security Act context, it has articulated principles guiding that analysis. *Sullivan*, 596 U.S. at 623. The Court has held that an order is normally "final" for purposes of 28 U.S.C. § 1291 "only when it 'resolves the entire case'—when it 'ends the litigation' (on the merits or otherwise) and 'leaves nothing for the court to do but execute the judgment.'" *Geo Grp., Inc. v. Menocal*, 607 U.S. 438, 443-44 (2026) (citations omitted). This approach prevents "piecemeal, prejudgment appeals" that would "undermin[e] efficient judicial administration." *Ritzen Grp., Inc. v. Jackson Masonry, LLC*, 589 U.S. 35, 38 (2020).

Most courts of appeals have concluded that these principles prevent private parties from appealing remand orders. In the D.C. Circuit, "it is black letter law that a district court's remand order is not normally 'final' for purposes of appeal under 28 U.S.C. § 1291." *Sierra Club v. U.S. Dep't of Agric.*, 716 F.3d 653, 656 (D.C. Cir. 2013). The D.C. Circuit has emphasized that, under Supreme Court precedent, a final order must "completely end[] the litigation on the merits." *Rose v. Kennedy*, 169 F.4th 294, 301 (D.C. Cir. 2026) (citations omitted). Because remand orders "leave the agency with more work to do," they "typically are considered interlocutory." *Id.* And although the D.C. Circuit has recognized an "exception permitting a government agency to appeal immediately," that "path is not normally available to a private party." *Sierra Club*, 716 F.3d at 656. "The reason for this asymmetry is that a government agency cannot later challenge its own actions complying with a remand order, whereas a private party dissatisfied with the action on remand may still challenge the remanded proceedings—as well as the remand order requiring them—after the proceedings are complete." *Id.* at 656-57.

Other circuits largely follow the D.C. Circuit's approach. Apart from this Court, other circuits "have uniformly held" that, with respect to private parties, "as a general rule, a remand order is 'interlocutory' rather than 'final,' and thus may not be appealed immediately." *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 329-30 (D.C. Cir. 1989) (collecting cases from the First, Second, Third, Fourth, Fifth, Sixth, Eighth, Ninth, Tenth, Eleventh, and Federal Circuits); *see* 15B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 3914.32 (3d ed.) (noting that "the general rule is that a remand is not appealable" and that "[m]ost of the cases permitting collateral-order appeal allow appeal by the agency"). For example, the First Circuit has determined that, except in cases where the government appeals, "generally orders remanding to an administrative agency are not final." *Mall Props., Inc. v. Marsh*, 841 F.2d 440, 441 (1st Cir. 1988). The Ninth Circuit likewise prohibits appeal from remand orders other than in narrow

circumstances where, among other requirements, an order "forces the agency to apply a potentially erroneous rule which may result in a wasted proceeding." *Chugach Alaska Corp. v. Lujan*, 915 F.2d 454, 457 (9th Cir. 1990).

In contrast to its sister circuits, this Court appears to permit private parties to appeal most remand orders. *See Rush Univ. Med. Ctr. v. Leavitt*, 535 F.3d 735, 738 (7th Cir. 2008). Like the D.C. Circuit, this Court allows the government to appeal remand orders because, "if the private claimant prevails [on remand], the agency cannot obtain judicial review of its own decision (even when that decision has been compelled by a judicial decision with which the agency disagrees)." *Id.* Unlike the D.C. Circuit, however, this Court has indicated that "any decision final from the agency's perspective also is final from the private litigant's." *Id.* This Court has accordingly suggested that private parties may appeal any remand order that "might conclude without a return to court," effectively authorizing appeal in a large category of cases. *Id.* In reaching this result, the Court reasoned that *Forney* and *Sullivan*—the Supreme Court cases construing the Social Security Act as authorizing appeal of remand orders—"control" outside that statutory context. *Id.*

2. Under the correct understanding of Supreme Court precedent, private parties generally cannot appeal orders remanding to agencies. By definition, a remand order does not "resolve[] the entire case," *Geo Grp.*, 607 U.S. at 443, and instead contemplates additional proceedings before the agency, with an opportunity for a private party aggrieved by the agency's remand decision to return to district court and then appeal in the normal course. Allowing private parties to immediately appeal from remand orders would thus result in the "piecemeal" litigation that the Supreme Court has taken pains to avoid. *Id.* at 444. This is a case in point: under Lilly's theory, it can appeal now and then, if it disagrees with FDA's remand decision and the district court upholds that decision, appeal a second time.

The risk of piecemeal appeals is especially apparent given FDA's recent issuance of a remand decision. On October 2, 2026, FDA issued a decision concluding that retatrutide is not an "analogous product" to a protein. *See* 42 U.S.C. § 262(i)(1). A redacted version of the decision is attached. According to Lilly, it is entitled to maintain this appeal while simultaneously challenging the remand decision in district court and then, if it loses there, taking another appeal to this Court. Under the approach taken by the D.C. and other circuits, however, Lilly would be required to await the district court's resolution of any challenge to the remand decision and then file a single appeal addressing all relevant issues.

This Court's contrary approach improperly extends to private litigants the exception permitting agencies to appeal remand orders. *See Rush*, 535 F.3d at 738. Under

the collateral-order doctrine, the Supreme Court has "treat[ed] as 'final'" certain "narrow" classes of orders "that do not end a case" but are nonetheless "practical[ly]" final. *Geo Grp.*, 607 U.S. at 444. As the D.C. Circuit has recognized, that logic authorizes an agency to appeal a remand order because it may be unable to "later challenge its own actions in complying with [the] order." *Sierra Club*, 716 F.3d at 657. The same rationale does not extend to private parties, who "may still challenge the remanded proceedings—as well as the remand order requiring them—after the proceedings are complete." *Id.*

In concluding that "any decision final from the agency's perspective also is final from the private litigant's," this Court mistakenly relied on the Supreme Court's decisions permitting appeal from remands to the Social Security Administration. *Rush*, 535 F.3d at 738 (citing *Sullivan*, 496 U.S. at 617; *Forney*, 524 U.S. at 266). As this Court elsewhere observed, those decisions were "based on language in the Social Security Act" that treated remand orders as final without regard to the identity of the party appealing the order. *Edgewater Found. v. Thompson*, 350 F.3d 694, 697 (7th Cir. 2003). *Sullivan* expressly declined to address the "great variety [of] remands" outside that particular statutory context, 496 U.S. at 623, and *Forney* likewise relied "primarily [on the Social Security Act's] language," 524 U.S. at 270.

There is nothing unusual about a jurisdictional rule that permits the appeal of remand orders by agencies but not private parties. This Court has observed that the collateral-order doctrine often creates "an asymmetric right of appeal." *Barnes v. Black*, 544 F.3d 807, 811 (7th Cir. 2008). For example, "a defendant may appeal the denial of official immunity immediately," "but a plaintiff may not appeal a grant immediately." *Id.* Such asymmetries reflect "the purpose of the collateral-order doctrine, which permits an appeal from a nonfinal order only when deferring appeal could inflict irreparable harm on a party." *Id.* Preventing agencies from appealing remand orders threatens to impose such harm because it may preclude those agencies from ever appealing at all. Private parties, by contrast, will generally either prevail before the agency on remand or have an opportunity to challenge the agency's remand decision and then appeal in the ordinary course.

Lilly has emphasized (Opening Br. 17) that the parties filed a joint motion urging the district court to enter a "final, appealable judgment," A.290, and that the court described its judgment as "final," ShA.18. But "district court judges cannot determine the scope of appellate jurisdiction or authorize appeals from interlocutory orders, other than through the means provided by 28 U.S.C. § 1292(b)," which is not at issue here. *Edgewater*, 350 F.3d at 697. And nothing in the joint motion is inconsistent with the view that the district court's remand order is appealable by the government, but not Lilly.

3. We acknowledge that under *Rush*'s logic, this Court would have appellate jurisdiction insofar as Lilly challenges the part of the district court order upholding FDA's refusal to designate retatrutide as a protein. *See* Gov't Br. 2. For the reasons given above, however, we respectfully submit that *Rush* reflects a mistaken understanding of governing principles, and that under the correct understanding of those principles, this Court lacks jurisdiction. Lilly has cursorily argued (Opening Br. 2) that even if the remand order is not a final decision under 28 U.S.C. § 1291, it nonetheless qualifies as an appealable "interlocutory order" "refusing an injunction" under § 1292(a)(1). But this Court construes § 1292(a)(1) "narrowly," to avoid opening "a floodgate . . . that would deluge the appellate courts with piecemeal litigation." *Chicago Joe's Tearoom, LLC v. Vill. of Broadview*, 894 F.3d 807, 812 (7th Cir. 2018). In general, this Court "allow[s] an interlocutory appeal" only where an order "strip[s] [a] case of its equitable component." *Id.*

Lilly has made no attempt to satisfy that standard. That is unsurprising, as even though Lilly's motion for summary judgment included a request for an injunction, the district court's denial of that motion does not prevent Lilly from renewing that request in any subsequent challenge to the agency's remand decision. To the extent that this Court elects to revisit its understanding of the finality of remand orders for purposes of appeal by private parties, a contrary understanding of § 1292(a)(1) would allow appeal whenever a private party chooses to include a request for an injunction in its motion for summary judgment, creating a flood of piecemeal appeals and essentially eliminating the prohibition on private-party appeals of remand orders. Lilly has identified no case from this or any other court concluding that § 1292 establishes jurisdiction in these circumstances.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 2,232 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally-spaced typeface.

/s/ Steven H. Hazel
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CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2026, I electronically filed the foregoing with the Clerk of the Court of the U.S. Court of Appeals for the Seventh Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the appellate CM/ECF system.

/s/ Steven H. Hazel
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